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

Dominique Constance McKenzie Mylod

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Hospital admission in the latent phase of labour is associated with higher rates of obstetric intervention, with increased maternal and fetal morbidity. Women sent home from hospital in the latent phase to 'await events' feel anxious and cite pain as their main drive to seeking hospital admission.

Using a birth ball to assume upright positions and remain mobile in the latent phase of labour in hospital is associated with less pain and anxiety. However, no research has examined the effect of using birth balls at home in the latent phase on pain perception, hospital admission or obstetric intervention. An animated infomercial was developed to promote birth ball use at home in the latent phase of labour to enhance women's self-efficacy, in order to reduce their pain perception.

As a pragmatic randomised controlled single centre trial, 294 low risk women were randomly allocated to two groups. At 36 weeks' gestation the Intervention Arm accessed the infomercial online and completed a modified Childbirth Self-Efficacy Inventory before and after viewing. They were also offered the loan of a birth ball to use at home. The Control Arm received standard care. On admission to hospital in spontaneous labour, all participants were asked to provide a Visual Analogue Scale score. Both groups were followed up six weeks postpartum with an online questionnaire. Data were analysed on an Intention To Treat basis.

A significant increase was found in Outcome Expectancy and Self-efficacy Expectancy after accessing the infomercial and Intervention Arm participants were more likely to be admitted in active labour. No significant differences were found between the VAS scores, or intervention rates. Most respondents (89.2%) described the birth ball as helpful and reported high satisfaction, with comfort, empowerment and progress.

The birth ball is a promising intervention to support women in the latent phase. Further research should consider a randomised cluster design.

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1.0 Introduction

In twenty-first century maternity care, obstetric intervention, culminating in caesarean section (CS) births has increased exponentially. 106 out of 169 countries have CS rates above the 10% to 15% of births thought to be optimal in reducing perinatal mortality whilst minimising iatrogenic complications (World Health Organization (WHO) 2015). In at least 15 countries the CS rate exceeds 40%, including the Dominican Republic (58.1%), Brazil (55.5%), Egypt (55.5%), and Turkey (53.1%) (Boema et al. 2018). In the United Kingdom (UK), CS births had increased from 19.7% of births in 2000 to 26.2% by 2015 (Wise 2018).

The continued rising trend in obstetric intervention in high-income countries such as the UK and the United States of America (USA) (Wise 2018), is not matched by improvements in maternal-fetal outcomes, family psychosocial wellbeing and public health (Lobel and DeLuca 2007; Sandall et al. 2018; WHO 2018). There has been considerable speculation as to the reasons for this increase in intervention, but an area that has received more attention recently is hospital admission in the latent phase of labour.

Most births in high-income countries occur in hospital (UNICEF 2018). However, the timing of admission can affect the outcome of labour. Hospital admission in the latent phase of labour is associated with higher rates of obstetric intervention, including amniotomy (Lundgren et al. 2013), Continuous Electronic Fetal Monitoring (CEFM) and synthetic oxytocin augmentation (Klein et al. 2004), epidural anaesthesia and CS, (Davey et al. 2013; Lundgren et al. 2013; Yang et al. 2013; Mikolajczyk et al. 2016; Rota et al. 2017), with the potential for increased maternal and fetal morbidity in the short and long terms (Sandall et al. 2018).

Latent phase admissions to labour wards in high-income countries may be as high as 47% of all labour admissions (Rota et al. 2017). With the associated increased obstetric interventions, a reduction in latent phase admissions would appear to be a key component of reducing interventions for women with straightforward pregnancies who plan hospital-based births. The potential benefits from such an initiative are considerable, in terms of reduced costs to maternity care systems and a reduced burden of intervention and complications in labours and births for women and their families.

This introductory chapter outlines the current definitions and understanding of the latent phase of labour and considers to what degree this is reflected in contemporary maternity care practice in high-income countries. The experiences, perspectives and needs of women and their families from research are also considered.

1.1 Defining the latent phase

Although undefined and unexplored until relatively recently, the concept of the latent phase of labour ('early' or 'prodromal' labour') marks the transition from pregnancy to active labour (Friedman 1954; McIntosh 2013; Eri et al. 2015; Hanley et al. 2016). The latent phase is considered to occur with maternal perception of the start of labour accompanied by contractions until the cervix effaces and is 3 – 5 centimetres (cm) dilated, depending on the country and the locality. Thus, definitions vary from 3 – 5cm dilated (Friedman 1954; Neal et al. 2010) to the recent USA recommendation that active labour care should be delayed until 6cm dilatation to reduce the CS rate (Zhang et al. 2010). The most recent recommendation proposes 5cm dilatation as the optimal point to implement intrapartum care pathways (WHO 2018). The UK National Institute for Health and Care Excellence (NICE) offers the following definition:

'…….. a period of time, not necessarily continuous, when:

- there are painful contractions **and**
- there is some cervical change, including effacement and dilatation up to 4cm'

(2017, p.24).

There is a continued disparity in beliefs and practice as to when and how the latent phase ends and active labour begins and there are grounds for doubt as to whether the labour / birth continuum should be delineated by cervico-centric measurements at all (Hanley et al. 2016; Hundley et al. 2017). Current definitions rarely resonate with women's experiences (Gröss et al. 2010; Dixon et al. 2013) and the labour onset and progression of contemporary women indicate slower cervical dilatation than those of the 1950s cohort on which current care parameters rely (Albers 2007; Oladapo et al. 2018). Contemporary maternal populations are older, with larger body sizes and subject to greater 'routine' obstetric intervention, such as amniotomy and CEFM, which are themselves associated with delays in labour progression (Zhang et al. 2010; Humphrey 2014). Given that the diagnosis of latent or active labour is central to women's labour experience and the degree of intrapartum intervention they experience, present parameters are inadequate (Hanley et al. 2016).

1.2 ‘Paracetamol, a bath, mobilise and keep hydrated’

Although many women who plan a hospital-based labour and birth state that they wish to remain at home until their active labour establishes, the standard advice of ‘paracetamol, a bath, mobilise and keep hydrated’ for women in the latent phase is perceived as a professional, generic response rather than personalised care which meets their needs and expectations (Nolan and Smith 2010; Spiby et al. 2014). Women sent home from hospital in the latent phase to ‘await events’, frequently feel anxious and unsupported (Spiby et al. 2006; Cheyne et al. 2007; Barnett et al. 2008; Cliffe 2017). They cite the need for reassurance in the face of uncertainty (Cheyne et al. 2007; Eri et al. 2015; Edmonds et al. 2018), with anxiety (theirs and their families’) being a key factor in their decision to seek admission (Barnett et al. 2008; Edmonds et al. 2018). Above all, women cite pain as their primary driver in seeking latent phase admission and care, whether in its manifestation at the time of admission or in anticipation of its increase in intensity and frequency (Barnett et al. 2008; Carlsson et al. 2009).

In the absence of non-reassuring indications such as vaginal bleeding or meconium stained liquor, current UK guidelines advise that women do not require hospital admission in the latent phase and should be encouraged to remain at home until active labour ensues (NICE 2017). However, women report midwives gatekeeping and coercing them into returning home (Nyman et al 2011; Shallow 2016). Whilst it might seem logical for midwives to postpone hospital admission and discourage it while it is safe to do so (Hundley 2013; Marowitz 2014), UK maternity services have attracted negative feedback for the perceived dearth of latent phase support (Care Quality Commission 2015). In a research agenda setting project, Scottish mothers identified the latent phase as a priority research topic (McCourt et al. 2013). There is growing awareness that leaving women and their families to manage the latent phase with minimal guidance and support adversely affects their labour and birth outcomes (Beake et al. 2018).

1.3 Thesis presentation

Having established the issue of latent phase admission, its association with increased obstetric intervention and the dearth of personalised latent phase care to support women and their families in this introductory chapter, Chapter 2.0 presents a critique of latent phase intervention research to date. This is utilised to present the case for a woman-centred, evidence-based intervention for the latent phase of labour, which directly addresses the needs and concerns of women and their families.

The underpinning neurophysiology of the latent phase is then considered in relation to intrapartum pain, anxiety and self-efficacy, with a rationale for promoting upright positioning and mobilisation in labour. This is accompanied by a critique of supporting evidence and the identification of the birth ball as a potential means of achieving this. Having justified the need for the literature review, the chapter concludes with an explanation of the study's potential for an original contribution to knowledge in reproductive health.

Chapter 3.0 details the structure and findings of a literature review which identifies and synthesises the extant literature in order to establish the gap in knowledge which the study will address.

Chapter 4.0 details the methods employed for the creation of a complex intervention and provides the rationale for the methodological approach of a pragmatic randomised controlled trial, whilst Chapter 5.0 details the research setting, ethical approval, recruitment, data collection and management.

The quantitative findings from the BALL trial are presented in tabular and graphic formats in Chapter 6.0, by a direct comparison of the experimental arm characteristics, followed by the outcomes for the primary and secondary aims of the research, including those of the postnatal questionnaire. These are followed by a qualitative thematic analysis of the free text questionnaire responses.

Lastly, Chapter 7.0 critically examines the trial outcomes and discusses whether the null hypothesis can be accepted or rejected. The meaning, importance and relevance of the trial outcomes are considered within the context of the wider literature, current knowledge and understanding. The thematic analysis of participants' experience is summarised in a thematic map. The trial is critically

discussed in terms of its strengths, weaknesses and original contribution to knowledge. Finally, implications for maternity practice and research are considered.

2.0 Background

In order to understand the impact of latent phase admission and its attendant complications in maternity care, it is necessary to critically examine the research, knowledge and approaches to date. The conclusions are then used to justify the need for a systematic review of the evidence and the research as a whole.

2.1 Latent phase research and initiatives to date

Midwifery-led research has explored a range of interventions. An algorithm to formalise the diagnosis of active labour reduced latent phase admission; however, women returned to the maternity unit more frequently following discharge home in a 'revolving door' effect (Cheyne et. al 2008). Two UK based service improvement evaluations of telephone triage suggested a reduction in CS and increased uptake of midwifery-led facilities as a birth location (Weavers and Nash 2012; Mackenzie 2014), but more robust evidence has yet to be forthcoming. With the development of more affordable and reliable technology, a recent paper has concluded that, with caveats of women's perspectives and ensuring privacy, midwives are open to the prospect of video-call based early labour triage on the grounds that it offers more contextual and non-verbal cues (Spiby et al. 2019). This strategy is attractive in that it has the potential for reducing uncomfortable and stressful journeys to maternity units and subsequent admission interventions such as vaginal examinations. However, telephone triage is not appropriate for women who have language or communication challenges or those who are scared or anxious (Henderson and Redshaw 2017).

A trial which compared women's labour experience of home assessment versus telephone triage unsurprisingly found that home assessment improved women's labour experience (Janssen and Desmarais 2013). Spiby et al. (2008) also found an improvement in women's experience from home assessment compared to standard care, even though the visits were restricted to 08:00 – 21:00. Home assessment is unlikely to attract further investment from maternity care commissioning bodies unless it can be definitively demonstrated to improve maternal-fetal outcomes, which was not realised in either study.

Nevertheless, this evidence reinforces women's stated wish to remain at home until their labour establishes.

In the UK, an 'early labour suite' is reported to offer on-site 'hands-off early labour care', although there is currently no evaluation data available (Herron 2014). A similar arrangement in Australia did not reduce obstetric intervention or improve birth outcomes (Williams et al. 2019), although it is notable that the duration of women's stay in the early labour suite was restricted to four hours, which in itself may have increased psychological pressure on women. By contrast, Breman et al. (2019) also report using an early labour lounge facility in the USA, offering information, activities and support to low risk primiparous women; the reported emergency CS rate of 7.1% was well below the national rate of 32% (Centers for Disease Control and Prevention 2017), even allowing for additional planned CS. Whilst this is promising, the sample cohort of 67 women was small and the report is based on a postnatal questionnaire prior to discharge rather than a prospective trial.

The lack of proven efficacy for all of these initiatives may be because in essence, these latent phase interventions centre on service-led appropriation and allocation of human, institutional and financial resources rather than on woman-centred care to enhance physical and psychosocial wellbeing and address women's priorities. A Cochrane review has concluded that to date, latent phase interventions have not wholly demonstrated a reduction in obstetric interventions, nor succeeded in offering women evidence-based strategies to postpone hospital admission until the active phase of labour (Kobayashi et al. 2017). Moreover, the standard advice of oral paracetamol in the latent phase is at best ineffective and at worst may be instrumental in prolonging the latent phase by the suppression of the prostaglandins which mediate it (The Undercover Midwife 2015). An alternative perspective is required to consider the evidence-base of current care and how it impacts on women's principal concern in the latent phase: that of their pain experience.

2.2 Latent phase pain

The International Association for the Study of Pain (IASP) offers the following definition of pain:

> ‘An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’
>
> (2014, p.1).

Latent labour involves the sensitisation of cervical afferent nerves and a localised inflammatory process in the cervix immediately prior to and during labour onset, combined with intermittent ischaemic nociception from uterine contractions (Eisenach 2010). However, the pathway through which latent phase nociception is perceived as pain involves affective, cognitive and behavioural components as a variable and individual experience (Whitburn 2013; Gibson 2014). These factors include beliefs, knowledge, social and family context, media and culture (Moseley 2013) and possibly genetics (Porter and Reddi 2015). This complexity is compatible with the diffuse activation of brain activity in the pain experience matrix (Cervero 2012).

The concept of pain in labour and birth is paradoxical in that pain’s association with suffering, fear and harm is at odds with the construct of birth and the transition to family life as joyful, transformational experiences (Lowe 2002). However, much of twentieth century research was conceptualised and undertaken in a context of women undergoing medicalised and obstetrically managed labours (Murphy-Lawless 2012). For example, Niven (1985) noted that more than half of her study’s respondents were undergoing synthetic oxytocin induction of labour or augmentation and / or were pharmacologically sedated, which cannot be considered as features of normal labour. Nevertheless, labouring women in Melzack’s study (1975) rejected the McGill Pain Questionnaire pain descriptors on the grounds that the positive experience of giving birth prevented them from using language with negative connotations. In short, labour pain was experienced as severe in intensity, but not negatively affective.

Rather than attempting to impose a pathophysiological paradigm, where labour pain is compared with that of cancer or arthritis (Melzack 1975), it seems apposite to accept labour pain as a fundamental component of normal labour in its commonality of women's experience (Gould 2002; Van der Gucht and Lewis 2015). Within the midwifery construct of 'working with pain', pain is viewed as a transformative force in the transition to motherhood (Leap and Anderson 2008). Pain drives normal labour, summons social support and engages complex neuro-hormonal cascades as interactions which are crucial to facilitate birth, lactation, parental bonding, social integration and survival (Leap and Anderson 2008; Moberg 2011; Dixon et al. 2013b).

Pharmacological pain relief is not always associated with increased maternal satisfaction (Green 1993; Dickenson et al. 2003); nor does it necessarily reduce psychological suffering or improve outcomes (Royal College of Midwives Advisory Group 2012). A Cochrane review concluded that regional anaesthesia options can be administered in the latent phase without increasing CS rates (Sng et al. 2014), however this may be offset by hospital admission exerting the opposite effect (Yang et al. 2013; Rahnama et al. 2014). Moreover, latent phase regional anaesthesia still presents the established complications of regional anaesthesia, including prolongation of the second stage of labour and the attendant increase in assisted births (Anim-Somuah et al. 2018). Given the potential for fetal and maternal morbidities associated with the consequences of regional anaesthesia (Anim-Souah et al. 2018), there is considerable scope for disagreement with IASP's assertion that regional anaesthesia represents the gold standard of intrapartum pain relief in terms of technique and effectiveness (Landau and Ciliberto 2011).

Pharmacological pain relief techniques, therefore, have yet to evolve to the point where they can provide analgesia without significant negative impacts on the physiology and psychosocial outcomes of labour, in addition to a burden on the resources and costs of health economies. What appears to be of greater importance for women in the latent phase of labour is their anxiety and need for reassurance.

2.3 Anxiety and self-efficacy in the latent phase

Heightened anxiety in the latent phase correlates with increased pain perception (Floris and Irion 2015). Conversely, an inverse relationship exists between confidence in ability to labour and pain perception (Lowe 1989). Women reporting greater self-efficacy as a self-perception of agency (Bandura 1997) experienced less fear, stress and anxiety during labour (Beebe et al. 2007; Nierop et al. 2008). Self-efficacy and confidence are associated with reduced obstetric intervention and epidural use (Beebe et al. 2007; Carlsson 2012; Carlsson et al. 2015). Evidence-based strategies to empower women and their birth supporters and to educate and de-medicalise their pain experience are needed to reduce latent phase admissions and their attendant obstetric intervention (Eri et al. 2015). This is not only a means of reducing the burden of maternal and neonatal morbidity associated with iatrogenic intervention. A cost-effectiveness analysis of latent versus active labour admission for low risk women in term labour concludes that the large reduction in interventions such as CS and epidural anaesthesia which are apparent in active labour admission is matched by equally sizable reductions in costs to individuals, care settings and health systems (Tilden et al. 2015).

One approach to de-medicalising labour pain and enhancing women's confidence may be through enabling mobility and upright positioning. When a woman adopts upright positions and remains mobile in the latent phase, she uses gravity to apply the fetal presenting part to her cervix, which increases oxytocin release (Lawrence et al. 2013). Oxytocin and endogenous opioids modulate her pain perception through an intrinsic pain modulation pathway (Viero et al. 2010; Yang et al. 2011). Oxytocin and prostaglandins promote uterine contractions and cervical effacement to allow her to establish active labour (Buckley 2015). However, since the primary biosocial function of the brain is to ensure survival, there is a developing understanding of its flexible response to contextual cues. The bright lights, unfamiliar environment and lack of privacy which women encounter on admission to hospital often reduce contraction strength and frequency (Hodnett et al. 2013), because anxiety or fear engender the release of the cathecholamines that inhibit oxytocin release (Lederman et al. 1985; Enkin 2006; Dixon et al. 2013b; Buckley 2015), whether harm is perceived as an actual or potential threat. The increase in circulating

catecholamines exerts an antagonistic effect on her oxytocin production and reduces her contraction frequency and efficiency (Buckley 2015). This disrupted physiological pathway leads to longer labours, greater pain perception and obstetric intervention.

Women who have freedom of movement and upright positions are less likely to use epidural anaesthesia in active labour (Lawrence et al. 2013) and are consequently less likely to experience assisted births and their attendant complications (Anim-Somuah et al. 2018). Escott et al. (2004) suggest that labouring women engage with a wide range of innate and acquired affective and cognitive strategies to work with their pain and manage their anxieties instead of resorting to taught skills and techniques. This contrasts with the deficit model that portrays women as under-prepared, unrealistic and ill-equipped for labour Lally (2011). Fostering parental confidence and understanding of women's intrinsic physiological pathways as a 'tool kit', rather than the 'pain relief menu' of pharmacological analgesia may be the key to effective care in the latent phase of labour (Eri et al. 2015).

An antenatal evidence-based intervention to promote and facilitate upright positions at home in the latent phase of labour may prove effective in enhancing women's self-efficacy and reducing their anxiety. The consequential reduction in catecholamines should engage and maintain the pain modulation pathway and encourage women to postpone hospital admission until active labour is established.

2.4 Birth balls

Having established the need for an intervention which could facilitate upright positions at home in the latent phase of labour, a viable and cost-effective means had to be identified. Whilst Kitzinger (2011) maintains that women are more likely to adapt their familiar home environment to support and facilitate upright positioning and movement, offering a tangible physical prop seemed more likely to engage the interest of women and their families. However, equipment such as the Combitrac ® and birth ropes may be costly, require structural installation or are unsuitable for smaller dwellings. Birth couches, seats and peanut balls, on the other hand, support static sitting or lateral positions, rather than enabling mobility. The one prop which potentially offered support for upright positioning, combined with mobility, portability and affordability was a birth ball. Vinyl physical therapy balls (‘Swiss’, ‘Pezzi’ or ‘birth’ balls) are not a new concept in maternity care. They are inexpensive, widely available to purchase and easy to clean. As a key feature of ‘functional kinetics’ in rehabilitation therapy, they provide an unstable surface which engages multiple deep muscle groups (Klein-Vogelbach 1990; Carriére 1998). They are frequently used in antenatal education programmes to promote and facilitate upright or kneeling positions and rocking movements (National Childbirth Trust 2015). 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 (Perez 2000). Sitting on the ball may alleviate pressure on the nerve filaments over the sacro-iliac area and reduce lumbar pain (Taavoni et al. 2011).

Trials from countries where hospital-based medicalised labours are a norm have reported reduced pain perception, particularly in back pain in active labour (Gau et al. 2011; Taavoni et al. 2011) and improved labour progress in terms of fetal descent and cervical dilatation (Zaky 2016). Two systematic literature reviews of using birth balls in active labour concluded that women reported less pain, but also concluded that the trials were small, at high risk of bias and the heterogeneity of outcomes and low grade evidence impeded firm conclusions (Makvandi et al. 2015; Delgado et al. 2019). Nevertheless, birth balls are widely accepted and indeed, recommended for pain management in active labour, including by the National Health Service (NHS) (2019).

Birth balls also stimulate a psycho-affective response to offer support, comfort and interest by activating other parts of the brain as a distraction (Perez 2000). Using the birth ball may enhance women's self-efficacy, providing a sense of mastery, confidence and well-being, rather than passive compliance (Gau et al. 2011; Makvandi et al. 2015). This was reported as the case for the 12 respondents of a qualitative study in South Africa, which explored the experience of multiparous women who had used the birth ball in labour (James and Hudek 2017). Although the authors acknowledged that limiting the study to multiparous respondents restricted transferability, the women described relief from back pain and feelings of calm, empowerment and even enjoyment, which may be a further key component to improving labour outcomes and experience for families (James and Hudek 2017).

On these grounds, using the birth ball was identified as a potential strategy to support women at home in the latent phase in order to assume upright positions, reduce their pain perception and thereby postpone their admission to hospital until their labour had established. The prevalence of birth ball use in antenatal education and the modest body of evidence cited for its use in active labour suggested that other research regarding the latent phase might be available. This made it imperative to undertake a literature review in order to identify and synthesise extant literature and identify gaps in knowledge (Sylvester et al. 2013). In doing so, the literature review stood to confirm birth ball use in the latent phase as a research problem or justify it as a contribution to new knowledge (Paré and Kitsiou 2017).

2.5 Conclusion

This introductory chapter has considered the evidence regarding the impact of the latent phase of labour on labour and birth outcomes and how this this is reflected in contemporary maternity care practice in high-income countries. A critique of supporting evidence has demonstrated that women and their families cite pain and anxiety as their principal drivers for seeking hospital admission in the latent phase and consider that their needs and concerns are largely disregarded at this time. Latent phase intervention research has yet to demonstrate convincing improvements in labour and birth outcomes. A woman-

centred, evidence-based antenatal intervention is needed to address these issues.

Birth balls have been identified as a potential means of facilitating upright positions to optimise contraction strength and frequency and also to engage and enhance the pain modulation pathway as well as reduce anxiety and promote calm and self-efficacy in the active phase of labour. These findings may also be significant for the latent phase and have the potential to improve labour and birth outcomes as well as contribute to new knowledge. Accordingly, a systematic literature search was undertaken with the aim of identifying primary research which could inform and underpin using a birth ball in the latent phase of labour. This will be detailed and reported in Chapter 3.0.

3.0 Literature review

Systematic literature reviews aim to identify, evaluate and summarise the findings of all relevant individual studies using explicit and reproducible methods; they can establish what is known about an intervention, but just as importantly, what is not known (Centre for Reviews and Dissemination 2009).

This chapter details the systematic literature review that was undertaken to inform the study, and prevent any duplication with previous research (Centre for Reviews and Dissemination 2009), commencing with its purpose, aims and objectives in relation to the guiding search question. The formulation of the search strategy within the Population-Intervention-Comparison-Outcome (PICO) framework (O'Connor et al. 2011) will be defined, including search limitations, inclusion and exclusion criteria and the electronic databases accessed. Literature identified as relevant to the research question is summarised and critically examined.

Search findings are presented in tabular form and the identification of relevant literature is demonstrated by means of a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart (Moher et al. 2009). The retrieved studies are then critiqued. The findings are considered in the current context of maternity care in high-income countries and gaps in the evidence are identified to determine the primary and secondary outcomes of the present research.

3.1 Literature review aims and objectives

The aim of the literature review was to systematically and comprehensively search for, identify, critique and synthesise evidence related to the search question.

The following objectives were set:

1. To comprehensively review the literature regarding using pelvic positioning AND / OR a birth ball in the latent phase of labour.

2. To examine the effect of pelvic positioning AND / OR a birth ball on pain, normal vaginal birth and latent phase hospital admission.

3.2 Guiding search question

The guiding search question had to balance a comprehensive summary of the evidence with manageability and specificity (O'Connor et al. 2011). For example, it was anticipated that any search into the 'latent phase' would generate a large and broad volume of results, whereas 'birth ball' was anticipated to generate a small volume of results. The search question was devised as shown in Box 3.1.

Box 3.1 Guiding search question

What is the effect of pelvic positioning AND / OR a birth ball in the latent phase of labour on pain, normal vaginal birth and latent phase hospital admission?

3.3 Search strategy

A systematic search strategy was planned and applied in order to identify all the literature pertinent to the search question (Aveyard 2014).

- No similar trials or reviews were identified on the Database of Abstracts of Reviews and Effects (DARE) – (1994 – 2015).
- The Cochrane Database of Systematic Reviews identified one search protocol (Hanada et al. 2015) to review all trials of early labour educational psychosocial interventions. By the updated search in 2017, Kobayashi et al. (2017) had published their review of assessment and support during the latent phase in order to improve birth outcomes (Section 1.3).
- The search question was framed within a PICO framework (O'Connor et al. 2011).

Population – women in the latent phase of labour or ('early labour'). Although the NICE guideline (2017) underpinned the study, some flexibility was allowed to enable international studies to be included.

Intervention – pelvic positioning and / or use of a birth ball (as previously defined)

Comparison – standard care

Outcome – the search was specifically concerned with three outcomes (pain, mode of birth and latent phase hospital admission); other studies were planned to be included if other obstetric interventions were outcomes.

Having identified the key concepts, these were compiled as Search Terms and put through the following databases in Box 3.2 as a Search Strategy.

The following databases were accessed via MySearch on the Bournemouth University portal hosted by the Elton B. Stephens Company (EBSCO):

Box 3.2 Databases searched through EBSCO Host

- BIOSIS (via Web of Science – 2008 only)
- British Nursing Index (BNI)
- Bournemouth University Research Online (BURO)
- Cumulative Index of Nursing and Allied Health Literature (CINAHL)
- British Library E-Theses Online Service (EThOS)
- Global Health
- Intermid (1996 - present)
- Internurse
- Journals@Ovid
- Medline complete
- MyiLibrary
- OAIster
- Open System for Information on Grey Literature (OpenSIGLE)
- PsychINFO
- Sage Journals Online
- Sage Reference Online
- ScienceDirect
- Scientific WebPlus
- Scopus
- UK PubMed Central
- Web of Science (incorporating Conference Proceedings Citation Index 1990 – present)
- World Health Organization (WHO) Reproductive Health Library
- Wiley Online Library
- WorldWideScience.org
- ZeTOC (1993-present) – conference proceedings

3.3.1 Search planning form

A standardised search planning form was used to construct the search strategy (Thames Valley and Wessex Healthcare Librarians 2013; Thames Valley and Wessex Healthcare Librarians 2016) for both searches.

Date search started: 27th November 2015 / 24th January 2017

Table 3.1 PICO search terms

Patient / Population / Problem	**Intervention / Exposure**	**Comparison / Control**	**Outcome**
early labour early lab*r	pelvic positioning pelvi* position*	*undefined*	admission normal birth
Alternative terms			
latent phase childbirth wom#n female maternal parturient	birth* ball		pain

Table 3.2 Search limits

Study type Any	**Publication date** Any
Age range Any	**Language** Any
Other Not specified	

Table 3.3 Key to search term wildcard and truncation symbols for EBSCO Host

Symbol	Meaning	Examples
#	denotes alternative spelling for geographical or plural variation	labour (UK) / labor (USA); woman / women
*****	denotes two or more alternative letters truncation for alternative word endings	labour / labouring maternal / maternity pelvis / pelvic position / positioning birth / births / birthing

(EBSCO 2015).

3.4 Inclusion and exclusion criteria

Inclusion criteria were applied to the literature search to restrict confounding factors on labour and birth outcomes. Table 3.4 demonstrates these criteria and the rationale for their application.

Table 3.4 Literature search inclusion criteria

Criterion	Rationale for application
No dates exclusions were applied	To widen search
Languages included on the basis of researcher linguistic competence to read and interpret the text. English, French, Portuguese and Italian included. For results beyond the researcher's linguistic competence, English abstracts were acceptable to determine relevance	To widen search and minimise language bias (Sterne et al. 2011)
Planned hospital based labour and vaginal birth	Research targeted at population planning hospital based labour and vaginal birth. To exclude planned home birth and elective CS
Singleton, term (> 37 weeks' gestation), cephalic pregnancies	Pregnancies at low risk of developing obstetric complications (NICE 2017)
Peer-reviewed original research relating to women's use of the birth ball in the latent phase of labour	To identify research literature specifically focused on the latent phase rather than antenatally or the active phase
Qualitative and quantitative full-text articles	To exclude meta-analyses, literature reviews, secondary analyses, including guidelines
Studies exploring the effect of maternal pelvic positioning / upright posture / postural aids including birth ball	To include pelvic positioning / upright posture or postural aids
Women without previous CS or uterine surgery No antenatally diagnosed fetal abnormality or intrauterine death No maternal co-morbidity e.g. diabetes mellitus No maternal obstetric complications	To exclude pregnancies at higher risk of developing obstetric complications (NICE 2017)

3.5 Literature review findings

The findings from the literature search are detailed in Tables 3.5 and 3.6.

Table 3.5 Search results from EBSCO Host 2015 / 2017

Search	Search term	2015 hits	2017 hits
S1	**((early or latent phase) and lab#r* or childbirth**	822, 734	762, 949
S2	**wom#n or female or matern* or parturient**	31,042,586	27,379,071
S3	**S1 + S2**	1,544	176,296
S4	**S1 and pain**	22,538	21,052
S5	**S1 and pelv* position***	37	77
S6	**S1 and pain and pelv* position***	7	9
S7 2015	**S1 and S2 and birth* ball** **duplicates eliminated** **opinions / articles / reviews eliminated** **systematic review**	72 29 6 1	N/A
S7 2017	**(birth or fit or gym or Swiss) ball**	N/A	8,647
S8 2017	**S1 and S2 and S7** **duplicates eliminated** **active labour trials eliminated** **trials planned /in progress eliminated**	N/A	74 53 50 44

Table 3.6 Search results from level 2 / 3 recommended resources 2015 and 2017

(Thames Valley and Wessex Health Care Librarians 2013; Thames Valley and Wessex Health Care Librarians 2016)

Database	2015 hits	2015 Comments	2017 Hits	2017 Comments
The Campbell Collaboration	N/A	N/A	0	None relevant
CasesDatabase **Journal of Medical Case Reports**	0	Closed 2014. Replaced by **Journal of Medical Case Reports**	0	None relevant
ClinicalTrials.gov	3	None relevant	179	Schnaider NCT03105839 did not meet criteria 178 irrelevant
Cochrane Trials Register	27	None relevant	1	Kobayashi et al. 2017
DART-Europe e-theses portal	6	None relevant	8	None relevant
British Library EThOS	7	None relevant	280	None relevant
Health Management Information Consortium		**Unavailable**	**Combined Unavailable**	
Kings Fund Library Database	0	None relevant		
Latin American and Caribbean Health Sciences Literature(LILACS)	209	None relevant	30	7 were relevant

metaRegister of Controlled Trials (mRCT)	0	Under review from April 2015 - present		Still under review
NHS Networks Commissioning Zone	N/A	N/A	0	None relevant
National Institute for Health and Care Excellence	1	NICE (2017) identified: guideline, not a study	3	Royal College of Midwives (RCM) (2012) & NICE (2017) identified as guidelines Hodnett et al. (2008) (duplicate)
National Institute for Health Research Journals Library	18	None relevant	38	None relevant
Networked Digital Library of Theses and Dissertations Search engine Global Electronic Dissertation and Theses (ETD)	1046	Refined : Health/Women/Childbirth/Care 1046 hits Eliminated (8) Swedish (2) Chinese and (1) German study (no English abstract) 1044 irrelevant Silva (2010) and Giaxa (2009) did not meet criteria	1391	Eliminated (1) Catalan (2) Swedish (no English abstract) Chang (2007) Giaxa (2009) Mota et al. (2011) Silva (2010) Silva et al. (2011) Tien (2010) Fournier (2014)

				did not meet criteria 1282 irrelevant
Open System for Information on Grey Literature in Europe **(OpenSIGLE)**	3	2 irrelevant Lally (2011) did not meet criteria	14	None relevant
Proquest **(incorporating Conference Papers Index)**	297, 630	Formerly **Index to Theses** Morson (2013) identified	367	Morson (2013) did not meet criteria 366 irrelevant
Prospero **(International Prospective Register of Systematic Reviews)**	3	1 irrelevant 1 duplicate; Hanada et. al (2015) Beake et al. (2014) did not meet criteria	3	1 irrelevant 1 duplicate; (Hanada et. al 2015) Beake et al. (2014) did not meet criteria
Quality Innovation Productivity & Prevention **(2010 – 2015)**	N/A	N/A	0	None relevant
UK Clinical Trials Gateway **(NIHR)** **combining ClinicalTrials.gov and ISRCTN**	17	1 duplicate; (Spiby et al. 2006) 16 irrelevant	9	1 duplicate (Spiby et al. 2006) None relevant
UK Database of Uncertainties about the Effects of Treatments (UK DUETS) **(archived 2008)**	N/A	N/A	0	None relevant

World Health Organisation Clinical Trials Registry Platform	14	13 irrelevant Davey et al. (2013); project awaiting funding (Davey 2015)	14	5 trials Davey et al. (2013); project awaiting funding (Davey 2015) Shirazi IRCT2016120631238N2 Parvin IRCT201208053081N2 Mirzakhani IRCT2014012816392N1 Akbary & Taavoni IRCT201611042172N20 did not meet criteria 9 irrelevant
The York Research Database	N/A	N/A	0	None relevant

Key to Tables 1 & 3 Findings included Findings not included

In the interval between the 2015 / 2017 searches, the following databases had been amalgamated:

- Health Management Information Consortium and the Kings Fund; currently unavailable.

The following databases had been archived or suspended:

- mRCT
- UK DUETS
- Quality Innovation Productivity and Prevention

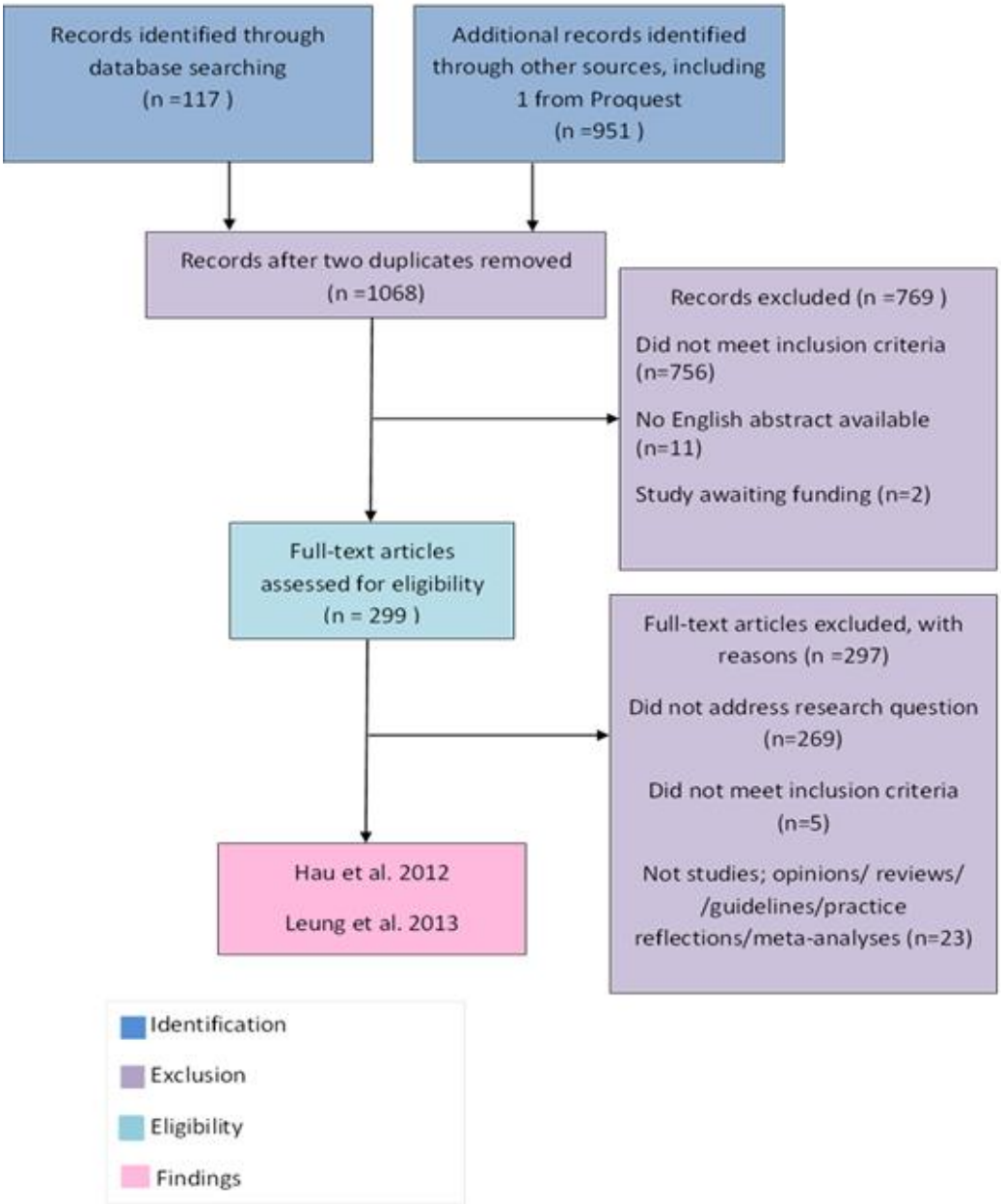
The following databases had become available:

- The Campbell Collaboration
- The NHS Commissioning Zone
- Quality Innovation Productivity and Prevention
- The York Research Database

The updated findings from the 2017 search are summarised below in Figure 3.1 as a PRISMA flow diagram (Moher et al. 2009).

- Studies which fulfilled the search criteria are summarised in Table 3.7.

Figure 3.1 PRISMA flow diagram (adapted)



(Moher et al.2009)

Table 3.7 Summary of eligible studies identified from literature search

Article	Country	Research design	Sample
Hau et al. 2012	Hong Kong	observational study birth ball for women choosing it as first choice of pain relief	217 primiparous women > 1cm dilated
Leung et al. 2013	Hong Kong	case series with before-after effects 30 min. group sessions on Labour Ward physiotherapy led	203 women (181 contracting, 22 not contracting) <4cm dilated low risk

Table 3.8 Summary of study outcome data

Study	Key findings	Comments
Hau et. al (2012)	↓pain at initiation, after 1 hour & on starting 2nd pain relief (p<0.001) ↓1st stage duration (p<0.03) ↓epidural uptake (p<0.01) 95% intervention group would use the birth ball again	no random allocation; women opted for birth ball use not known how many women in latent or active labour high rates of IOL and synthetic oxytocin augmentation, confounding reduced duration of 1st stage not designed or powered to detect changes in obstetric intervention rates Relative Risk not given no details or analysis of questionnaire for women's experience
Leung et al. (2013)	↓pain (p<0.001) ↓back pain (p<0.001) ↓stress / anxiety (p<0.001) ↑satisfaction (p<0.001) no change in pethidine uptake ↓CS (9% v. 22%) ↓IOL / augmentation (5% v. 27%)	intervention specifically targeted at latent phase not designed or powered to detect changes in obstetric intervention rates case series design unable to provide risk ratios measurements of stress / anxiety / satisfaction by VAS outcomes only compared against background rates in unit – no p values low risk women compared with high / low risk background population

3.5.1 Studies identified

Hau et al. (2012) recruited 217 women labouring at term across three hospitals. The study concluded that women using the birth ball experienced significantly shorter first stages of active labour and reported significantly less pain perception and anxiety on Visual Analogue Scale (VAS) scores. There was no difference between the study and control groups in terms of second stage duration, birth mode or episiotomy.

Leung et al. al (2013) concluded that 203 women offered 30 minute group sessions to teach birth ball use while in the latent phase reported reduced back pain, stress, anxiety and abdominal pressure. There appeared to be a significant reduction in CS, and induction of labour (IOL) / augmentation results when compared against background rates in the research setting.

Both studies reported high rates of maternal satisfaction.

Both studies were undertaken in public hospitals in Hong Kong, which restricts the generalisability of findings since they focus on a particular care model. Moreover, the observational nature of both studies places them at higher risk of bias and confounding factors (Sackett 2000). However, both studies state that recumbent medicalised labours are the norm in the research setting, which is evidenced by high rates of IOL and synthetic oxytocin augmentation. It is also a cultural norm that in public hospitals, women are admitted in latent labour to a public ward without their birth partners (Chilcott 2016). This differs to practice in other high income countries such as the UK (RCM 2012; NICE 2017).

The other immediate issue with both studies is that, as previously mentioned, there is no consensus as to when the latent phase ends and active labour begins (Hanley et al. 2016). Hau et al. (2012) included primiparous women who were at least 1cm dilated, but the lack of maximum criteria suggests that some participants might have been in more advanced active labour and therefore the cohort may have been more heterogenous.

Neither study specifically states whether participants were at high or low risk of obstetric intervention, although both evidenced high rates of IOL / synthetic oxytocin augmentation.

It can be argued that as a pragmatic observational study, the purpose was merely to evaluate the effect of exposure to the birth ball. Moreover, creating a homogenous participant group without clear parameters as to what constitutes latent labour in the first place is unrealistic. The lack of clarity regarding participants' obstetric risk also presents a confounding factor because it is not possible to evaluate whether the sample is representative of the general population (Jepson et al. 2004).

Neither study was designed or powered to detect changes in obstetric interventions, although raw data suggests that using the birth ball may reduce intervention. However, it is possible that participants in Leung et al. (2013) gained as much from the companionship and professional support from the group sessions on the birth ball as they did from the intervention itself. Hau et al. (2012) had participants who elected to use the birth ball and may have been women who were more likely to opt for non-pharmacological options and assume more upright positions.

3.6 Discussion of literature review

Current evidence from a meta-analysis indicated that using a birth ball in active labour reduces pain perception (Makvandi et al. 2015), however only two observational studies (Hau et al. 2012; Leung et al. 2013) had considered evaluating birth ball use in the latent phase. Apart from the methodological limitations associated with observational studies, both were undertaken in an environment where latent phase hospital admission was a sociocultural norm. This hinders generalisability to other care contexts where emerging evidence suggests that implementation of intrapartum care pathways should be postponed.

By association, women will be encouraged to postpone hospital admission until their labour has established and there is a clear need to offer strategies and support to meet their needs and address their concerns during the latent phase. For many high-income countries, this means considering strategies which may be adopted whilst at home. The high levels of maternal satisfaction and the

reductions in pain perception reported by participants in both studies suggested that using birth balls warranted further research.

3.7 Implications of literature review

Both studies suggested that using a birth ball in early labour, if not a concisely defined latent phase, might be an inexpensive, simple and effective means of promoting upright positions, facilitating labour progress and engaging the intrinsic pain modulation pathway of childbirth. This is significant because a recent Cochrane review concluded that to date, early labour interventions may have reduced epidural uptake and improved maternal satisfaction, but had otherwise had little impact on labour and birth outcomes (Kobayashi et al. 2017); more research and alternative approaches to latent phase care are needed.

In particular, the literature search highlighted that there is no current evidence base regarding the use of the birth ball while at home in the latent phase, even though it is widely recommended and publicised in many maternity care contexts. It is also of interest to explore the most acceptable and cost-effective means to deliver information and advice about using the birth ball, such as one-to-one or group instruction by midwives, physiotherapists or antenatal educators, written or media-based information.

It may be that strategies for latent phase labour have been under-researched because the home environment and women's behaviour there are not seen to be observable, responsive to encouragement or quantifiable. It is certainly impracticable and potentially harmful to require labouring women to assume defined postures for fixed periods of time, since the artificial imposition of maternal positioning is not responsive to fetal positioning and corresponding maternal sensation. Research should ensure that women are free to assume positions according to their wishes and the fluctuating dynamics of their labour.

Testing whether the birth ball might be an effective intervention in the latent phase had the potential to inform and strengthen the current evidence base. A randomised controlled trial (RCT) was the objective study design of choice to determine whether a causative relationship existed by minimising bias and confounding factors (Davidoff et al. 1995; Cluett 2006). Nevertheless, as the above points illustrated, a pragmatic research design needed to incorporate the

birth ball as part of a complex intervention (Medical Research Council (MRC) 2006) to ensure that participants were orientated to using a birth ball. Additionally, the design needed to allow participants to use the birth ball at home in latent labour as their needs and wishes dictated, rather than complying with a strict protocol. These and similar design features would ensure that the study tested the clinical effectiveness of the birth ball in the latent phase under 'real life' conditions (Loudon et al. 2015) as the Ball Assisted Latent Labour (BALL) Trial.

3.8 Conclusions from literature review

The literature review established that the current evidence base for using a birth ball in the latent phase of labour consisted of two observational trials and that no research had been undertaken to evaluate using a birth ball at home in the latent phase prior to hospital based labour and birth, thereby identifying a gap in the evidence.

It also established that further research would have to be based on a pragmatic and multi-faceted design to incorporate orientation to the birth ball and encouragement to use it whilst at home in the latent phase of labour. Moreover, in order to strengthen the evidence base, a pragmatic randomised controlled trial would provide a more robust experimental model to test the impact of birth ball use in the latent phase on pain perception, labour and birth outcomes and women's experience of the latent phase.

Chapter 4.0 details the development of the birth ball within a complex intervention and justifies the methodological approach and design for the trial in order to address the research question.

4.0 Methodology

This chapter discusses the development of the birth ball and the infomercial as a complex intervention (Medical Research Council (MRC) 2006). The experimental approach in the research design is explained and justified. The research setting is introduced and examined as a significant component in the design and construction of the complex intervention, in conjunction with the literature review findings, the feedback from a Patient Public Interaction (PPI) exercise and the principles of social marketing. These considerations underpin the choice of methods, as the sequential practices and techniques to collect, process and analyse the data (Bowling 2014), which are detailed in the subsequent chapter.

4.1 A complex intervention

An intervention is considered as the independent variable whose effect the study evaluates (Parahoo 2014). In order to test whether using a birth ball at home in the latent phase of labour reduced pain perception, two issues were considered. Firstly, as stated previously, birth balls were already available for use in the physiotherapy department, the maternity unit for active labour and in the public domain. Therefore, norms and guidelines regarding their correct inflation, cleaning and use were available from the manufacturers and local guidelines. For the trial, the context of use changed to the home environment, as did the motivational and decision-making locus, in that participants would make the decision to initiate, maintain or discontinue using the ball, rather than at the suggestion or recommendation of a supervising midwife.

A means had, therefore, to be identified to ensure that participants had physical access to a birth ball to use at home in the latent phase of labour. However, the anxiety which exacerbates pain perception and drives latent phase hospital admission, combined with Eri et al.'s (2015) recommendation for a latent phase 'toolkit' meant that an effective intervention could not be restricted to providing access to a birth ball, but needed to address participants' psycho-affective needs. In addition to orientating participants to the appropriate use and management of the birth ball, the intervention needed to enhance their

confidence, reduce their anxiety and provide the requisite information to de-medicalise their pain experience, because, as discussed in Chapters 1.0 and 2.0, current maternity care and research to date have neither addressed nor met families' needs and concerns.

This meant that the intervention would need to consist of several interacting components and thereby meet the criteria of a complex intervention (MRC 2006).

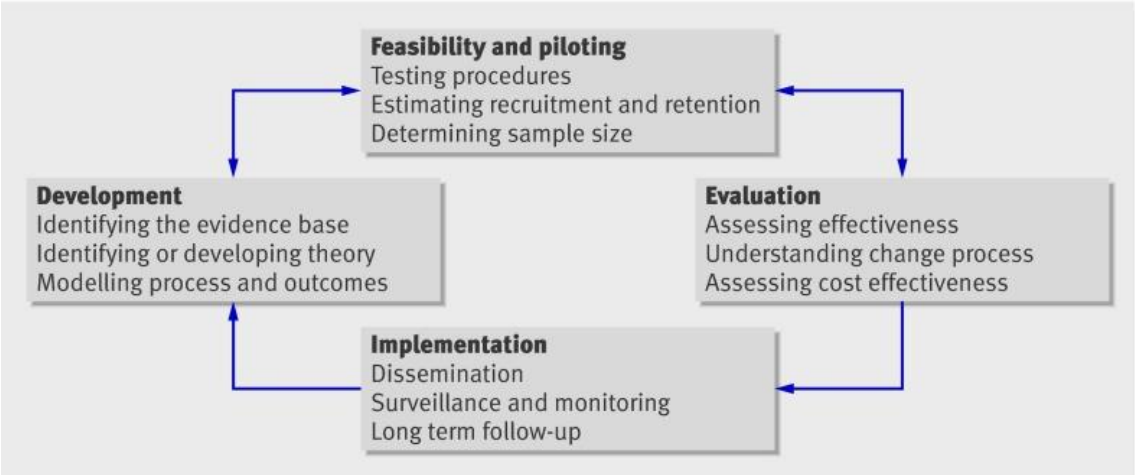
The complex intervention for the BALL trial comprised:

- the loan of a birth ball for use in the latent phase while Intervention Arm participants were in their home environment.
- a bespoke online animated infomercial, entitled '*Having A Ball in Early Labour*', to promote the potential advantages of using the birth ball in the latent phase.

The development and provision of these interventions are described below.

A systematic, comprehensive approach is required to complex intervention design to enhance the design, increase the value of the intervention(s) and reduce the likelihood of exposing participants to ineffective interventions which take no account of the context in which they will be implemented (Craig et al. 2008; O'Cathain et al. 2019). The MRC Framework (Craig et al. 2008) was applied to the development of the intervention of the BALL trial as shown below in Figure 4.1 and subsequently described. Since the conclusion of the BALL Trial, the MRC has enhanced its framework through Bleijenberg et al. (2018) and O'Cathain et al. (2019), both of which highlight the dynamic, iterative nature of intervention development as well as the importance of stakeholder involvement, in agreement with NIHR (2016). The rationale and details of the development for each intervention component are provided in Sections 4.1.5 and 4.1.6; however, the development journey within the MRC model (Craig et al. 2008) is outlined below.

Figure 4.1 Complex Intervention Development and Evaluation Model



(Craig et al. 2008, p.981).

4.1.1 Feasibility and piloting

It was decided to forgo formal feasibility and piloting on several grounds: firstly the comparatively small size of the trial and secondly the constraints of time and financial resources. Secondly, the ubiquity of birth ball use in the community and the PPI exercise (Section 4.1.4) evidenced that the birth ball and the infomercial formats would be acceptable and indeed, popular with potential participants.

4.1.2 Development

As summarised in Section 3.8, following a systematic review of the literature, it was concluded that using the birth ball in the latent phase of labour might reduce pain perception and subsequently reduce intrapartum obstetric interventions. The researcher's embeddedness in the research context allowed an understanding of the logistics that participants would manage in order to effect the transfer from home to the maternity unit and the admission procedures and advice they would receive. This understanding facilitated the construction of an intervention which would appeal to participants not only aesthetically, but as engaging and helpful activities during their latent labour.

4.1.3 Evaluation

As stated in Section 2.4, the birth ball was already well-established in rehabilitation and active labour care. In terms of cost-effectiveness, both the

birth ball and the infomercial components were managed at a modest cost. Moreover, since they could be reused if found to be effective, they had the potential for sustainability beyond reducing the cost burdens on the maternity service by a reduction in obstetric interventions (Tilden et al. 2015).

The BALL Trial planned to test the birth ball's effectiveness in a previously unevaluated context of participants' home in the latent phase; this informed both the methodological approach and the decision design the trial as pragmatic i.e. under 'real life' conditions and the supporting guidelines and information that participants would need to use the birth ball safely and to best advantage.

4.1.4 Implementation

The findings of the BALL Trial aimed to inform latent phase care and to determine if there was evidence to recommend and support its use in the latent phase. The wide availability of birth balls suggested that women may choose to obtain a birth ball to use at home but lacked an evidence base and a means to formalise advice and directions for their use. Hypothetically, it was considered that maternity units might offer birth ball loan schemes to families, with the educational component to disseminate evidence-based information and advice.

4.1.5 The birth ball

To provide access to a birth ball, 31 *Birth-ease* birth balls were purchased from a reputable supplier with sound technical specifications (Birth-ease 2018). To accommodate women of varying heights, 21x 65cm (for women <1.74m) and 10x 75cm (for women >1.75m) '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 with a PDI Sani-Cloth Chlor™ and air dried before being placed in a new polythene bag.

Each participant received a Safety Sheet with the birth ball (Appendix 13).

Funding for the purchase was met by donations from the local Federation of Women's Institutes (2 balls), Birth-ease (an additional ball and free delivery to the Trust) and an award from the Iolanthe Midwifery Trust.

4.1.6 The infomercial

Health information affects health decisions and behaviours as well as increasing understanding of key concepts (Cusack et al. 2018). Since using a birth ball at home appeared to be supported by anecdote alone, it was concluded that offering trial participants information on how to use the ball and the evidence base were key to maximising uptake in the Intervention Arm and enhancing women's confidence and autonomy. Previous studies about the birth ball, whether in the active or latent phase had already set a precedent in offering participants an educational component, whether as a group physiotherapy-led session (Leung et al. 2013), a booklet (Hau et al. 2012), or videotape (Gau et al. 2011). However, for this trial, local conditions and a contemporary study population had to be considered.

In terms of access to the educational component, the research setting was semi-rural and participants often had work, other children and commitments to fulfil; therefore, asking them to attend hospital-based group sessions was judged as impracticable even when meeting travel and parking expenses. Individual face-to-face sessions at home were considered time-consuming and beyond the research budget. Additionally, it would diminish the pragmatic trial approach, because the sessions would be unlikely to continue on conclusion of the trial due to funding constraints. Moreover, it was concluded that paper-based information in the form of leaflets or brochures might lack impact and using a two-dimensional medium to illustrate movement related, three-dimensional concepts would prove ineffectual. Additionally, 15% of adults in the UK (National Literacy Trust 2017) and 14% in the US (National Center for Educational Statistics 2006) are functionally illiterate, which means that a significant proportion of participants could be expected to struggle with unfamiliar text in leaflet format.

Traditional methods of disseminating health related information are becoming outdated and new channels for social marketing are needed (Carr et al. 2007). 'Social marketing' is a term which embraces proven marketing communication techniques over a wide range of media to promote health-related behaviours (Evans 2006). Social marketing techniques have been employed by such bodies as Public Health England (2014) with the national *Start4Life* initiative,

which was specifically targeted at families in lower socio-economic groups to promote improved nutrition throughout pregnancy and early years. Key features of the campaign included an aesthetic of bright colours and informal language together with accessibility across multiple media, apart from posters and leaflets.

Start4Life also used short animated infomercials designed as a means to generate an immediate viewer response (Zager 2012) across social media platforms such as Facebook, YouTube and Twitter, The flexibility and extensive coverage that could be achieved through animated infomercials made the format practicable and realisable at a comparatively low cost.

At least 90% of women in the USA and UK have online access (Anderson et al. 2019; Office for National Statistics 2019) and digital platforms avoid the cumbersome formats and information overload which hinder social marketing in maternity care (Evans 2016). Contemporary media can, therefore, improve inclusivity and accessibility to health-related information.

An animated infomercial was developed with the aim of educating women about the potential benefits of using a birth ball at home in the latent phase of labour, in the format which could overcome barriers to accessibility:

- as mentioned previously, to effectively demonstrate positions and movements on the birth ball
- to reduce the literacy requirement for accessibility
- to allow minimal costs for dissemination after the initial outlay for design and production.

Following negotiation with Bournemouth University's Faculty of Media and Communication, a Masters level graduate 3D Generalist in Animation was employed as a Research Assistant. The university provided technical facilities and support. The Chief Investigator (CI) designed a storyboard and proposed an aesthetic (Appendix 2); the design and production occupied a period of 10 months and cost £2,000. The design incorporated the following features:

- the character was limited to one pregnant female, to limit production costs

- the character was designed as dark haired with a medium – dark skin tone as a representation of all ethnic groups
- the narrative soundtrack was undertaken by volunteers; unfortunately, this did not include ethnic representation outside of White British. However, this could be modified in future
- the musical soundtrack was accessed as royalty free from the Internet, but credited as per Conditions of Use
- the aesthetic incorporated a contemporary colour palette and background décor
- the duration of the infomercial was restricted to 90 seconds, as per industry norm (Zager 2012)
- a statement of Intellectual Property and copyright was agreed with the University Legal Department and displayed on the closing credits.

The infomercial can be viewed at:
https://drive.google.com/open?id=1mN_6OTRAmZtcz-blDtRKatQJRFnxDF0X

Alternatively, see Appendix 2 for the storyboard, script and aesthetic.

4.1.4 Patient and Public Interaction activity

A PPI discussion with a local Maternity Service Liaison Committee was undertaken as recommended by the National Institute of Health Research (NIHR) INVOLVE to improve research quality (Hayes et al. 2012; NIHR 2016). 15 new mothers were invited to participate in a discussion at a local children's centre. Following verbal consent, the discussion was facilitated by the CI. Following a short introduction to the research project and a display of the proposed storyboard, participants were asked:

1. What is helpful for a positive early labour experience?
2. What did you find helpful or unhelpful in your early labour?
3. What would you do differently in a future early labour?
4. What do you think about using a birth ball in early labour?
5. What do you think about the project title, '*Having A Ball in Early Labour?'*

6. Are there any comments you would like to make about the proposed storyboard for the infomercial?

Participants' responses were summarised to inform the title and content of the planned animated infomercial. With consent, excerpts of participants' verbatim comments were incorporated anonymously into the infomercial soundtrack, read by volunteers.

In general, participants' feedback comments were positive regarding the format, title and content (Appendix 3). In particular, participants disclosed that they rarely had time or the motivation to read the large amount of written information they received antenatally and felt that the information was shared rapidly and accessibly on the infomercial. They reacted positively to the proposal that the infomercial could be shared in antenatal care waiting areas.

One participant remarked that the content glamourised early labour. The script narrative was revised to include content to reflect women's experience of the latent phase as tiring and frustrating (Appendix 2).

4.2 Rationale for an RCT design

RCTs are often described as the 'gold standard' of empiricism and the most robust and replicable means of establishing the existence or otherwise of a causal relationship between given variables (Davidoff et al. 1995; Cluett 2006). RCT design uses probability theory to create an experimental context where an hypothesised causal force acts upon an Intervention Arm and is absent from the Control Arm, thereby allowing for the valid identification and evaluation of a causal agent (Blackwood et al. 2010).This manipulation of variables and the minimisation of bias allow a therapeutic intervention to be tested on two or more groups of randomly assigned participants (Pocock 1983).

Whilst RCT design has traditionally been adopted to test the effect of pharmacological and surgical interventions in disease reduction and elimination, it is increasingly used for interventions aimed at enhancing and improving health in salutogenic and social science contexts (Craig et al. 2008; Roberts et al. 2008).

In order to address the research question:

‘Does using the birth ball at home in the latent phase of labour reduce pain perception?’, an appropriate methodological approach had to be identified.

The first factor to consider was the prevailing evidence available from the quasi-experimental trials identified in the literature review. Hau et al. (2012) and Leung et al. (2013) both offered evidence that participants found using the birth ball helpful in terms of pain and anxiety reduction in the hospital environment. However, the care context was based in Hong Kong and did not reflect that of countries such as the UK (NICE 2017), or the USA (American College of Obstetricians and Gynecologists 2017) where, as discussed in Section 1.2, women in the latent phase are discouraged from hospital admission and are likely to experience much of their latent phase at home (Beake et. al 2018). By contrast, in Hong Kong maternity units, latent phase admission is a care norm (Chilcott 2016).

The second issue was that participants in both trials (Hau et al. 20112; Leung et al. 2013) were not identified as at low or high risk of obstetric intervention, so both studies may have included women who were at high risk of obstetric intervention. This might have explained the high rates of obstetric interventions such as IOL and synthetic oxytocin augmentation in the settings, or at least allowed an understanding that these interventions were considered routine within the research setting. Since it was not possible to interpret the findings without this information, it was probable that there were significant confounding factors, because obstetric interventions are associated with a classic ‘cascade of intervention’ which affects, amongst other factors, birth modes and maternal and fetal outcomes (Tracy et al. 2007). These would have affected both arms equally had an RCT been used, but this was not the case. Additionally, it was not possible to draw firm conclusions as to whether using the birth ball reduced obstetric intervention, since local intervention rates and outcomes were only briefly and descriptively compared with background rates.

Lastly, the trials adopted a quasi-experimental model, because participants in both trials (Hau et al. 2012; Leung et al. 2013) opted to use the birth ball or not according to their own preference, rather than being randomised to a Control Arm (standard care) or Intervention Arm (using the birth ball). This self-selection and indeed, the quasi-experimental design, introduced bias because women’s

choices may have reflected their belief and value systems. For example, as discussed in Section 2.5, women who opt for non-pharmacological strategies are more likely to have higher self-efficacy (Beebe et al. 2007) than those who opt for pharmacological analgesia and so are correspondingly less likely to undergo obstetric intervention.

With these issues under consideration, the methodological approach for the current study needed to inform and strengthen the current evidence base by minimising bias and confounding factors and adopting an objective approach. This could be achieved by:

- a direct comparison between two similar participant groups, one of which would use a birth ball in the latent phase and the other not;
- random allocation to the two participant groups;
- recruiting participants at low risk of obstetric intervention, which would reduce the number of confounding factors and allow an objective comparison of pain perception and obstetric intervention;
- using objective measurement tools to allow direct comparison between two similar groups.

Above all, addressing the research question objectively was most likely to provide robust evidence as to whether there is a causal link between birth ball use and reduced pain perception.

The RCT was identified as the most appropriate study design to determine whether pregnant women, who used a birth ball (in the Intervention Arm):

- reported less pain on a VAS when admitted to hospital in labour (primary outcome);
- experienced less obstetric intervention;
- recorded increased Outcome Expectancy and Self-Efficacy scores on the modified Childbirth Self-Efficacy Inventory© (CBSEI) (Lowe 1991), after accessing the infomercial *Having A Ball in Early Labour;*
- reported greater use of the birth ball in the latent phase, increased acceptability and satisfaction;

than women who received standard care (in the Control Arm).

Providing that the foremost maxim of research interpretation is observed: ‘Correlation does not imply causation’, then RCTs are more likely than other study designs to identify a causal link between two variables. Unlike observational studies, the RCT design is less likely to inflate the potential effect of an intervention by ensuring groups are similar in terms of participant preference (in this case women who might actively chose to use a birth ball reflecting a value set of those who were less likely to experience obstetric intervention).

Chambliss and Schutt (2016) proposed five criteria to determine a causal relationship between two variables, three of which are core and two of which strengthen causal explanations. These are summarised in Table 4.1, together with an identification of how these criteria could be applied to the BALL trial outcomes.

Table 4.1 Criteria for a causal relationship (adapted from Chambliss and Schutt 2016)

Criterion	Definition	Application to the BALL Trial primary outcome
Empirical association	An empirical (observed) correlation between the independent and dependent variables.	Correlation between birth ball use and reduced pain and anxiety scores in Hau et al. (2012) Leung et al. (2013) in the latent phase in hospital.
Temporal priority of the independent variable	Time order; the independent variable precedes the dependent variable.	Using the birth ball at home in the latent phase preceded hospital admission and the VAS score.
Non-spuriousness	Change occurs due to a third variable.	Reduced pain perception when using the birth ball in the latent phase.
Identifying a causal mechanism	The process which connects changes in the independent and dependent variables.	Section1.5; the intrinsic pain modulation pathway. Optimisation of intrapartum neurophysiology.
Specifying the context in which the effect occurs	Not explanatory or causative in itself, but supports interpretation of findings.	Section 1.2; a high-income country where the latent phase is usually spent at home for pregnancies at low risk of obstetric intervention.

Key ☐ **Core criteria** ☐ **Strengthening criteria**

As the analysis in Table 4.1 demonstrates, the study design components fulfilled the criteria for a causal relationship, which in turn, justified the RCT design.

4.2.1 Pragmatic RCT design

RCTs minimise bias by the application of rigorous inclusion and exclusion criteria which means that they can present high internal validity (Frome and Owen 2014) and should be generalisable to other contexts, i.e. present robust external validity (Pierce 2013). Nevertheless, RCT statistical significance does not always translate into clinical significance (Thompson 2017). For example, the Hands On Or Poised (HOOP) trial (McCandlish et al. 1998) found a statistically significant reduction in perineal pain from participants whose midwives had adopted a 'Hands On' approach to protecting the perineum during birth. However, the difference was small and whilst the findings informed the practice of 'Hands On' at birth, they could not be extrapolated to other contexts such as water birth, where guarding the perineum is not advised, or a mother who does not wish to be touched, or receives her baby herself.

The HOOP trial example demonstrates that having established criteria through which a causal effect may be reliably identified, the most important distinction to observe is the continuum which bridges intervention trials and considers whether the trial evaluates the intervention 'efficacy' (under laboratory conditions) as explanatory trials or effectiveness (in real-life conditions) as pragmatic trials (Singal et al. 2014; Weinfurt et al. 2017). Both explanatory and pragmatic trials confirm hypotheses; however, pragmatic trials provide evidence for the adoption of interventions into real-world practice, thereby overcoming the disparities between internal and external validity (Schwartz and Lellouch 1967; Patsopoulos 2011). This demonstrates how pragmatic RCT trial design cannot be predicated on imposing laboratory conditions onto a real-world study population, but rather constructs the protocol within the real-world setting (Rushforth 2015) and bridges the gap between theory and practice (James 2017; Zuidgeest et al. 2017).

With consideration of these factors, the BALL Trial was designed as a pragmatic RCT. The design was incorporated through the lens of the Pragmatic – Explanatory Continuum Indicator Summary 2 (PRECIS–2) wheel (Loudon et

al. 2015) and evaluated in Table 4.2, to examine the balance of trial design on the Pragmatic-Explanatory continuum (Appendix 1).

The PRECIS-2 wheel presents 9 domains reflecting different aspects of trial design. Each aspect is scored on a scale from 1 (Very explanatory) to 5 (Very pragmatic) (Loudon et al. 2015). The total score and the representation on the wheel allow an evaluation of the overall trial approach, as shown in Table 4.2.

Table 4.2 PRECIS–2 Evaluation of the BALL Trial (adapted from Loudon et al. 2015)

Domain	Score	Comments
Eligibility To what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care?	2	Participants excluded from the trial included women with [1]BMIs>35, [2]VBAC, those with endocrine or cardiac conditions, women with [3]IUGR / [4]SGA babies and any other conditions where the woman was more likely to be offered IOL. It also excluded women who planned a home birth or elective CS and women who lack sufficient English language skills or did not have home Internet access.
Recruitment How much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients?	3	Participants were identified and initially approached by their named [5]CMW or by self-referral to their CMW / CI.
Setting How different are the settings of the trial from the usual care setting?	5	Trial settings identical to real-life, i.e. home, then the maternity unit as the woman's choice of birth place.
Organisation How different are the resources, provider expertise, and the organisation of care delivery in the intervention area of the trial from those available in usual care?	4	Almost identical. Intervention Arm participants had access to an infomercial, promoting use of the birth ball in the latent phase. For the rest of the care, resources and provider expertise did not differ.
Flexibility (delivery) How different is the flexibility in how the intervention is delivered and the flexibility anticipated in usual care?	4	The addition of the infomercial component was a new aspect of maternity care, as was the offer to lend a birth ball to use at home in the latent phase. However, many potential participants already owned a birth ball or provided their own.
Flexibility (adherence) How different is the flexibility in how participants are monitored and encouraged to adhere to the intervention from the flexibility anticipated in usual care?	5	Participants were not required to adhere to any schedule or regime of use, regardless of the allocation.
Follow up How different is the intensity of measurement and follow –up in usual care?	3	Measurement of the primary outcome was with a VAS, which was not standard care. The postnatal questionnaire was also not a standard care component, although there was a midwifery-led standard postnatal telephone interview 6 weeks postnatally.

Primary outcome To what extent is the trial's primary outcome directly relevant to the participants?	4	An evidence-based strategy to reduce pain perception and facilitate labour progress which is currently lacking. Pain has been identified as a primary driver for latent phase hospital admission. Although the VAS is a subjective assessment, it was not a component which would directly inform the participants' care.
Primary analysis To what extent are all data included in the analysis of the primary outcome?	5	Analysed as [6]Intention-To-Treat to minimise selection bias.

[1] Body Mass Index
[2] Vaginal Birth After Caesarean
[3] Intrauterine Growth Retardation
[4] Small for Gestational Age
[5] Community Midwife
[6] Intention To Treat

Key

1. **Very explanatory**
2. **Rather explanatory**
3. **Equally pragmatic and explanatory**
4. **Rather pragmatic**
5. **Very pragmatic**

Total PRECIS-2 score

35/50

The BALL Trial PRECIS-2 score (35/50) reflected a strong orientation towards a pragmatic rather than an explanatory methodological approach and was designed as an effectiveness trial.

Having justified the methodological approach, the research context is described in Section 4.2.2. Specific methods are explained with details of accommodations made in order to address the research question. Facilitators and barriers to the research process are discussed at salient points.

4.2.2. Study area and population

The research setting was home-based, in collaboration with an NHS Trust serving a semi-rural population in the south of England. The birth rate is approximately 1,400 babies per annum, with 95% of births occurring in the hospital. The hospital Labour Ward has five birthing rooms; one room offers a birth pool and another room offers an active birth environment. As well as an obstetric theatre, there is a co-located Special Care Baby Unit, which can accommodate neonates from 32 weeks' gestation. In the event of any suspected or planned pre-term births below this gestation, an *in utero* transfer is undertaken to a larger unit with a Neonatal Intensive Care Unit. Home births are attended by the on-call community midwives. Antenatal education sessions are held fortnightly and run by the midwifery teams. Midwives work as either shift-based core (antenatal, intrapartum and postnatal ward-based) or on-call community (antenatal, intrapartum and postnatal) (General Practitioner (GP) surgery, Family Centre and home-based).

4.2.3 Baseline data

An initial audit in the host NHS Trust was conducted to gain anonymised background data of latent phase hospital admission, obstetric intervention and birth modes in order to conduct a power calculation. Consent to undertake the audit was obtained from the NHS Trust Quality department in conjunction with the Trust Research and Development department.

A one month period was chosen firstly, for manageability of data collection, to inform routine data collection and interpretation for the Trust and to represent maternity care activity within the research setting. The data were extracted from routinely collected data from the period 1st October – 31st October 2015 from

the Trust electronic maternity records. A total of 98 women gave birth during this period, which included 97 singleton pregnancies and one twin pregnancy. Five women had planned home births and six women gave birth by elective CS; these data were excluded from the audit. A total of 87 women planned to labour in the research setting maternity unit (see Table 4.3 below), of whom 40 were classified as 'at low risk of obstetric intervention' i.e. women with live singleton, cephalic pregnancies between 37 – 41+5 weeks' gestation in the absence of significant maternal medical / obstetric history or fetal anomaly.

Table 4.3 Host Trust labour and birth admissions and interventions October 2015

	Total hospital & labour planned births	**Low risk hospital and labour planned births**
Births	**87** (100%)	**40** (46%)
Parity	**Primiparous 35** (40%) **Multiparous 52** (60%)	**Primiparous 18** (45%) **Multiparous 22** (55%)
Pre-term	**10** (11%)	**N/A**
Birth mode		
Normal birth	**66** (76%)	**33** (82%)
Forceps / Ventouse	**8** (9%)	**4** (10%)
Emergency CS	**13** (15%)	**3** (8%)
Interventions		
IOL	**30** (34%)	**5** (12.5%)
Amniotomy	**34** (39%) 5 maternity notes unavailable	**14** (35%) 2 maternity notes unavailable
Synthetic oxytocin	**17** (19%)	**14** (35%)
CEFM	**48** (55%) 1 precipitate labour not auscultated	**17** (42%) 1 precipitate labour & 2 unplanned home births, not auscultated
Regional anaesthesia	**Total births 29** (32%) **Normal births 13** (15%)	**Total births 12** (30%) **Normal births 7** (17.5%)
Latent phase admissions	**15** (17%)	**9** (22%)

The data were interpreted with caution, as they represented a small number of births within a short period of time, with a potential for bias. It was also noted that data were lacking on CEFM for seven women whose maternity notes were unavailable. However, the following observations were made:

- The number of latent phase admissions was below the rates reported in research literature (Rota et al. 2017).
- The normal birth rate was higher than the national average of 60%; conversely, the CS rate (elective and emergency) and assisted birth rates were lower (24%) than the national rate (NHS Digital 2016).
- IOL rates were higher overall than the national average of 13.6% (NHS Digital 2016); this may also have correlated with a higher rate of CEFM, in itself a recognised contributory factor towards increased intervention (Alfirevic et al. 2017). The total IOL rate reflected the inclusion of high risk pregnancies, as would be expected. More in-depth statistical analysis may have revealed a correlation of IOL with increased CS, but was beyond the scope of this audit.
- Amniotomy and synthetic oxytocin rates also reflected the IOL rates as established IOL interventions in the UK (NICE 2008).

As per host NHS Trust procedure, the audit findings were summarised and presented to the Quality and Labour Ward management teams, with the recommendation that the audit should be repeated the following year to monitor IOL rates within the Trust.

In the months following this audit, based on the recommendations of NHS England (2016) to reduce national stillbirth rates, the host NHS Trust adopted the Growth Assessment Programme (GAP) to detect sub-optimal fetal growth (Perinatal Institute 2019) and a local guideline was implemented to manage pregnant women who reported reduced fetal movements. The effect and implications of these interventions on the trial population are discussed in detail in Sections 6.5.2 and 7.2.

These data were used to perform a power calculation to support the RCT, as detailed in Section 5.4.1.

4.3 Summary

The rationale for a complex intervention and its components has been discussed and justified. Additionally, the literature review, the trial setting, feedback from a PPI exercise, the principles of social marketing and the recommendations of the MRC (2006) have been critically examined to inform the development and content of the birth ball and an animated infomercial as a complex intervention. The choice of a pragmatic RCT as the most appropriate methodological approach to address the research question has been explored and justified. The methods utilised for the trial implementation will be detailed and justified in the following chapter.

5.0 Method

The order and detail of the methods implemented to conduct the BALL trial reflect those recommended by the Standard Protocol Items: Recommendations for International Trials (SPIRIT) statement (Chan et al. 2013) to maintain consistency with publication.

5.1 Hypotheses

5.1.1 Primary and null hypothesis

The primary hypothesis was stated as:

Relative to controls, Intervention Arm participants would report less pain on a VAS when admitted to hospital in labour.

This was stated as the null hypothesis, namely:

Box 5.1 The null hypothesis

> Using a birth ball at home in the latent phase of labour does not reduce pain perception.

5.1.2 Secondary hypotheses

- Participants accessing the infomercial *Having A Ball in Early Labour*, would demonstrate increased Outcome Expectancy and Self-Efficacy scores on the modified CBSEI© (Lowe 1991).
- Intervention Arm participants would experience fewer obstetric intrapartum interventions than Control Arm participants including CEFM, amniotomy, intravenous synthetic oxytocin and regional anaesthesia.
- Intervention Arm participants would report greater use of the birth ball in the latent phase, increased acceptability and satisfaction.

5.2 Primary outcome

Since women cite pain as their primary driver to requesting hospital admission in the latent phase (Barnett et al. 2008), it was apposite that a new approach should focus on their concerns and experience. Women using a birth ball in the

latent phase reported reduced pain perception in both Hong Kong trials, (Hau 2012; Leung et al. 2013), however, as stated in Section 3.5.1, sociocultural and care norms differed from those of other high-income countries in that women in Hong Kong were more likely to present to a maternity unit in the latent phase and spend less time at home than in countries such as the UK and the USA. Consequently, it was logical that if women perceived less pain, then they would feel less anxious and be more likely to stay at home until labour established.

5.2.1 Primary outcome measurement

As discussed in Section 2.2, as a subjective and complex experience, pain eludes standardised description and quantification (Carvalho and Cohen 2013). It is the contention of the CI that the underpinning mindset of childbirth pain in high-income societies may be described as a progression of 'no pain' in pregnancy to an incremental augmentation of pain and suffering throughout labour culminating in the birth. Thus, a woman may expect to experience the most severe pain immediately before the birth of her baby. However, this is contradicted by women's experiences; for example, women may start to labour managing a variety of painful conditions such as back, pelvic and ligament pain. Labour onset may then be experienced as a relief or a further pain burden. By contrast, writers such as Kitzinger (2012), Gaskin (2009) and Odent (2009), attest to the role of oxytocin and endogenous opiates in mediating 'orgasmic' or 'ecstatic' states at birth, which does not refute the pain experience, but highlights the neurophysiological response as pleasurable.

A systematic literature review of quantitative and qualitative studies (Whitburn et al. 2018) concluded that despite the negative connotations of labour pain in high-income countries, labour pain itself is not directly correlated with suffering and is dependent on the meaning that a woman places on her perceptions, the environment and the presence or absence of trusted caregivers. Therefore, if women are anxious and unhappy at home in the latent phase of labour, then they might be expected to experience greater pain at that point and if they feel safer on arrival in the maternity unit as their chosen place for labour and birth, then they might then experience less pain. This is at odds with the 'incremental pain model' since women's pain perception might fluctuate considerably in the

course of her labour according to her neurophysiological and emotional landscape.

The attempted quantification of the multi-factorial, subjective and labile pain experience can only be meaningful when it is by self-report (Cervero 2012) and a VAS is widely used as a 'snapshot' for clinical and social investigation (Wewers and Lowe 1990; Takegata et al. 2011). However, sequential VAS scoring throughout labour is contra-indicated because of the 'ceiling effect' where women may indicate a score beyond the point of 'worst pain imaginable' (Wei et al. 2010; Jones et al. 2015). Moreover, as Whitburn et al. (2018) point out, because of the multi-faceted nature of pain, a VAS score encapsulates and quantifies it, but cannot explain the experience.

Nevertheless, it was decided to capture participants' VAS scores at the time of admission to the maternity unit as a subjective, self-report of their pain perception following their decision to seek admission in labour. The VAS offered an inexpensive, speedy, simple and relatively non-intrusive means of capturing women's perception of their pain experience.

In order to reduce the 'ceiling effect' of a numerical VAS from 0 – 10 and encourage participants to report their pain with consideration of their emotional and cognitive response, the VAS instrument was designed with verbal descriptors, from 'no pain' to 'worst pain imaginable'.

The VAS consisted of a 10 centimetre horizontal line, to represent a continuum of pain intensity from 'no pain' at one extremity to 'worst pain imaginable' at the other, as shown in Figure 5.2:

Figure 5.1 The VAS

no pain **worst pain imaginable**

The participant was asked to mark her perceived pain on the VAS on admission to the hospital. The CI measured the woman's mark with a cm / millimetre (mm) marked ruler. Each score was recorded within one decimal point (Cole 2015) to offer greater sensitivity to the detection of a 1.0 difference in the primary outcome.

5.3 Secondary outcomes

As a component of the complex intervention, evaluation of the effectiveness of the infomercial component was required. The infomercial aimed to inform and empower women about using the birth ball at home in the latent phase. Since, as stated in Section 2.3, self-efficacy is associated with reduced obstetric intervention, effective information sharing with the infomercial would empower women and enhance their self-efficacy. On this basis, the CBSEI© was identified as an appropriate instrument to detect whether women reported enhanced self-efficacy before and after exposure to the infomercial.

Since early hospital admission is associated with greater obstetric intervention, labour and birth data were collected with the key interventions implicated in the 'cascade of intervention', namely: CEFM, amniotomy, synthetic oxytocin augmentation and regional anaesthesia.(whether epidural, epi-spinal or spinal anaesthesia). Additionally, as routine vaginal examination on admission in labour was usually undertaken in the research setting, cervical dilatation on admission was recorded where the information was available.

5.3.1 Secondary outcome measurement

5.3.1.1. The Childbirth Self-Efficacy Inventory© (CBSEI) (Lowe 1991)

The CBSEI© is a 62-item scale that requires responses on a 10-point Likert scale. High scores indicate stronger Self-efficacy Expectancy (or confidence in personal resources) or Outcome Expectancy (confidence to utilise a given strategy) for birth. The CBSEI© has been validated for use in a wide variety of populations and languages as well as English speaking (Avery et. al 2014). Although the CBSEI© is described as addressing the first and second stages of labour in Parts I and II respectively, Part I encompasses the latent and active phases because women did not differentiate between the two (Lowe 1993;

Gröss et. al 2009; Gröss et. al 2010) and there is no recognised standard or consensus of the onset of active labour (Hanley et. al 2016).

The author's permission was obtained to apply the CBSEI© Part I alone to the study participants on the grounds that as it asks:

> '…..when contractions are every five minutes or less'
>
> (Lowe 1991),

this was most likely to reflect women's perceptions that their labour had commenced and that they would be making a judgement as to whether to seek hospital admission (Appendix 4).

The CBSEI© Part 1 was provided in two hard copies marked with the Participant Identifier Number (PIN) and Before and After to Intervention Arm participants, to be completed prior to viewing the infomercial and again three days later. The completed questionnaires were then returned in a stamped addressed envelope to a dedicated mail point in the maternity unit. Self-efficacy Expectancy and Outcome Expectancy scores were then calculated and recorded on the Case Sheet.

5.3.1.2 Postnatal questionnaire

In order to determine the uptake, acceptability and satisfaction of participants' experience use of the birth ball, a confidential on-line questionnaire was designed for distribution and completion at 6 weeks' postpartum.

The *Online Survey* platform was used to design, distribute and analyse the postnatal questionnaire as it is one of the most widely used survey platforms in UK research and higher education (Jisc 2019) and offered flexibility and security. The draft questionnaire was distributed to ten postgraduate and lecturing staff within the faculty to identify any errors or ambiguities and revised on the strength of their feedback.

The postnatal questionnaire is available in Appendix 5.

5.4 Operational definitions

The operational definitions for the research are summarised in Table 5.1 below:

Table 5.1 Operational definitions

Conceptual variable	Operational definitions
Latent phase of labour	As per NICE (2017) UK guidelines (Section 1.1) with maternal perception of uterine contractions accompanied by cervical changes and / or cervical dilatation up to 4cm
Active labour	As per NICE (2017) UK guidelines. Maternal perception of regular uterine contractions of 1 every 3-4 minutes accompanied by cervical dilatation of 4cm or more
Routine antenatal care	As recommended by NICE (2008). Includes parents' optional access to NHS antenatal education face-to-face sessions and print or online resources
Labour pain	The participant's subjective report of labour pain experienced as 'an unpleasant sensory and emotional experience' (IASP 2014 p.1) Number of centimetres marked on a 10cm VAS from 'no pain' to 'worst pain imaginable' to one decimal point (Section 4.2.1)
Outcome Expectancy	Sum of 10 point Likert scale scores for 15 latent phase strategies as to how much the participant anticipates that they will be helpful in the latent phase of labour
Self-efficacy Expectancy	Sum of 10 point Likert scale scores for 15 latent phase strategies as to how much the participant anticipates that they will be able to utilise them in the latent phase of labour
Satisfaction	Percentage of respondents selecting 'Helpful' to Q.10 on the postnatal questionnaire: 'How helpful did you find using a birth ball at home in your recent labour?' Percentage of respondents selecting 'Yes' to Q.11 on the postnatal questionnaire: 'Would you use a birth ball home in early labour for a future labour?'
Maternal acceptability	Percentage of respondents selecting 'Likely' to Q.12 on the postnatal questionnaire: 'How likely would you be to recommend a birth ball in early labour to a friend or family member?'
Maternal satisfaction	Percentage of respondents responding 'Likely' to Q.12 on the postnatal questionnaire: 'How likely would you be to recommend a birth ball

	in early labour to a friend or family member?’

5.5 Recruitment

Inclusion and exclusion criteria were applied for prospective participants to identify women at low risk of obstetric intervention and minimise confounding factors, as summarised below in Table 5.2.

Table 5.2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Aged 18 years or older	< 18 years old
Able to understand, read and speak English	Not able to understand, read and speak English
Planned hospital labour and vaginal birth	Planned home birth Elective CS
Spontaneous labour	Planned Induction of labour
Singleton cephalic pregnancy > 37 weeks' gestation	Non-cephalic presentation < 37 weeks gestation
Home Internet access	BMI >35 at booking
	Previous CS or other uterine surgery
	Antenatal diagnosis of fetal anomaly, IUGR, fetal growth <10th centile or intrauterine death
	Pre-existing maternal medical conditions e.g. cardiac, endocrine
	Previous stillbirth
	Obstetric complications e.g. intrahepatic cholestasis
	Current use of recreational or prescribed analgesic medication

In keeping with the trial design of a pragmatic RCT (Section 4.2), a balance had to be achieved between excluding women who were likely to be offered an IOL and would therefore not experience spontaneous labour at home and having a sufficiently wide pool of potential participants. The decision was made to not exclude women who smoked, those who had undergone assisted conception procedures and those aged 40 years and above, even though they received serial ultrasound growth scans at 28, 31, 34, 37, 40 and 41 weeks in line with GAP (Perinatal Institute 2016). Participants who had tested as positive for Group B Streptococcus and planned to receive intravenous intrapartum antibiotics as per local and NICE (2012) guidelines were not excluded from the trial.

Women who managed mental health conditions or had safeguarding issues (with the exception of recreational drug use, which was an exclusion criteria) were only approached for recruitment if their named CMW considered their circumstances stable enough to allow them to potentially benefit from using a birth ball and to undertake the trial activities. Some 10% of participants had safeguarding issues, which included mental health conditions, young parenthood, unsupported lone parents, vulnerable housing, care leavers and domestic violence.

5.5.1 Power calculation

A power calculation was conducted for the BALL Trial with the assistance of the faculty statistician. 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 as found by Leung et al., 2013) based on standard deviations of 2.6 and 2.5 in each group respectively (Leung et al. 2013), a two-sided 5% significance level, and 90% power. To account for 20% not contributing to the main analysis (Sackett et al. 2000), 332 would need to be recruited (166 in each trial arm).

From the initial audit, as reported in Section 4.2.2, there were approximately 100 births a month in the research setting; according to the inclusion / exclusion criteria detailed in Table 4.3, 40% of these births could be considered at low risk of obstetric intervention. On this basis, 8 months was set as the minimum data

collection period from 1 February 2018 – 31 October 2018, with projected recruitment of 40 recruitments and consent per calendar month. This proved to be unrealisable and the recruitment period was extended to 31 December 2018.

5.5.2 Recruitment strategies

The CMWs were each provided with a Recruitment Pack containing:

- 2 recruitment posters to display in their antenatal clinic area and Blu-Tack®
- Trial exclusion and inclusion criteria
- A recruitment / data collection pathway (Appendix 6)
- 10 Demographic Details Forms
- A small confectionary gift

Core hospital midwives received a Data Collection Pack containing:

- 1 recruitment poster
- Trial exclusion and exclusion criteria
- A recruitment / data collection pathway (Appendix 6)
- A small confectionary gift

Training was provided either in the Community Midwives Office or at Maternity Ward handovers.
Following explanation of the trial, the midwives signed the Delegation Log in the Site File to confirm their training and understanding of their roles.

The trial was publicised by means of posters which were displayed in antenatal waiting areas in the maternity unit, in GP surgeries and in Children's Centres. The CI visited antenatal education sessions and anti-D clinics in the hospital and antenatal clinics held in GP surgeries and Children's Centres. The poster was also displayed in the host maternity service public Facebook page. Potential participants also directly contacted the CI by phone or e-mail.

Potential participants were only approached from 28 weeks' gestation onwards if their CMW had discussed the trial with them or had identified them as potentially eligible and appropriate for approach. If the woman expressed an interest, she was asked to complete a Demographic Details Form (Appendix 7) for contact after 24 hours and reassured that should she choose not to join the

trial, then her details would be destroyed. The woman was also provided with the Participant Information Sheet (PIS) to read (Appendix 8).

After at least 24 hours had elapsed, then contact was made with the woman. If she declined to participate, then she was thanked and her Demographic Details Form disposed of as confidential waste. If she decided to join the trial, then a consent appointment was made either at her home, in the Maternity Unit or the venue for her antenatal checks according to her preference and convenience. Having ensured that the participant had read the PIS, understood the requirements of an RCT and met the inclusion criteria, she was asked to read and sign the Consent Form (Appendix 9).

Following randomisation and allocation to either the Control or Intervention Arm of the trial, a PIN was generated and a Participant Sticker (Appendix 12) placed on the front of the participant's hand-held maternity notes. A VAS pro-forma was labelled with her PIN and placed at the front of her notes, where it would be most likely to be noticed by the midwife on admission to hospital in labour. The participant was informed of her allocation and provided with the appropriate Participant Pack and instructions (Appendix 10). For Intervention Arm participants who accepted the loan of a birth ball, a note was made of the participant's height to ensure that the correct size of birth ball was provided. Where women had their own ball, advice was provided re: size and the correct inflation.

The participant's GP and CMW were then informed of the woman's participation via the GP/CMW Letter (Appendix 11). The original Consent Form was filed in the woman's hospital notes, with an additional Participant Sticker; one copy was placed in the Site File and one copy was posted to the woman. Participant details (but not allocation) were recorded on EDGE Version 2.0.44 as a clinical data management system (Clinical Informatics Research Unit, University of Southampton 2017). Anonymised recruitment data were uploaded to the NIHR Central Portfolio Management System monthly.

5.5.3 Enablers to trial recruitment

The trial attracted considerable interest within the research setting and recruitment benefited from 'word of mouth' and recommendations to friends and relatives. Many participants expressed an altruistic desire to help other women and enhance maternity care.

Women reported that the prospect of using the ball at home was attractive and were interested in the prospect that using the ball might reduce pain perception and interventions for vaginal birth. A substantial number of multiparous participants had experienced obstetric interventions in previous labours which they wished to avoid in their current pregnancy. Additionally, families were encouraged by the status and size of the trial on the NIHR Portfolio and the fact that the trial aimed to provide evidence which was lacking. Many families expressed civic pride and satisfaction that their community and maternity services were represented as the setting for the trial.

The trial also benefited from the provision of pool cars funded either by the maternity service or the Research and Development department. This enabled the researcher to travel freely within the research setting to consent participants. Given the size of the study and the benefit to the portfolio, the NIHR Clinical Research Network made funds available to support a research midwife to assist with recruitment for one day a week.

5.5.4 Barriers to recruitment

The launch of the BALL Trial coincided with the restructuring of the midwifery teams from integrated i.e. community and core to separate community (day and on-call hours) and core hospital-based (shift) roles. As a result, many CMWs moved their locality teams and antenatal clinics and adjusted to new caseloads, colleagues and facilities. In the transition period, many CMWs were not ideally placed to absorb and implement the additional information for the trial and this was complicated by not allowing for a gradual increase in recruitment whilst the CMWs settled into their new posts and felt confident about discussing the trial.

The transition phase also meant higher caseloads to manage with CMW vacancies and the withdrawal of Maternity Support Worker assistance in

antenatal clinics with appointments, venesection and administration. As a result, opportunities to approach potential participants were missed because the pressure on appointment time was increased. This was overcome by the CI and research midwife travelling extensively to antenatal clinics to publicise the trial and approach those women who the CMWs identified as willing / suitable for approach.

The Research Ethics Committee did not accept a proposal for a monthly draw for spending vouchers for either participants or recruitment midwives. As an alternative, the CI provided a monthly home-baked Appreciation Cake for the staff, advertised as in honour of the CMW team which had referred the highest number of potential participants (regardless of consent). This proved to be a well-received gesture. A recruitment total was also kept in the maternity ward office and was updated regularly, which also engaged staff interest.

5.5.5 Sample

Following an expression of interest in participating in the trial and completion of the Demographic Details Form, 414 pregnant women were contacted by the CI and / the Trust's research midwife.

295 pregnant women were recruited to the trial, of whom:

165 were primiparous

130 were multiparous

Reasons for not participating in the trial are detailed in Table 5.3.

Table 5.3 Reasons for not participating in the BALL Trial

Reason for not participating	n
Not contactable	35
Declined	30
Other	14
Did not meet inclusion criteria	
Age < 18 years old	3
BMI	1
Breech presentation	3
EDB after 31/03/2019	4
Fetal anomaly	1
Maternal condition	2
Moved away	2
Planned home birth	2
Planned IOL	3
Previous CS	9
Small for Gestational Age (SGA)	3
Gave birth before consent	7

5.5.6 Blinding and allocation

One form of selection bias can occur when participants are recruited onto a trial on the basis of knowledge regarding what the next allocation is likely to be (Kahan et al. 2015). In order to avoid both selection and allocation bias, randomisation and allocation should be undertaken at a distance from the research and recruitment team (Mansournia et al. 2017).

Randomisation for the trial was constrained by a small budget and the fact that recruitment and consent were undertaken by the CI with some assistance from a research midwife. An online randomisation service was employed (Sealed

Envelope 2016), which allocated participants to the Control or Intervention Arm, stratified for primiparity or multiparity to balance the greater obstetric intervention associated with primiparous labours and births (Dahlen et al. 2014; Royal College of Midwives 2016). As an additional strategy against allocation bias and to balance allocation, randomisation was set to blocks of 2, 4 and 8 (Suresh 2011).

Randomisation was undertaken following consent.

The nature of the intervention precluded blinding of the CI, research midwife, participants or midwives.

Participants were randomised to the Control or Intervention Arms as shown in Table 5.4.

Table 5.4 Participant allocation by randomisation

	Control Arm n	**Intervention Arm n**
Primips	83	82
Multips	66	63

One participant was consented, but gave birth before randomisation and was withdrawn from the study.

Recruitment and allocation are summarised in Figure 6.1.

5.6 Data collection

Participants' demographic details were recorded following consent, including:

- name
- age
- parity
- marital status
- educational level

5.6.1 Control Arm

Control Arm participants received standard antenatal care. Instructions and VAS proformas were provided to each participant as detailed in Section 5.4.2.

5.6.2 Intervention Arm

Intervention Arm participants were each provided with:

- CBSEI© pro-formas and a stamped addressed envelope. Each pro-forma was pre-coded with the Participant Information Number and Before / After to differentiate between pre- and post- test completion.
- instructions with on-line access to the intervention and the loan of a birth ball (Appendix 10)
- a Safety Advice sheet regarding birth ball use (Appendix 13)
- VAS pro-formas were also placed in the front of the participants' hand-held antenatal care notes with a Participation Sticker (Section 5.4.2).

The completed Before and After CBSEI© pro-formas were returned to a designated mail point via the provided stamped addressed envelopes.

All participants were asked to report their pain levels on the VAS pro-forma when they were admitted to hospital in labour. The admitting midwife VAS placed the completed VAS proformas in a designated collection box.

Labour and birth outcomes for Control and Intervention participants were collated retrospectively from the host Trust maternity notes and electronic records system by the CI.

An access Uniform Resource Locator (URL) to an online postnatal questionnaire was e-mailed to all Control and Intervention Arm participants who

had experienced a spontaneous onset of labour 6 weeks postnatally. These were collected and processed by the CI.

5.7 Adherence to protocol

Adherence to protocol refers to the degree to which trial participants' behaviour matches their allocated intervention (Chan et al. 2013). Because it was apparent that the birth ball was a popular intervention and, as stated previously, that it would not be possible to dictate or control participants' choices or activities in the latent phase, the research design incorporated the following measures to maximise participant adherence to the protocol.

A birth ball was only provided for Intervention Arm participants and access to the infomercial was restricted to Intervention Arm participants, who were specifically asked not to share or forward the infomercial to avoid contamination. It was accepted that some Control Arm participants would use a birth ball, but this would be balanced by Intervention Arm participants who would not. Additionally, the complex intervention component meant that Control Arm participants who used the ball would not access the infomercial and thus would still not access the whole intervention.

Adherence to the protocol through using the birth ball or not was monitored by means of the self-report in the postnatal questionnaire, Question 7 (Appendix 5):

'Did you use a birth ball at home in early labour in your recent labour?'

This enabled a sensitivity analysis to calculate the degree of crossover between the trial arms (Thabane et al. 2013).

Intervention Arm participants were emailed personalised messages and instructions with their infomercial link and a separate Short Message Service (SMS) was also sent as a reminder to maximise CBSEI© and postnatal questionnaire completion. Receipt was acknowledged with another SMS expressing thanks. If a questionnaire had not been completed, the participant received either a reminder phone call or an SMS.

The participants' involvement timeline in the study is summarised in Table 5.5.

Table 5.5 Participant study timeline

Activity / Assessment	Time point	Person	Time required	Comments
Advertising	[1]AN	CI	[2]N/A	Via posters in clinic and postnatal areas, on Trust website and maternity notes
Recruitment	28 weeks AN	Midwives	5 minutes	AN check in clinic or at home Provision of PIS if interested
Consent		CI	15 minutes	Face-to-face AN clinic or at home; at least 24 hours after receipt of PIS
Randomisation		CI	N/A	Participant informed by letter with relevant information
Completing CBSEI©	36 weeks AN	Participant	5 minutes	Intervention Arm only Immediately before accessing infomercial
Accessing infomercial			5 minutes	Intervention Arm only
Completing and sending CBSEI©			10 minutes	Intervention group only 24 hours after accessing infomercial
Reminder/acknowledgement SMS	36 / 37 weeks AN	CI	N/A	Acknowledgement SMS when CBSEI© received Reminder SMS if CBSEI© not received by 38 weeks AN
Using birth ball in the latent phase	>37 weeks AN	Participant	As participant wishes	Intervention Arm intended Control group may use birth ball of own volition – calculate on Intention to Treat basis
Hospital admission VAS proforma	>37 weeks AN	Admitting midwife & participant	1 minute	Control and Intervention Arms Proforma placed in collection tray by admitting midwife
Completion of online PN questionnaire	6 weeks [3]PN	Participants	15 minutes	Control and Intervention Arms
Reminder/acknowledgement SMS	8 weeks PN	CI	N/A	Acknowledgement SMS when questionnaire received Reminder SMS if questionnaire not received by 8 weeks PN
Dissemination of findings and thanks	PN	CI	N/A	e-mailed to all participants on conclusion of trial

[1] antenatally
[2] Not Applicable
[43]postnatally

5.8 Safety

Participant recruitment and retention were reviewed monthly and monitored against study timeframes, the intention of the research, feedback from participants and to monitor outcome indicators along with any adverse events.

A Trial Management Committee, consisting of the CI, Academic Supervisors and the Trust Midwifery Risk Manager met at the trial mid-point to review the trial outcomes. A report was generated and the decision was made to continue the trial in the absence of any Serious Untoward Incidents or concerning outcomes at that point (Appendix 15).

If participants wished to withdraw from the study, or if their pregnancy or latent phase of labour manifested any of the following:

- pre-term labour < 37 weeks
- non-cephalic presentation
- diagnosis of SGA(< 10^{th} centile) or Intrauterine Growth Retardation (IUGR)
- diagnosis of intrauterine death
- antepartum haemorrhage
- meconium stained liquor
- Induction of Labour
- obstetric complications e.g. intrahepatic cholestasis
- agreement with obstetrician for elective CS

they were advised not to remain at home in the latent phase of labour, but to contact the maternity unit as per local protocols and guidelines. This was explained verbally and displayed prominently on Participant Instructions sheets (Appendix 10).

5.9 Indemnity

Participants were covered by indemnity for negligent harm through the standard NHS indemnity arrangements. Bournemouth University acted as Sponsor and insured for non-negligent harm associated with the protocol. This included cover for additional health care, compensation or damages whether awarded voluntarily by the Sponsor, or by claims pursued through the courts.

5.10 Data integrity

Data integrity is the extent to which all data are complete, consistent, accurate, trustworthy and reliable throughout the data lifecycle (Rutherford 2018).

All data were entered electronically either at site, the CI's workspace or the university. Original study forms were kept on file at the participating site during the study. Cleaned, anonymised data will be stored in the University Data Repository as per university policy (Bournemouth University 2014; Bournemouth University 2016; Digital Curation Centre 2014) on completion.

Data integrity was enforced through checks applied at data entry into a specific field and/or before the data was committed to the database. Data entered into the database was retrievable for viewing through the data entry applications. The data were double checked against the Trust online electronic records system by the CI and research midwife and the error rate was calculated, as measured by:

$$\frac{\text{data errors}}{\text{total data points}} \text{ x100\%}$$

The initial data error rate was 5.6% which was unacceptable, so the process was repeated three times until the error rate was < 1%.

Confidentiality was safeguarded through electronic anonymised data transmission through the university Information Technology (IT) system without Trust IT system involvement.

The short duration and low risk status of the BALL Trial precluded the need for a Data Management Committee (Chan et al. 2013). Data monitoring and quality assurance requirements were met through Trial Management Committee scrutiny at monthly educational supervision meetings.

In line with university guidelines (Bournemouth University 2016), the cleaned anonymised dataset will be uploaded to the University online digital repository,

Bournemouth Online Research Data Repository (BORDaR) following publication of the study results.

5.11 Data management

For each outcome, data were collated onto a digital Case Control Form and analysed using Statistical Package for Social Sciences (SPSS) Version 25.0 software.

Please refer to Data Management Plan (Digital Curation Centre 2010 – 2019) (Appendix 16).

The block randomisation strategy removed the need for secondary analysis to control for parity bias.

To prevent attrition bias, outcome data obtained from all participants were included in the data analysis, regardless of protocol adherence on an 'Intention-To-Treat' approach, including withdrawal and losses to follow up (Gupta 2011). An Intention-To-Treat approach offered a more conservative statistical analysis, because with dilution from non-compliance, there may be a bias towards the null hypothesis (Hernán and Hernandez-Diaz 2012); nevertheless, inclusion of all data is consistent with the pragmatic trial design (Loudon et al. 2017) By the same token, Intention-To-Treat prevents an inflation of effect, preserves randomisation integrity and strengthens internal validity (Polit and Gillespie 2010). On balance it was concluded that an Intention-To-Treat approach would provide the best means of minimising potential sources of bias in the trial.

5.12 Quantitative data analysis

Quantitative data analysis for each outcome was undertaken as summarised in Table 5.6, using Statistical Package for Social Sciences (SPSS) Version 25.0 software. For consistency, numbers were reported rounded to one decimal point (Cole 2015).

Table 5.6 Quantitative analysis of trial outcomes

	Objective	Distribution	Statistical test
Demographic details Maternal age when gave birth Civic status Educational achievement Parity	To compare demographic characteristics between trial arms.	N/A	Descriptive analysis
Primary outcome VAS score	To compare mean VAS scores between trial arms.	Normal	Independent t test
Secondary outcomes			
Labour interventions CEFM Amniotomy Synthetic oxytocin Regional anaesthesia	To compare frequency of obstetric interventions between trial arms.	N/A	Pearson's Chi-square
Birth outcomes Induction of labour Cervical dilatation on admission Birth mode Gestation Birth weight Sex Apgar @ 1 minute Apgar @ 5 minutes	To compare frequency / means of birth outcomes between trial arms	N/A	Descriptive analysis
Infomercial effect Outcome Efficacy (OE) Before / After Self-Efficacy (SE) Before / After	To determine whether mean OE and SE scores change Before / After accessing the infomercial	Normal	Two sample t test

Postnatal questionnaire Birth ball uptake Birth ball acceptability (see Section 6.8.9 and Appendix 17) Maternal satisfaction (see Section 6.8.9 and Appendix 17)	To determine birth ball uptake To determine birth ball acceptability to women To determine maternal satisfaction with the birth ball	N/A	Descriptive analysis

5.13 Qualitative data analysis

Qualitative data analysis of the free text responses to the postnatal questionnaire was undertaken using thematic analysis. The decision to adopt this method was made on several grounds: firstly, because it is flexible and because it does not require commitment to a particular theoretical framework (Braun and Clarke 2006). Secondly, the data were obtained from short free text responses to the postnatal questionnaire which either amplified or clarified formatted responses or allowed the respondent to introduce new information. This meant that the context was supported by shorter formatted fragments rather than residing within denser discourse blocks

In order to address the trial's secondary hypothesis that the Intervention Arm would report greater use of the birth ball and increased acceptability and satisfaction (as stated in Section 5.1.2), the postnatal free text responses were analysed to identify themes which would elucidate respondents' experience of using the birth ball at home in the latent phase. 'Themes' may be defined as discourse elements which embody prevalent aspects of data related to the research question within a patterned or meaningful manner across the data set (Flick 2014). The salience and embodied meaning of responses directed their identification and inclusion rather than their size or frequency within the discourse (Braun and Clarke 2006).

The six phase model proposed by Braun and Clarke (2006) was adopted as a recursive process, as shown in Figure 5.2.

Figure 5.2 Phases of thematic analysis (Braun and Clarke 2006)

Phase	Description of the process
1. Familiarizing yourself with your data:	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
	6. Producing the report: The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Data from the postnatal questionnaire were collated and grouped by question. Preliminary codes were generated as words or brief phrases which encapsulated the relevance of the data to the research question (Braun and Clarke 2013). However, they were 'open codes', i.e. they were not pre-set, but developed and modified throughout the coding process (Maguire and Delahunt 2017). The preliminary codes were then reviewed in relation to the data extract, the questionnaire question and the whole data set in relation to the research question in order to generate themes and a 'thematic map' of the analysis to illustrate the relationship between the themes (Maguire and Delahunt 2017) (Appendix 17). Findings were collated by theme with compelling data extracts (Braun and Clarke 2006) and are presented in Section 6.9. This qualitative exploration was underpinned by Tracey's eight quality criteria (2010), which are presented and annotated in Appendix 17 in order to strengthen the credibility of the findings.

5.14 Ethical considerations

The infomercial and the birth ball did not present major risks or harm to women or their babies providing that they were used in accordance with their designated purpose and manufacturer instructions. Moreover, Intervention Arm participants were advised to use the ball according to their individual needs, wishes and circumstances rather than with the imposition of a prescriptive regime which would not have met their individual needs. This reduced the potential burden of the intervention to a minimum, particularly because participants were free to desist using the ball if it increased their pain or caused discomfort. Overall, using the ball had the potential to reduce participants' pain perception, reduce intervention and therefore met the requirements of the *Declaration of Helsinki* (World Medical Association 2013) that this research was unlikely to prejudice their health or that of their babies. Indeed, as Goldstein et al. (2018) highlight, the standard premise that research participation offers participants greater risk and less benefit than standard care rarely applies to pragmatic RCTs in general and objectively could not be true of the BALL trial.

Most potential ethical challenges were anticipated and met through trial design. These included the potential for an unplanned home birth or a participant

disregarding concerning signs such as meconium stained liquor, which warranted prompt contact with the maternity unit. The Participant Instruction Sheets (Appendix 10) clearly and prominently stated the circumstances in which participants should contact and attend the maternity unit, as outlined in Section 5.7.

Additionally, the CI's dual clinician-researcher role presented some considerations. Firstly, the CI provided direct care to several participants, which led to some role blurring (Hay-Smith et al. 2016). For example, one participant texted the CI asking for an additional antenatal check-up; the CI responded by texting back to offer a Day Unit appointment for that day and informing the participant's named midwife as the woman was vulnerable. On a separate occasion, the CI arrived at a potential participant's residence for an agreed appointment to discuss consent and recruitment; the woman then disclosed that she had experienced a reduction in fetal movements. The interview was postponed and an immediate review appointment at the Day Unit was arranged. These episodes were straightforward in themselves because the need to prioritise the wellbeing of the woman (and by implication her baby) is protected under the professional code of conduct (Nursing and Midwifery Council (NMC) 2018) and the *Helsinki Declaration* (World Medical Association 2013).

However, the CI had to be vigilant in latent phase telephone triage to offer neutral advice to all women in labour and neither promote nor dissuade women from using the ball unless the women disclosed that they were actively using it. Although this measure reduced bias of further encouragement to use the ball, it represented a conflict of interest for the CI since outside of the trial, a birth ball may have been recommended to women in the latent phase as a possible means of comfort and labour progression However, this conflict was resolved by consideration of *The Code* (NMC 2018) which states the requirement for midwives to provide evidence-based care; since the trial served to inform a notable gap in the evidence, the only recommendation for the birth ball would have been anecdotal at best. Therefore, the decision for neutral advice was considered as ethical.

The CI's clinical role in intrapartum and postnatal care was potentially problematic in that participants may have felt that any dissatisfaction with their care might have

jeopardised their involvement in the trial and vice versa. This was offset by ensuring that the Participant Information Sheet (Appendix 8) provided a route and contact details for participants who were concerned about the conduct of the researcher or the trial in addition to the NHS Trust Complaints information. The Study Protocol specifically stated that women who were dissatisfied with their clinical care would be signposted to a senior midwife. Participants' named CMWs also visited participants postnatally and would have signposted them appropriately had they been dissatisfied with the CI's clinical care.

Lastly, there was consideration of confidentiality and safeguarding as participants were usually visited at home for recruitment and consent, the CI followed the NHS Trust *Lone Worker Policy*. This did not entail breaching the confidentiality of which women were considering participation, but the CI carried a mobile phone and the staff were informed of departure and arrival times and the area of travel. The CMWs were the main source of information about which residences should not be visited alone, however, this only affected one participant, who was happy to meet at the maternity unit. In terms of participants and their children, the Participant Information Sheet (Appendix 8) explained that as a Registered Midwife, the CI had a duty of care to report any safeguarding concerns via the established routes, to ensure transparency for participants.

The BALL Trial was undertaken under the sponsorship of Bournemouth University, applied for under *Standard Operating Procedures* (Bournemouth University 2017). Ethical approval was granted through the University Research Ethics Committee (Ref. 13783) (University Research Ethics Committee 2014) and the Health Research Authority (Ref.17/SC/0534) on 17 December 2018.

5.15 Trial registration

The BALL Trial was retrospectively registered with an International Standard Randomised Controlled Trials Number 10755909 on 10th May 2018. Available at: https://www.isrctn.com/ISRCTN10755909

5.16 Summary

Having detailed the methods adopted to implement the BALL Trial with rationales for the way in which they contribute to addressing the research question and minimising bias, the following chapter will furnish the findings and outcomes of the data analysis.

6.0 Findings

This chapter reports the findings and outcomes from the BALL Trial. The descriptive and inferential quantitative data are presented and described in narrative, tabular and graphic forms with accompanying clarifications.

The participants' demographic profiles are detailed first, followed by the trial's primary outcome findings and finally the secondary outcomes. Labour and birth interventions and outcomes are reported, including neonatal outcomes derived from quantitative data collated from the host Trust maternity notes and online maternity data collection system. Quantitative findings from the postnatal questionnaire are presented and participants' reported ball use and activities at home in the latent phase are compared between the trial arms. Participants' reported satisfaction and their perceived acceptability of the birth ball at home during the latent phase are also quantifiably reported.

Finally, qualitative data arising from the free text questions in the postnatal questionnaire were analysed using thematic analysis (Braun and Clarke 2006), as described in Section 4.12 and are reported according to the question content and the identified themes. Responses are quoted verbatim to support these findings.

6.1 Demographics of the sample

As detailed in Figure 6.1 and Table 6.1 below, a total of 295 women at low obstetric risk and who met the inclusion criteria consented to join the trial; 294 were subsequently randomly allocated to the Control and Intervention Arms of the trial. 160 (54.4%) participants were primiparous and 134 (45.6%) were multiparous.

All participants declared that they planned to labour and give birth in the local maternity unit.

Following randomised allocation, the Control and Intervention groups demonstrated the following characteristics (Table 6.1):

Figure 6.1 Recruitment and allocation (Consolidated Standards for Reporting Trials (CONSORT) 2010)

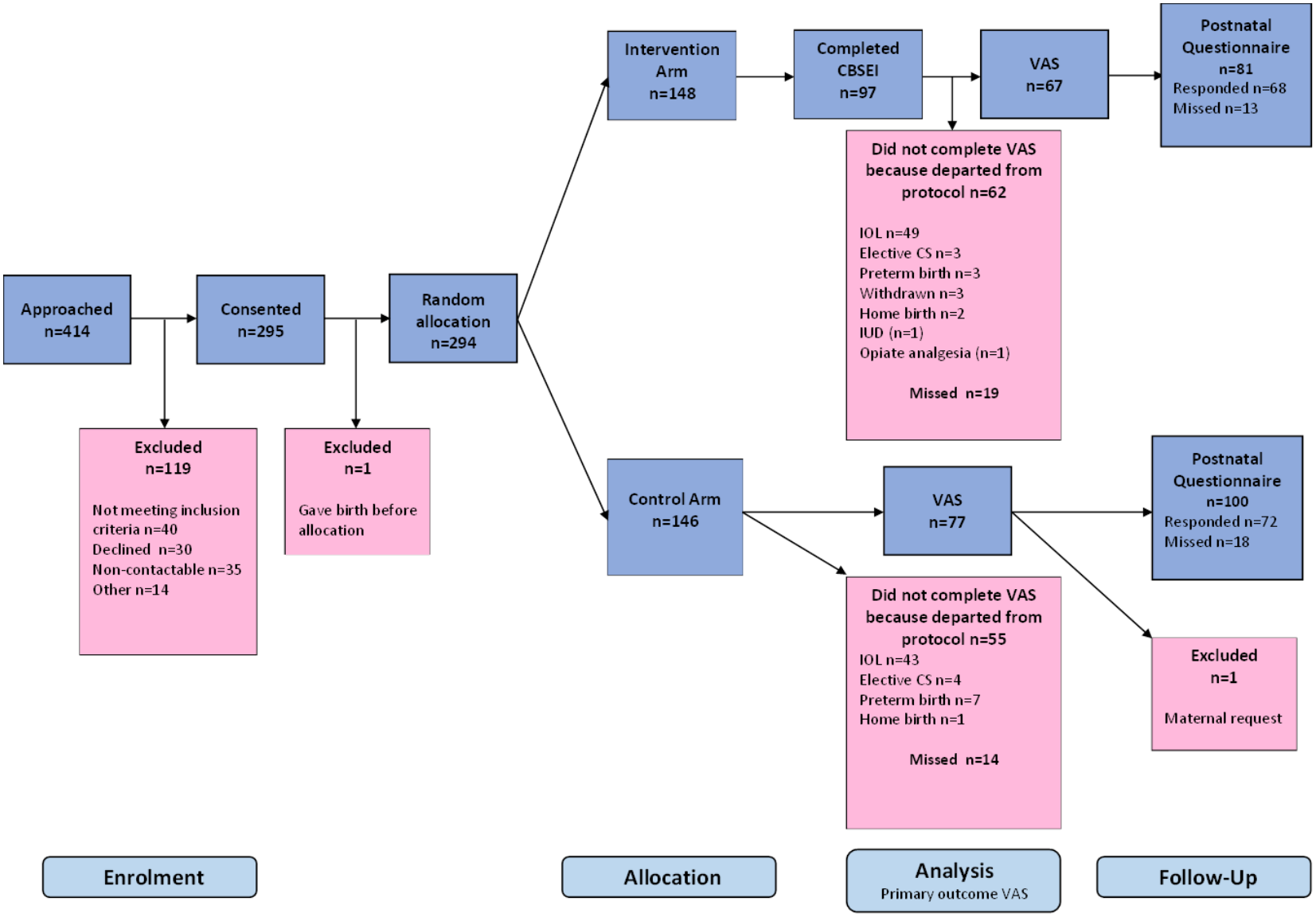


Table 6.1 Comparison of demographic details by trial arm

n=294	Control Arm n=146	Intervention Arm n=148
Age [SD]	28.35 [4.9]	28.37 [5.3]
Parity n (%)		
Primiparous	77 (52.7)	83 (56.1)
Multiparous	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)

The comparison of the Control and Intervention Arms demonstrates that randomised allocation resulted in two groups of similar demographic characteristics, therefore it can be assumed that randomisation was successful.

6.2 Pain perception by VAS score on admission

177 participants were eligible to provide a VAS score on admission to the maternity unit. However, 33 (18.1%) of these VAS scores not completed (Control Arm 14, Intervention Arm 19).

This left 144 VAS admission scores, of which 77 were from the Control Arm and 67 from the Intervention Arm. The reasons for the missing scores were:

- the admitting midwife was unaware that the woman was in the study or unsure of when the VAS should be taken.
- some participants presented at the maternity unit in the second stage of labour or with a rapidly progressing labour where the midwife had to prioritise the participant's intrapartum care.

The mean VAS scores are shown in Table 6.2 below:

Table 6.2 Mean VAS scores by trial arm

	Overall n=144 [SD][1]	**Control Arm n=77 [SD]**	**Intervention Arm n=67 [SD]**
Mean VAS	6.4 [2.2]	6.3 [2.1]	6.5 [1.8]
Missing	150 (51.0%)	***	***

[1] Standard Deviation

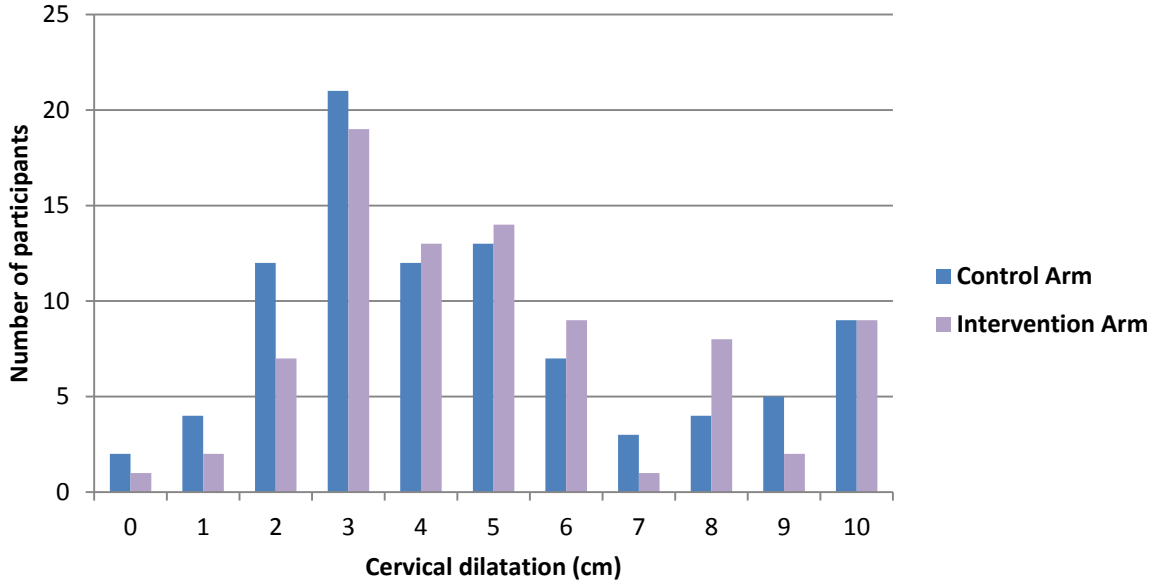
VAS score distribution followed a normal curve (Appendix 18) and fulfilled the criteria for an independent t-test. Levene's test for Equality of Variances F=0.2 ($p > 0.05$) meant that equal variance could be assumed.

The mean VAS was 0.2 higher in the Intervention Arm compared to the Control Arm, however, this difference was not statistically significant; mean difference -1.72 (SE 0.33; CI 90% -0.72 – 0.37), t –0.52 (df 142), p = 0.6.

6.3 Cervical dilatation on admission

The participants' cervical dilatation on admission to the maternity unit from 0 – 10cm were compiled from maternity notes where vaginal examination had been undertaken on admission in suspected labour. Where participants were admitted in strong labour which precluded routine examination, an assumption of full dilatation (10cm) was made if they gave birth within one hour of admission. If this was not the case and women were not offered a vaginal examination to assess cervical dilatation, then no assumption could be made for the dataset. Data from participants who underwent IOL, an elective CS or who had withdrawn from the trial were excluded. Figure 6.2 shows cervical dilatation on admission by group.

Figure 6.2 Cervical dilatation on admission by allocation



Cervical dilatation distribution followed a normal curve (Appendix 18) and fulfilled the criteria for an independent t-test. Levene's test for Equality of Variances F=0.5 ($p > 0.05$) meant that equal variance could be assumed.

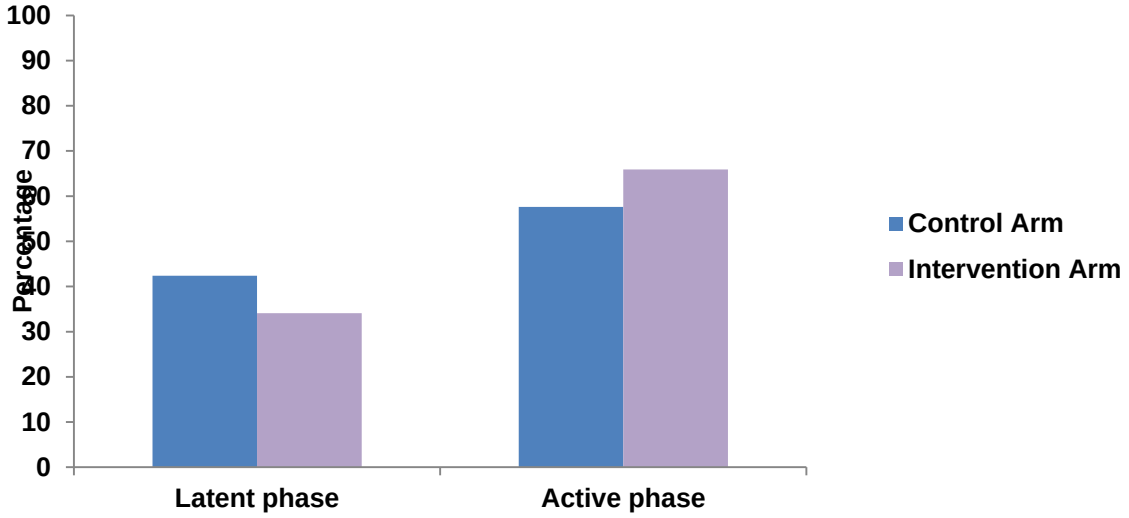
Table 6.3 Mean cervical dilatation on admission

n=177	**Mean Cervical Dilatation (cm) [SD]**	**[1]p**
Control Arm n=92	4.7 [2.7]	***
Intervention Arm n=85	5.0 [2.6]	0.6 (>0.05)
[1]Calculated for spontaneous labours only		

The mean cervical dilatation was 0.3cm greater in the Intervention Arm compared to the Control Arm, however this difference was not statistically different; mean difference -0.3 (CI95% -1.1 – 0.5), t -0.8 (df175), p = 0.6

Using cervical dilatation as an indicator, 42.4% of Control Arm participants were admitted in the latent phase, compared to 34.1% of Intervention Arm participants. There were, therefore, 8.3% fewer latent phase admissions in the Intervention Arm, where local and NICE (2017) guidelines define active labour from 4cm cervical dilatation (Figure 6.2).

Figure 6.3 Latent / active phase admission by trial arm (NICE 2017)



The difference persists, but is less marked when recalculated according to WHO (2018) guidelines, which define active labour from 5cm cervical dilatation (Figure 6.4). 55.4% Control Arm participants were admitted in the latent phase compared to 49.4% of Intervention Arm participants, a difference of 6.0%.

Figure 6.4 Latent / active phase admission by trial arm (WHO 2018)

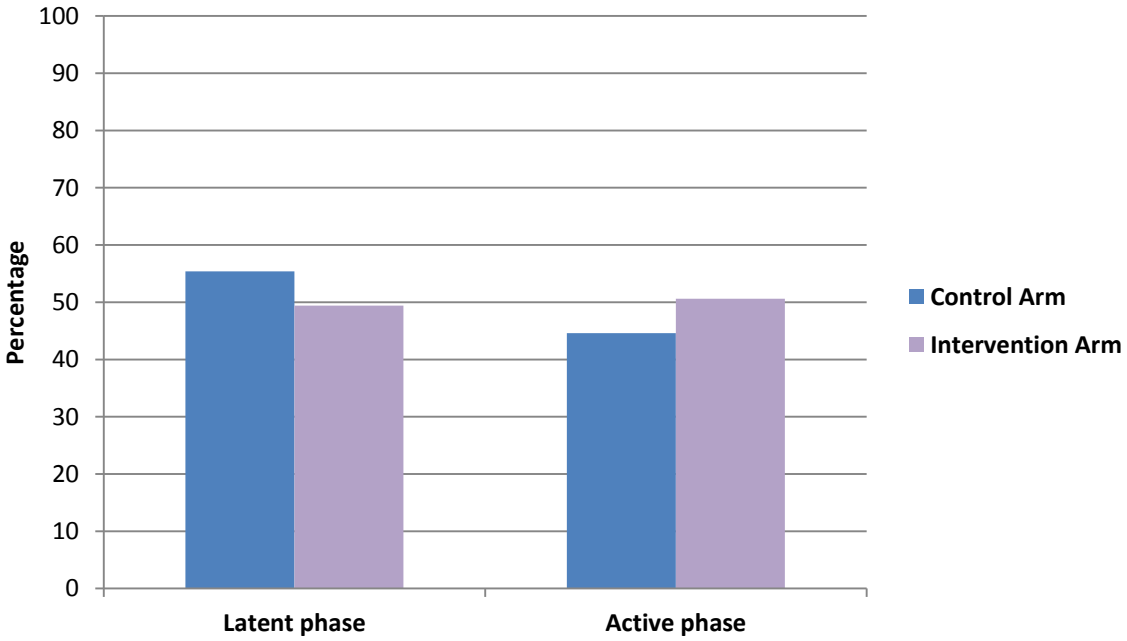


Table 6.4 Latent versus active phase admission

	[1]NICE (2017) n (%)	[1]WHO (2018) n (%)
Control Arm n=92		
Latent phase	39 (42.4)	51 (55.4)
Active phase	53 (57.6)	41 (44.6)
Intervention Arm n=85		
Latent phase	29 (34.1)	42 (49.4)
Active phase	56 (65.9)	43 (50.6)
[1]Not calculated on Intention-To-Treat ; spontaneous labours only		

6.4 Labour interventions

The rates of obstetric interventions for the Control and Intervention Arms are detailed in Table 6.5 below. For comparison, the host Trust (2018) background intervention rates are included.

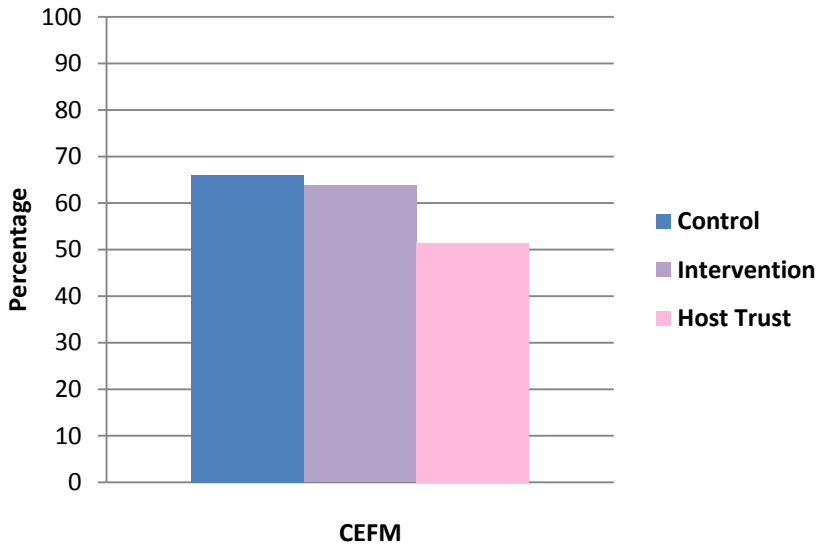
Table 6.5 Obstetric interventions by trial arm

Intervention	Control Arm n=143 (%)	Intervention Arm n=138 (%)	Host Trust (2018) (%)
CEFM	95 (66.0)	88 (63.8)	(51.5)
amniotomy	63 (44.0)	63 (45.0)	(35.4)
synthetic oxytocin	32 (22.4)	27 (19.6)	(19.5)
regional anaesthesia	53 (37.0)	48 (34.7)	(23.2)

6.4.1 Continuous Electronic Fetal Monitoring

In both trial arms, there were higher rates of CEFM compared to the host Trust background rates of 51.5% as shown in Table 5.5. The Control Arm showed a slightly higher rate of CEFM (66.0%) compared to the Intervention Arm (63.8%) (Figure 6.5), but this was not statistically significant, chi-square of 0.2 (df 1), $p > 0.05$.

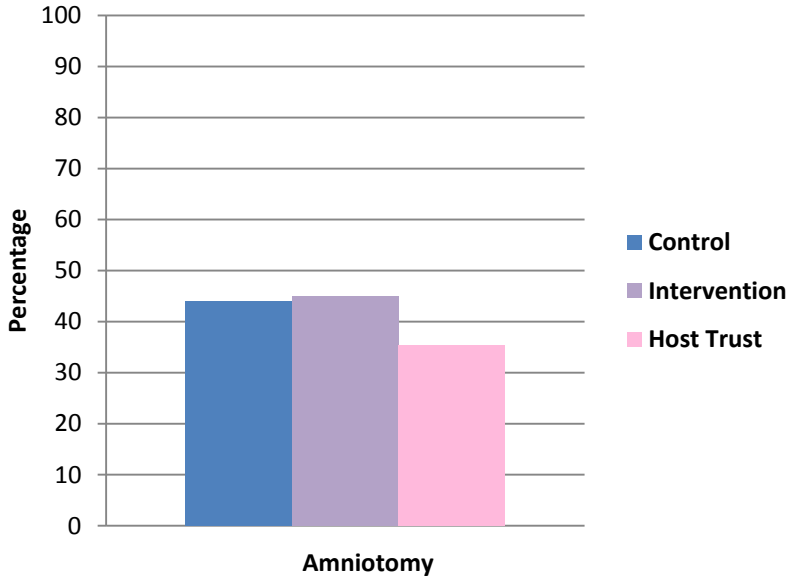
Figure 6.5 CEFM by trial arm



6.4.2 Amniotomy

In both trial arms, there were higher rates of amniotomy compared to the host Trust background rate of 35.4%, as shown in Table 6.5. Amniotomy rates were equally distributed between the Control and Intervention Arms (44.0% and 45.0% respectively), chi-square 0.7 (df1) p>0.05 (Figure 6.6).

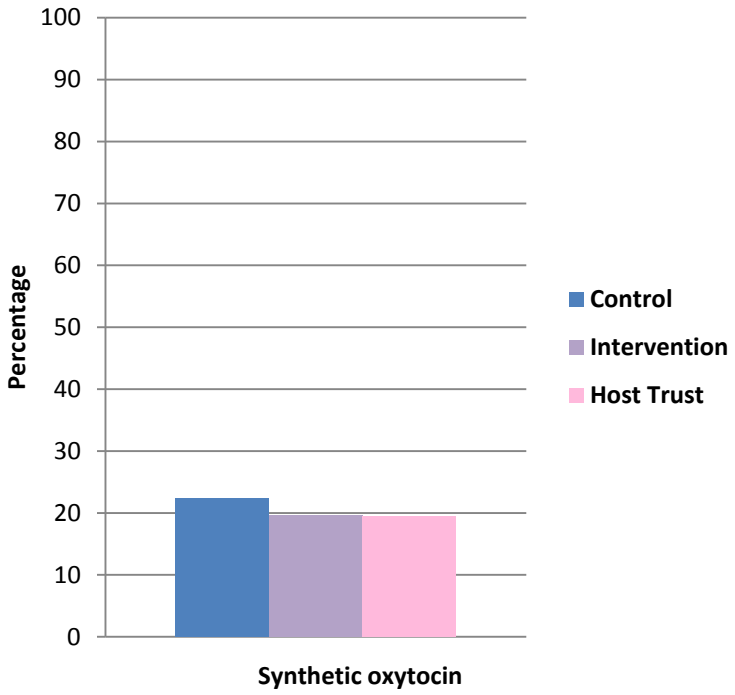
Figure 6.6 Amniotomy by trial arm



6.4.3 Synthetic oxytocin

Use of synthetic oxytocin was comparable with the host Trust background rate of 19.5%, as shown in Table 6.5. The Control and Intervention Arms showed equivalent rates of synthetic oxytocin use (22.4% and 19.6% respectively) with a chi-square value of 0.34 (df1) $p > 0.05$, however the 2.8% reduction in the Intervention Arm compared to the Control Arm is of note (Figure 6.7).

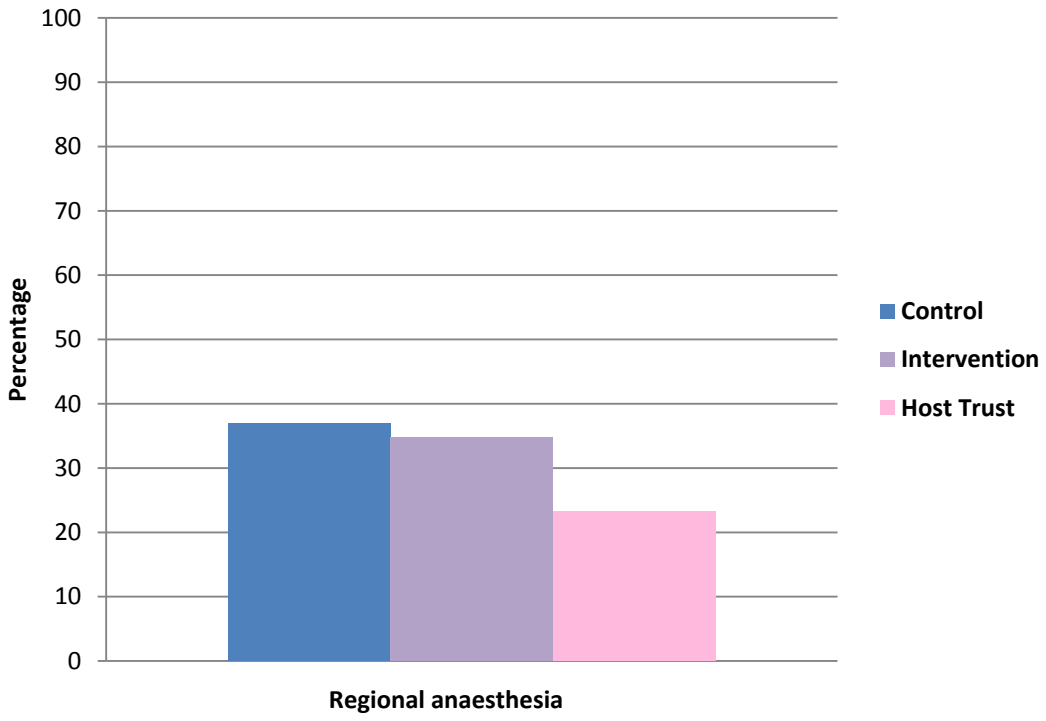
Figure 6.7 Synthetic oxytocin by trial arm



6.4.4 Regional anaesthesia

The rates of regional anaesthesia in both arms were higher than the host Trust background rate of 23.2%, as shown in Table 6.5. The Control Arm showed a 2.3% higher rate of regional anaesthesia (37.0%) compared to the Intervention Arm (34.7%) but this was not significant, chi-square value 0.95 (df1) $p > 0.05$) (Figure 6.8).

Figure 6.8 Regional anaesthesia by trial arm



6.5 Birth outcomes

Birth outcomes for trial participants are summarised in Table 6.6 below. There were similar gestations and birthweights between the trial arms. Host Trust background rates are provided for comparison.

Table 6.6 Birth outcomes by trial arm

	Control Arm n=141	**Intervention Arm n=137**	**Host Trust 2018 (%)**
Mean gestation [SD]	278.2 [11.6]	280.12 [8.9]	[1]
Mean birthweight [SD]	3411.57 [517.1]	3565.67 [450.0]	[1]
Birth mode	**n (%)**	**n (%)**	
Normal vaginal births	96 (65.8)	104 (70.3)	(65.6)
Assisted births	14 (9.5)	19 (12.8)	(9.2)
Elective CS	4 (2.7)	3 (2.0)	(11.3)
Emergency CS	26 (17.9)	11 (7.5)	(13.7)
Vaginal breech	1 (0.7)	0 (0.0)	[1]
Pre-term birth (< 37+0)	7 (5.0)	3 (2.2)	(11.0)
Apgar scores			
@ 1 min.	8.38 [0.1]	8.69 [0.1]	[1]
@ 5 mins.	8.73 [1.5]	8.98 [0.3]	[1]

[1] Data unavailable

6.5.1 Birth mode

The rate of elective CS was comparable between trial arms and there was one vaginal breech birth.

Whilst unassisted vaginal birth rates in the Control Arm (65.8%) were comparable with the host Trust background rate (65.6%), the Intervention Arm rate had a higher rate (70.3%).

Similarly, the Control Arm's rate of emergency CS was higher than the host Trust background rate. The Intervention Arm, by contrast had a rate of 7.5%, which was below that of the host Trust (13.7%) and more than half that of the Control Arm (17.9%).

6.5.2 Induction of Labour

A total of 91 participants underwent IOL. Intervention Arm participants had the highest IOL rate (32.4%) compared to the Control Arm (29.4%), which were comparable with the host Trust rate of 32.0%. Recorded reasons for IOL were recorded as shown in Table 6.7:

Table 6.7 Reasons for IOL by trial arm

Reason for IOL	Control Arm n=146(%)	Intervention Arm n=148 (%)
Total IOL	43 (29.4)	48 (32.4)
Reduced fetal movements	8 (5.5)	13 (8.7)
Reduced growth / SGA/ fetal condition concerns	10 (6.8)	13 (8.7)
[1]PROM or [2]PPROM	7 (4.8)	6 (4.0)
Post-term	6 (4.1)	6 (4.0)
LGA / previous shoulder dystocia	3 (2.0)	8 (5.4)
Maternal condition	8 (5.5)	1 (0.6)
Unknown	1 (0.7)	0 (0.0)
[1] Prolonged Release of Membranes [2] Pre-term Prolonged Release of Membranes		

IOL for PROM, PPROM or post-term was equally distributed between the trial arms (Control Arm 8.9%, Intervention Arm 8.7%). More Intervention Arm participants

experienced IOL for reduced fetal movements (Control Arm 5.5%,Intervention Arm 8.7%), reduced fetal growth/ SGA / fetal condition concerns (Control Arm 6.8%, Intervention Arm 8.7%) and Large for Gestational Age (LGA) or a previous shoulder dystocia 2.0%, Intervention Arm 5.4%). However, markedly more Control Arm participants experienced IOL for maternal condition, which included anxiety, pelvic pain, acute non-hypertensive oedema and polyhydramnios (Control Arm 5.5%, Intervention Arm 0.6%).

6.5.3 Neonatal outcomes

A total of 281 live babies (155 male and 126 female) were born to BALL Trial participants and one term male infant was diagnosed as an intrauterine death antenatally (Section 6.6). There were similar mean gestations and mean birthweights between the trial arms (Table 6.6). A total of 10 (3.6%) infants were pre-term, (Control Arm 5.0%, Intervention Arm 2.2%) from 30+5 to 36+5 days, compared to the host Trust background rate of 11% pre-term births (Table 6.6).

Apgar scores at 1 minute and 5 minutes were marginally higher in the Intervention Arm than the Control Arm (Control Arm 0.31, Intervention Arm 0.22) (Table 6.6). However, these differences were neither statistically nor clinically significant.

6.6 Adverse events

One Intervention Arm participant experienced an antenatal Intrauterine Death diagnosed at 38 weeks' gestation. Labour was subsequently induced and a male infant was stillborn. The participant was withdrawn from the trial from the point of diagnosis of intrauterine death. Death occurred antenatally, not intrapartum and was not associated with the trial, so a Serious Untoward Incident (NIHR 2016) was not raised.

One multiparous Intervention Arm participant gave birth at home in an unplanned home birth at term, but attended by CMWs. This was attributed to precipitate labour, rather than inappropriate advice or procrastination in seeking admission. Accordingly, a Serious Untoward Incident (NIHR 2016) was not recorded;.

Following review of both incidents by the Trial Management Committee, as per protocol (Section 5.7), the trial was continued.

Having reviewed the primary and secondary clinical outcomes, the following sections will focus on the participants' reported experiences through the findings from the CBSEI© and postnatal questionnaire in relation to the secondary outcomes.

6.7 Infomercial effect

The infomercial was made available online to the 148 Intervention Arm participants as a component of the complex intervention in order to offer education and evidence-based information about the potential benefits of using the birth ball in the latent phase, as outlined in Section 5.5.2. Intervention Arm participants were asked to complete the modified CBSEI© Part 1 questionnaires (Appendix 4) immediately before and 3 days after accessing the infomercial at 36 weeks' gestation.

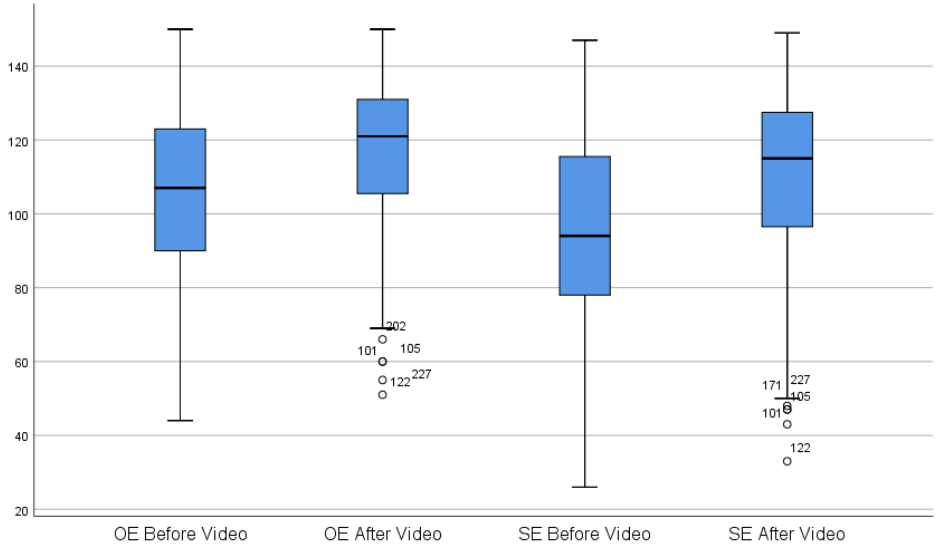
In total, 97 CBSEI© Part 1 questionnaires were completed, with a response rate of 65.5%. Due to an administration error, the first 34 returned questionnaires

recorded only the Outcome Expectancy and Self-efficacy Expectancy Before scores, leaving 63 completed data sets for analysis. Control Arm participants received standard care and therefore did not access the infomercial or complete the CBSEI©.

The distributions of the Outcome Expectancy and Self-Efficacy Expectancy Before / After were normal (Appendix 19) and the data met the additional conditions for a paired t-test: namely, a continuous data variable, dependent observations (i.e. paired samples), a random population sample and no outliers in the differences between the Before/After groups for Outcome Expectancy and Self-efficacy Expectancy.

On average, Intervention Arm participants reported an increased mean Outcome Expectancy after accessing the infomercial compared to before accessing it. This difference was statistically significant, t (62) = 5.02, p< 0.05; this represented a medium effect size, Cohen d=0.63 (Figure 6.9).

Figure 6.9 Box plots of Outcome Expectancy and Self-efficacy Expectancy Before / After scores



Additionally, Intervention Arm participants reported an increased mean Self-efficacy Expectancy after accessing the infomercial compared to before accessing it. This difference was statistically significant, $t\ (62) = 6.17$, $p<0.05$; this represented a medium effect size, Cohen $d=0.78$ (Table 6.8).

Table 6.8 Paired samples t-test Outcome Expectancy and Self-efficacy Expectancy

	Mean [SD]					
Pair 1 (n=63)						
OE Before Video	104.92 [24.23]					
OE After Video	115.38 [23.22]					
Pair 2 (n=63)						
SE Before Video	92.90 [28.18]					
SE After Video	108.40 [27.07]					
	Mean [SD]	**95% Confidence Interval**	**t**	**df**	**p**	**Cohen d**
Pair 1 (n=63)						
[1]OE After Video – OE Before Video	10.46 [16.55]	6.29 -14.63	5.02	62	<0.05	0.63
Pair 2 (n=63)						
[2]SE After Video – SE Before Video	15.49 [19.94]	10.47 – 20.51	6.17	62	<0.05	0.78
[1] Outcome Expectancy [2] Self-efficacy Expectancy						

6.8 Birth ball use

Data were collated retrospectively six weeks' postnatally using the online questionnaire which was sent to all participants who had laboured spontaneously at term (n=171). Participants who had undergone IOL, elective CS, pre-term birth or been withdrawn did not receive the survey. A total of 140 participants responded to the questionnaire, as shown in Table 6.9. The overall response rate between the trial arms was comparable (Control Arm 51.4%, Intervention Arm 48.6%). Moreover, within the trial arms, the response rates between primiparous and multiparous respondents were comparable with those of the trial cohort overall (Control Arm 52.7% and 47.3%, Intervention Arm 56.1% and 43.9%) (Table 6.1).

Table 6.9 Postnatal questionnaire respondents

n=140	**Control Arm n=72 (51.4%)**	**Intervention Arm n=68 (48.6%)**
Primiparous respondents	42 (58.3)	37 (54.4)
Multiparous respondents	30 (41.7)	31 (45.6)

6.8.1 Previous experience of using the birth ball

There was an equal distribution of multiparous respondents who had used a birth ball in a previous labour and those who had not. Of the 31 who had used a birth ball previously, 27 (87.1%) had found the birth ball helpful and 4 (12.9%) had found it unhelpful. Most respondents (27) provided free text reasons that they had found the ball helpful and 14 provided reasons that they had found the ball unhelpful (Appendix 17).

6.8.2 Birth ball use at home in the latent phase

These data were collated from the postnatal questionnaire. Findings are summarised in Table 6.10:

Out of 140 respondents, 93 respondents (67.2%) across the study used the birth ball at home in the latent phase of labour and 47 (33.8%) did not.

Table 6.10 Birth ball use at home in the latent phase

	Used birth ball at home in the latent phase	**Did not use birth ball at home in the latent phase**
Total n = 140 (%)	93 (67.2)	47 (33.8)
Control Arm n = 75 (%)	39 (52.0)	36 (48.0)
Intervention Arm n = 65 (%)	54 (83.1)	11 (16.9)

Control Arm participants used a birth ball of their own volition, putting Control Arm protocol compliance at 52%; Intervention Arm protocol compliance was 83.1%.

6.8.3 Time spent on the ball

The estimated time respondents from both trial arms spent on the ball whilst at home is shown in Table 6.11 below.

Table 6.11 Time spent on the ball at home

Estimated time	Respondents 93 (%)	Control Arm 38 (%)	Intervention Arm 55 (%)
Less than 1 hour	19 (20.4)	9 (23.7)	10 (18.2)
1 - 2 hours	25 (26.9)	9(23.7)	16 (29.1)
2 – 4 hours	21 (22.6)	6 (15.8)	15 (27.3)
More than 4 hours	28 (30.1)	14 (36.8)	14 (25.4)

Overall, there was an even spread of reported ball use duration in both trial arms, with the majority of respondents reporting birth ball use between 2 to > 4 hours (Control Arm 52.6%, Intervention Arm 52.7%). Proportionately more Control Arm respondents reported using the ball for longer than 4 hours (Control Arm 36.8%, Intervention Arm 25.4%), however, more Intervention Arm participants reported using the birth ball from 1 – 4 hours (Control Arm 39.5%, Intervention Arm 56.4%).

6.8.4 Activities on the ball

The activities that the respondents undertook on the ball are summarised in Table 6.12.

Table 6.12 Activities on the ball

Activity	Respondents [1]93 (%)	Control Arm [1]38 (%)	Intervention Arm [1]55 (%)
Sat on the ball and circled or rocked hips	75 (80.6)	31 (81.6)	44 (80.0)
Sat on the ball and bounced	71 (76.3)	28 (73.7)	43 (78.1)
Knelt over the ball and circled or rocked hips	26 (28.0)	11 (28.9)	15 (27.3)
Knelt over the ball and relaxed	23 (24.7)	9 (23.7)	14 (25.5)
Stood up and leaned on the ball to circle and rock hips	4 (4.3)	2 (5.0)	2 (3.6)
Stood up and leaned on the ball to relax	3 (3.2)	1 (2.6)	2 (1.8)
Other (Sat still, breathing though contraction)	1 (1.1)	1 (2.6)	0 (0.0)

[1] More than one option could be selected, therefore response % did not total 100%.

The most popular activity was sitting on the ball, with participants reporting a preference for rhythmic movement related activity such as bouncing, rocking and circling. Overall there appears to be no difference in activity type between the trial arms.

6.8.5 Home support

Most respondents reported that they were supported by their partners (94.3%) and / or family and friends (17.9%). Four participants laboured at home on their own and one started to labour while outside the home. A further four received home support from a midwife. None were supported by a doula. As seen in Table 6.13, there was no apparent difference in home supporters between the trial arms.

Table 6.13 Home support

Supporter	Respondents 140 (%)[1]	Control Arm 72 (%)[1]	Intervention Arm 68 (%)[1]
Partner	132 (94.3)	69 (95.8)	63 (92.6)
Family and friends	25 (17.9)	12 (16.7)	13 (19.1)
Midwife	4 (2.9)	2 (2.8)	2 (3.3)
Doula	0 (0.0)	0 (0.0)	0 (0.0)
Other	5 (3.6)	2 (2.8)	3 (4.4)

[1] More than one option could be selected, therefore response % did not total 100%.

6.8.6 Decision for hospital admission

Overall, the majority of decisions to seek hospital admission were made either by the respondents themselves (65%) or on the advice of the midwives (24.3%), as shown in Table 6.14. This did not vary substantially according to each trial arm.

Table 6.14 Decision for hospital admission

Decision to seek admission made by:	Respondents 140 (%)	Control Arm 72 (%)	Intervention Arm 68 (%)
Participant	87 (65.0)	47 (65.3)	40 (58.8)
Partner	11(7.9)	7 (9.7)	4 (5.9)
Family member / friend	4 (2.9)	2 (2.8)	2 (2.9)
Doula	0 (0.0)	0 (0.0)	0 (0.0)
Midwife / hospital advice	34 (24.3)	16 (22.2)	18 (26.5)
Other	4 (2.9)	0 (0.0)	4 (5.9)

Overall 7.9 % partners were reported as taking the decision, with family / friend decision making reported by four respondents; again, this did not vary in the trial arms. Four Intervention Arm respondents (5.9%) clarified in Other that they had been on their own whilst their partners were at work.

It would appear that across both trial arms, respondents were most likely to be the ones making the decision to seek hospital admission in labour.

6.8.7 Reasons for hospital admission

As shown in Table 6.15, the majority of respondents (83.6% overall) decided to seek hospital admission because their contractions were more frequent. Wanting further analgesia accounted for a further 25.7% of respondents, followed by Spontaneous Release Of Membranes (SROM) (23.6%). Respondents' anxiety and that of their birth partners was reported as 13.6% and 7.9% respectively. It is notable that the incidence of partners' anxiety exactly matches that of the decision maker for hospital admission (Table 6.14).

The findings are consistent across the trial arms, with the exception of 'Wanting more pain relief'; 21 (29.2%) Control Arm respondents cited 'Wanting more pain relief' compared to 15 (22%) Intervention Arm respondents. The difference is small, but may indicate that Intervention Arm participants overall were less likely to seek admission on the grounds of wanting to access pharmacological analgesia.

Table 6.15 Reasons for hospital admission

Reasons for hospital admission	Respondents n [1](%)	Control Arm [1]72 (%)	Intervention Arm [1]68 (%)
More frequent contractions	117 (83.6)	60 (83.3)	57 (83.8)
SROM	33 (23.6)	17 (23.6)	16 (23.5)
Not feeling well	4 (2.9)	3 (5.6)	1 (1.5)
Participant's anxiety	19 (13.6)	9 (12.5)	10 (14.7)
Birth partner's anxiety	11 (7.9)	5 (6.9)	6 (8.8)
More pain relief	36 (25.7)	21 (29.2)	15 (22)
Other	14 (10.0)	6 (8.3)	8 (11.7)

[1] More than one option could be selected, therefore response % did not total 100%

'Other' responses included two from women who wanted further reassurance. Seven women reported concerning symptoms, which included reduced fetal movements (2), vaginal bleeding (2), feeling unwell (1), a breech presentation (1) and meconium (1). One respondent reported that she knew her labour had

established. Two respondents attended the maternity unit in early labour for membrane sweeps and another wanted to ensure she had access to the birth pool. One multiparous respondent did not travel to the maternity unit as her labour progressed rapidly and she gave birth at home with two midwives in attendance.

6.8.8 Time at home

Table 6.16 shows that the majority of respondents (65.7% overall) attended the maternity unit within 8 hours of perceptible contractions / SROM. There was a small difference between the Control and Intervention Arms which suggests that more Control Arm respondents may have been more likely to postpone admission until more than 12 hours after the onset of contractions or SROM (Control Arm 16.7%, Intervention Arm, 8.8%).

Table 6.16 Time at home in the latent phase of labour

Time at home in the latent phase	Respondents 140 (%)	Control Arm 72 (%)	Intervention Arm 68 (%)
Less than 4 hours after contractions / SROM	44 (31.4)	22 (30.6)	22 (32.4)
4 – 8 hours after contractions / SROM	48 (34.3)	23 (31.9)	25 (36.7)
8 – 12 hours after contractions / SROM	21 (15.0)	10 (13.9)	11 (16.2)
More than 12 hours after contractions / SROM	18 (12.9)	12 (16.7)	6 (8.8)
Other	9 (6.4)	5 (6.9)	4 (5.9)

A further 15% remained at home beyond 8 hours and another 12.9% laboured at home beyond 12 hours. Out of 9 ‘Other’ responses, one multiparous respondent attended with contractions every 7 – 10 minutes and gave birth just over an hour of arrival. Two received sweeps and one an amniotomy. One woman attended with an antepartum haemorrhage and was subsequently induced and another two attended in the latent phase and remained in the hospital. As explained in Section

6.8.7, one woman gave birth as an unplanned home birth with two midwives in attendance.

6.8.9 Maternal satisfaction and acceptability

These data were obtained from the online postnatal questionnaire, which was distributed to all trial participants who had experienced a spontaneous labour. Overall, as shown in Table 6.17, 83 (89.2%) of respondents described using the ball as helpful. 86 (92.5%) would use the birth ball at home in early labour again and 82 (89.1%) would recommend using it to friends and family. This was consistent across both trial arms; there was a small increase in satisfaction in the Intervention Arm compared to the Control Arm (90.1% versus 86.8%). The high number of positive responses and the small number of negative responses indicate that using the birth ball at home in the latent phase is highly acceptable to women and was a source of great satisfaction to them.

The reasons that respondents provided for their answers are explored in Section 6.9.

Table 6.17 Maternal satisfaction with the birth ball

Satisfaction	Respondents 93 (%)	Control Arm 38 (%)	Intervention Arm 55 (%)
Found the ball:			
Helpful	83 (89.2)	33 (86.8)	50 (90.9)
Unhelpful	10 (10.8)	5 (13.2)	5 (9.1)
Would use in a future labour:			
Yes	86 (92.5)	35 (92.1)	51 (92.7)
No	6 (6.5)	3 (7.9)	4 (7.3)
Would recommend to a friend / family member:			
Likely	82 (89.1)	33 (86.8)	49 (89.1)
Neither likely nor unlikely	10 (10.8)	5 (13.2)	5 (9.1)
Unlikely	1 (1.1)	0 (0.0)	1 (1.8)

6.9 Postnatal questionnaire

The free text responses were analysed by thematic analysis (Braun and Clarke 2006) as detailed in Section 5.12.

Eight themes and one sub-theme were gleaned from the free text responses These were: Rhythm, Movement (sub-theme Freedom), Upright positions, Empowerment, Focus, Support, Comfort and Drug-free pain relief. Maternal recommendations, negative responses and respondents' involvement in the trial were discussed holistically in the light of the themes. The themes were identified from primiparous and multiparous respondents. For all themes, there was strong concordance in themes regardless of parity or allocation arm. The themes were collated as a thematic map on the basis of respondents' descriptions of their experiences, as shown in Figure 7.1. These are discussed as a whole in Section 7.2.6.1

Note: all cited free text responses are denoted by the question number, followed by the respondent PIN.

6.9.1 Previous experience of the birth ball

Multiparous respondents were asked about their previous experience of using a birth ball to gain insight as to whether it influenced their experience in the trial or their decision to use or not use the birth ball.

Multiparous respondents' experience of the birth ball was both physical and cognitive. Rhythmic movement such as bouncing and rocking were the most reported activities, however walking and bending were also described.

Q.6a.1. '*The soft, rhythmic bouncing up and down and side to side movements helped with lower back pain relief as labour progressed. I recall I rotated as well.*'

Q.6a.2. '*I found it relaxing to bend over it in the early stages of contractions. My babies were quite big and bending over it seemed to relieve some pressure*.'

Q.6a.5. ' …. *I felt that I either wanted to be walking or bouncing and not sitting on something solid helped.*'

Respondents also reported a sense of comfort and ease from pain, strain and pressure.

Q.6a.6. '*It was more comfortable than sitting on a bed or standing.*'

Q.6a.9. '*It took the edge off the pain slightly, eased pain to hips*.'

Q.6a.12. '*Helped ease the pain in early labour …..*'

Respondents reported that they had employed cognitive strategies, with the ball described as distracting women away from their pain but also focusing onto other activities.

Q.6a.14. '*Moving on the ball helped to give me a focus away from the pain and concentrate on breaths as I moved.*'

Q.6a.17. '*Using the birthing ball helped to keep me moving, bouncing on the ball gave me something to concentrate on whilst having contractions.*'

Q.6a.21. '*Helps to have something to do, to distract from pain ……*'

They also reported a sense of cognitive empowerment and self-determination to progress their labour and optimise fetal position.

Q.6a.23. '*Definitely helped managing my contractions.*'

Q.6a.22. ' ….. *it felt good to* [sic] *knowing that it would progress labour …… I used my ball to rest on and to encourage my back-to-back baby to turn the right way.*'

Q.6a.23. '*I found it helped me cope with the contractions better.*'

Q.6a.26. ' *…… it helps move things along quicker ……..*'

Of the 14 responses from women who had not found the ball helpful in their experience, 4 were discounted as the responses indicated that they were 'not applicable'. The other 10 notably reported that sitting on the ball was uncomfortable or intensified their pain perception. This was apparent as their labour progressed, mostly reported as the sensation from fetal descent.

Q.6b.1. ' *…… the ball made the pain worse.*'

Q.6b.5. '*It hurt my back (existing problem) when sitting on it ……*'

Q.6b.3. '*As my labour progressed I found sitting really uncomfortable as baby's head lowered*.'

Q.6b.13. '*I did not sit on a ball as was too painful to sit down …… (it) was exacerbated when baby's head became engaged*.*'*

6.9.2 Rhythm and movement

Respondents' rationales for using the ball in the trial reiterated the themes from Q.6.a, namely those of rhythmic bouncing and rocking and remaining upright and mobile:

Q.11a.1 *'The bouncing was great and stopped my hips hurting so much*' (P0).

Q.11a.18. ' *….. being mobile helped ease the pain, and the ball can assist in this, even if it's just a gently bounce / rock'* (P0).

Q.11a.28 '*It really helped and even now my baby loves being bounced on the ball!'* (P0).

Q11a. 44. *Because it was relaxing to move the lower body* (P0).

Bouncing, rocking and circling on the ball were initially double coded as 'movement' and 'rhythm'; the frequency with which respondents described these aspects of their movement and the rhythm as a means to ease their physical and cognitive responses to labour led to them being coded as separate, but closely linked (Appendix 17).

6.9.3 Freedom

Respondents referred to their perceived freedom to move or change position:

Q.10a.68. *'…… I could vary the movement depending on whether I was having a contraction or not'*

Q.11a.19. '*….. because you could use it in multiple positions, you could keep changing positions as needed.'*

Q.11a.55. ‘ *…….. could move it as I wanted.’*

‘Freedom’ was introduced into the thematic map as a sub-theme because it was inextricably linked with movement, although it could also have been interpreted as an expression of self-determinism and self-efficacy under ‘cognitive response’ (Figure 7.1).

6.9.4 Upright positions

Respondents described using the ball as a tool to adopt, maintain and vary upright positions as a key central theme to their experiences:

Q.10a.10 ‘*Possibly helped speed up labour as it helped me to be active and upright’* (P1).

Q.10a.20 ‘*It was good to intersperse a bit of walking with using the ball in different positions*’ (P1).

Q.10a.27 ‘*Great position for managing contractions’* (P0).

Q.10a.38 ‘*Found it the most comfortable place to sit whilst in labour*’ (P0).

Q.11a.67 ‘*I found it helped with staying in the right position’* (P0).

6.9.5 Support

They also included using a ball for physical support:

Q.11a.37 *‘Comfortable to lean on ….’* (P0).

Q11a.62 *‘It helped with the weight off of my legs and hips ……’* (P1).

Some respondents suggested psychological and physical support from the ball:

Q.10a.55 *‘It was the only thing that helped, as I could lean over it, hug it tight during contractions …….*’ (P1).

Q.11.61 *‘…….. I was able to move position and the ball as I liked and being able to put all my weight onto and over it and squeeze it really helped’* (P1).

6.9.6 Comfort

Respondents reiterated their sense of physical and psychological comfort, ease and relaxation while using the ball:

Q.10a.45 '*It not only eased my pain of contractions but also helped stretch my back, which I found helped'* (P0).

Q.11a. 2 '*The birthing ball was a great comfort and a focus during strong contractions'* (P1).

Q.11a. 60 *'It really eased the pain'* (P1).

Q.11a. 63 *'It was comfortable between contractions to be on the ball'* (P1).

It was notable that respondents did not express an expectation or need for absolute analgesia; they expressed satisfaction with a perceived release from their pain or pressure.

6.9.7 Empowerment

Additionally, respondents cited using the birth ball as a source of cognitive empowerment as protagonists to progress their labours and enhance their feelings of control and self-efficacy.

Q11a.3 *'It helped me to birth beyond what I thought I could cope with'* (P3).

Q.11a.42 *'To help me regulate my breathing*' (P0).

Q.11a.72 '*I really feel that it gets things moving* ……..' (P0).

Q.11a.74 *' ….. feel it was a great influence in my relatively quick labour'* (P0).

Q.17.62 *'This was my 5th baby, every other labour I've arrived at hospital at 3cm dilated, this time I was 7-8cm, I think the ball helped speed things up, and helped me stay in control for longer'* (P4).

6.9.8 Focus

Respondents described using the ball either as a focus onto their labours or a focus away from their pain as a distraction:

Q.10a.1 '*It helped my hips and took my mind off labour'* (P0).

Q.10a.23 '*It helped me to concentrate on something else when I started to feel contractions as I had to focus on rocking and keeping balance. Made me think of something else rather than the pain*' (P0).

Q.10a.36 '*It helped ease pain by giving me something else to focus on'* (P0).

Q.10a.48 '*It felt like a distraction from the contractions'* (P0).

Q.10a. *'It helped me remain focused and calm during contractions as I kept rhythm throughout'* (P1).

6.9.9 Drug-free pain relief

Respondents to Q.11, Q.12 and Q.17 introduced a new theme, that of not resorting to pharmacological analgesia:

Q.11.4 *'Because it's a drug free pain relief, which is important for me as I try to avoid medication where necessary'* (P1).

Q.12.16 *'…….. enabling me not to have to take any analgesia'* (P1).

Q.12.3 *'Drug free pain relief'* (P1).

Q.12.14 *'Great means of pain relief without drugs'* (P0).

Q.17. 11 *'It's an easy and cheap alternative to drugs during early labour'* (P0).

This suggests that respondents found the birth ball useful in reducing their pain perception and that not resorting to pharmacological analgesia was important to many of them. This links with the theme of 'Comfort' (see above).

6.9.10 Maternal recommendations

In response to Q.12, 82 (88.2%) respondents reported that they would be likely to recommend using a birth ball at home in the latent phase to a friend or family member. These respondents based their affirmative responses on their own experiences:

Q.12.15. '*I found it provided some relief in early labour so would always recommend anyone to try it out'* (P0).

Q.12.32 *'I feel it made a difference to me so would recommend it as an option to friends etc.'* (P1).

Q.12.72. '*It could help someone else feel the relief I felt'* (P2).

Q.12.74. '*Yes, I highly recommend the birth ball and feel it was a great influence in my relatively quick labour*' (P0).

It can be concluded that respondents were highly likely to recommend the birth ball to their friends and family on the basis of their own experiences where they found the birth ball helpful.

6.9.11 Negative responses

As seen from responses to Q.10.b, in Section 5.8.9, 10.8% of respondents did not find the birth ball helpful. 7.5% (7 respondents) reported that they would not use the ball in a future labour in Q11.

In response to Q.12, 1 respondent (1.1%) would not recommend the birth ball to friends and family; a further 10 respondents (10.8%) provided a qualified response of 'neither likely nor unlikely':

Q.12.10 *'Not used it enough to comment, likely or not. But I get a lot of positive information about the ball'* (P0).

Q.12.18 *'Don't think it helps but everyone is different!*' (P2).

Q.12.19 *' Some people may find it easier as I'm not very good with pain as it is'* (P0).

Q.12.30 *'Although it didn't work for me, it could work for someone else'* (P0).

Q.17.37 *'I would be keen to learn more about the birth ball more and give it a better and more fair try next time'* (P0).

Q.12.43 *'I know it can help. Just because I didn't find it useful, it doesn't mean someone else won't'* (P2).

From these comments, it can be concluded that many respondents who did not find the ball effective for their own experience, still considered it as potentially useful for other women or for another birth.

6.9.12 Trial participation

An unforeseen but prevalent theme which emerged from the free text responses in Q.17 was the positive value placed by respondents on their participation in the trial.

Q.12.63 *' … the help and advice you get from the midwives involved with the birth balls is brilliant'* (P0).

Q.17.4 *'I wish you all the best for your study*' (P1).

Q.17.20 *'Thank you for proving* [sic] *one!'* (P).

Q.17.44 '*I truly believe that I could not have got through without my labour without the ball and I didn't use any pain relief. (Researcher) is amazing and I thank her for introducing me to the ball* (P0).

Q.17.49 '*Thanks for letting me be part of the programme'* (P0).

Q.17.57 '*Thank you for letting me borrow it :-)*' (P1).

This aspect will be discussed in Section 7.3.7.

6.10 Conclusion

This chapter has presented the findings of the BALL Trial. Quantitative and qualitative data from the CBSEI©, VAS scores, labour and birth outcomes and a postnatal online questionnaire have been presented in tabular, graphic and narrative forms.

In the following Discussion chapter (Chapter 7.0), these findings will be discussed in relation to the primary and secondary outcomes of the trial as the basis on which the null hypothesis may be accepted or rejected.

7.0 DiscussionThis Discussion chapter will consider the findings from the BALL Trial within the context of the wider literature. Additionally, the primary and secondary outcomes of the trial will be examined to determine whether the null hypothesis can be accepted or rejected. and to examine the trial's original contribution to the knowledge concerning using a birth ball at home in the latent phase of labour. The design and implementation of the trial will be critically examined to explain the strengths and limitations of the trial and the learning opportunities it afforded. The impact, implications for clinical practice and further research will be considered as a conclusion.

7.1 Context in the wider literature

This is the first study to focus on a women-centred intervention to address the challenging issue of latent phase labour. Previous studies have looked at interventions targeted at midwives (Cheyne et al. 2006) or service changes (Spiby et al. 2008; Janssen and Desmarais 2013) and it may be for this reason that they were not successful in changing women's behaviour in the latent phase. By contrast, the BALL Trial offered participants an evidence-based strategy which directly addressed women's concerns of pain and anxiety as their primary drivers to seeking hospital admission (Cheyne et al. 2007; Barnett et al. 2008; Carlsson et al 2009). Additionally, the trial addressed women's own wishes to remain at home until their labour established (Cheyne et al. 2007) and their priorities for latent phase interventions on the research agenda (McCourt et al. 2013). Above all, the intervention moved the decision-making locus to the women in their homes, furnishing them with the choice to adopt the positions of greatest comfort and to intensify or desist from using the ball as their labours dictated.

This complex intervention thus encouraged and enabled women to work positively with their pain to progress their labours. The intervention thereby addressed the findings of the meta-synthesis which recommended interventions which could educate and empower women to de-medicalise their pain experience and allow them to postpone their hospital admission until their labour had established (Eri et al. 2015). Additionally, the methodological design made a timely response to a

recent Cochrane review's call for robust latent phase intervention studies to reduce obstetric interventions (Kobayashi et al. 2017).

7.2 Primary outcome

The trial did not demonstrate a 1.0 reduction in the reported VAS pain score on admission to the maternity unit between the trial arms, unlike that reported by Leung et al. (2013); in fact, Intervention Arm participants reported a slightly higher mean VAS score (Control Arm 6.3, Intervention Arm 6.5), although this difference was neither clinically nor statistically significant. The null hypothesis is rejected in this instance, but with caution, for the following reasons.

Firstly, the research population of women at low risk of obstetric intervention experienced considerable attrition, principally in the form of IOL (32.7%) (Section 6.5.2). Despite an 89% recruitment rate, the subsequent attrition reduced the statistical power to detect the 1.0 difference on the VAS, because only 20% had been allowed for participants not contributing to the final analysis in the original power calculation.

Two fundamental issues should be considered: firstly, whether the VAS was a valid and reliable measurement tool which required more effective methodological implementation and secondly, whether the original hypothesis was flawed and can no longer be considered..

Whilst a subjective self-report of pain, whether as a VAS or questionnaire, is still considered the only reliable means of evaluating pain (Cervero 2012), as mentioned previously, its repeated administration in intrapartum care at intervals is contra-indicated, due to a 'ceiling effect' (Jones et al. 2015). However, in the BALL Trial, the VAS was obtained as a single score at the point of admission to the maternity unit and no VAS score was reported as higher than the maximum '10'. The normal distribution of VAS scores (see Appendix 19) suggests that participants gave a considered, rather than an *ad hoc* response when reporting the VAS score. On these grounds, and in agreement with the literature (Cervero 2012), it can be concluded that the VAS was a valid and reliable self-report tool.

However, the 1.0 difference on the VAS, derived as it was, from Leung et al.'s (2013) observational study, may not have been an appropriate outcome. Midwives in the research setting routinely advised women in the latent phase of labour to request admission when they were 'no longer coping' in telephone triage. This may be representative of widely shared attitudes towards labour support and a powerful subliminal message to the labouring woman and her birth supporters that there was an expectation at some point in labour where the woman would no longer be capable of labouring and giving birth without additional help. It also articulated an expectation that the woman would experience a crisis, whether physical or psychological.

At the point of data collection in the BALL Trial, unlike the cohorts in Hau et al. (2012) and Leung et al. (2013) who had already been admitted to hospital, participants had already undertaken an uncomfortable car transfer from home to the maternity unit. Some participants would have been seeking admission following a previous visit to the maternity unit. It has already been mentioned how families feel that they have to justify or negotiate admission with the midwives as gatekeepers (Nyman et al. 2011; Shallow 2016). Under these circumstances, it is of note that only 25.7% of trial respondents stated that they sought admission for pain relief. However, a further 21.5% claimed that they had sought admission for their own or their birth partners' anxiety, which is reflected in the wider literature (Barnett et al. 2008). Both groups might be expected to be in a mindset where they needed to convince their midwives of their need for admission (Nyman et al. 2011; Shallow 2016) and with their birth supporters, expressed their pain accordingly. In view of these considerations, the derived 1.0 difference in the VAS scale may have reflected the scenario of women who had already reached their perceived place of safety in Leung et al.'s study (2013), in contrast to the BALL Trial participants, whose admission context was more liminal.

As discussed in Section 2.2, there is a disparity in the underpinning philosophies of care between the midwifery and obstetric concepts of normal labour and pain, despite the general consensus of its multi-faceted nature (IASP 2014). The obstetric model views labour pain as incremental, nocive, objectively quantifiable

and dose-responsive to pharmacological analgesia. The midwifery model conceptualises labour pain as fluctuating and dynamic, subjective and purposeful as a fundamental, but not necessarily universal component of normal labour (Gould 2000; Whitburn et al. 2019). Logically, obstetrics would consider labour to proceed from 'no pain' (numerical value 0) to 'worst pain ever' (numerical value 10) at the point of birth. By contrast, a midwifery model anticipates that a woman's pain score would reflect her psychological and emotional response to labour as much as her physical sensation and will fluctuate accordingly in labour. Again, this is reflected in the normal distribution of the VAS scores.

Whilst maternal confidence is associated with a reduced uptake of pharmacological analgesia (Lawrence et al. 2013) (Section 2.3) , it does not detract from the intensity of the labour experience, which has led researchers to conclude that labour pain may be perceived as intense, but not necessarily negatively affective. The problem with the VAS is that it cannot differentiate between the components of a woman's subjective self-report. For example, a VAS of 9.0 could be reported by a woman who is distressed and overwhelmed by fear and noxious pain perception or another woman who is deeply locked into her labour and confidently navigating transition. As Mander (2011) and Whitburn (2013) highlight, labour pain is not always synonymous with psycho-affective suffering.

This situation contrasts with respondent information about their use of the birth ball at home (Section 6.9). Respondents reported high levels of uptake of using the birth ball at home and high levels of satisfaction, since 89.2% of respondents found the ball helpful and 92.5% would use it again. Additionally, thematic analysis (Braun and Clark 2006) of respondents' free text comments revealed themes of easing, release and comfort as well as empowerment from using the birth ball. Intervention Arm participants also demonstrated significant increases in Outcome Expectancy and Self efficacy Expectancy (Section 6.7).

Since, as established previously, heightened maternal self-efficacy is associated with reduced uptake of pharmacological analgesia (Lawrence et al. 2013),the intensity of labour pain may not be so relevant in terms of perception, as women's belief that their strategies are helpful (Outcome Expectancy) and their belief in their

own ability to undertake them (Self-efficacy Expectancy). Whilst this may explain why the admission VAS scores for the Intervention Arm showed no difference, it does not explain why there was no reduction in the uptake of regional anaesthesia (Section 6.4.4), as might have been anticipated, although this may not have been demonstrated with the smaller numbers in the trial.

A possible explanation may be that the enhanced comfort and confidence participants experienced at home was overridden by the medicalised environment and discourse that were experienced during the admission procedure to the maternity unit, which preceded the VAS score This would not have been unique to the research setting; the primacy of the bio-medical model of care and the impact of the hospital environment on the latent and birth outcomes are well-established (Machin and Scammell 1997; Williams et al. 2019). By extension, latent phase strategies may be enhanced and family experience improved, but they may be inadequate to overcome maternity care which remains posited on an industrialised, standardised and bio-medical system.

7.3 Secondary outcomes

7.3.1 CBSEI© outcomes

Although the response rate was good at 65%, an error in questionnaire administration meant that the first 28 questionnaires only had the ‘Before’ Outcome Expectancy and Self-efficacy Expectancy scores available, with the ‘After’ scores not collected. It was noted that more socially vulnerable participants, i.e. younger and with less time in education, were less likely to complete and return the questionnaire. Apart from managing conflicting priorities, this may have been related to undisclosed literacy problems, difficulty in understanding or recalling how to respond or finding a postal response unfamiliar or clumsy. The response rate also suggests that 35% of Intervention Arm participants may not have accessed the infomercial, as a component of the complex intervention; they would have been more likely to do this had they undertaken the questionnaire.

Nevertheless, from the 63 paired samples that were applied to the paired t-test, there was a significant increase in the Before / After CBSEI© scores for Outcome

Expectancy and Self-efficacy Expectancy. This suggests that participants increased their belief and confidence that latent phase strategies would be effective (Outcome Expectancy) and also increased their confidence that they would be able to undertake these strategies (Self-efficacy Expectancy). It should be noted that the 15 strategies in the CBSEI© Part 1 do not include birth ball use (Appendix 4). However, it is reasonable to suggest that there was a degree of transferability in these beliefs, so that women who were confident and expressed higher self-efficacy were more likely to implement a range of latent labour strategies. In itself, this is a question which merits further research.

Anecdotal evidence suggests that women have been utilising birth balls at home in the latent phase of labour for some time, at the suggestion of friends, relatives or their own midwives. However, the high recruitment in the trial and the substantial crossover, where more than half of Control Arm participants used a birth ball regardless of allocation, suggests that there was a pool of received wisdom amongst women in the research setting that the birth ball was a useful strategy in the latent phase. The information conveyed by the infomercial would have served to reinforce that belief and enhance participants' Outcome Expectancy and Self-efficacy Expectancy.

7.3.2 Induction of Labour

Although the trial did not consider IOL as an outcome, the change in national and local guidelines profoundly influenced the participants and the trial outcomes and therefore requires consideration. As reported in Section 6.5.2, IOL was administered chiefly for reduced fetal movements (8.1%) and suspected restricted fetal growth (7.5%). Both these measures were adopted by the host Trust as per the NHS England recommendations of the *'Saving Babies' Lives'* (O'Connor 2016) care bundle. The current available evidence from the Awareness of Fetal Movements and Care Package to Reduce Fetal Mortality (AFFIRM) trial (Norman et al. 2018) confirms the higher rates of IOL and CS arising from the reduced fetal movements protocol.

With regards to the Growth Assessment Protocol (Perinatal Institute 2016), generalisable findings are awaited from the Detection of the Small for Gestational

Age Neonate (DESiGN) trial (Viera et al. 2019); nevertheless, IOL for reduced growth, SGA or fetal concerns accounted for 7.5% of the study population. A further 3.2% of participants underwent IOL on the basis of the fetus being identified as LGA or for a previous shoulder dystocia. This was an idiosyncratic feature of the trial population and the host Trust as there is no agreed definition of LGA and it is not synonymous with macrosomia (Royal College of Obstetricians and Gynaecologists 2018) as an acknowledged red flag for intrapartum problems.

Overall, the IOL rate for trial participants concords with the 32.6% cited as the national rate in England (NHS Digital 2018). However, it should be noted that the national rate is universal, including women with complex health issues and complex pregnancies. By contrast, the BALL trial population was low-risk and would be anticipated to demonstrate a higher rate of spontaneous labours. This was not the case, which poses local and national questions as to the guidelines and protocols which offer IOL to 1 in 3 pregnant women. Leung et al. (2013) reported fewer IOLs or labour augmentations in women using the birth ball in hospital in the latent phase (5% versus 27%) but the different context of routine latent phase admission and lack of detailed data obfuscate clear conclusions.

Overall, increased rates of IOL have implications for future research design into perinatal health, because higher population samples will be needed to offset the reduction in spontaneous labours and the consequent increase in associated obstetric interventions. At the time of writing for example, ‘The Big Baby Trial’ is launching to compare IOL with expectant management for babies perceived to be at risk of macrosomia (Warwick Clinical Trials Unit 2019), which may affect other research into normal labour, since some otherwise low risk participants are likely to be recruited.

7.3.3 Labour admission

As for IOL, admission in latent or active labour was not a trial outcome, but was considered because hospital admission and subsequent interventions are based on the clinical decision making of whether women are in active labour or not. Although there was no significant difference in the mean cervical dilatation between the trial arms, when recoded as ≥ 4cm cervical dilatation (as per NICE

2017 guidelines), more Intervention Arm participants were admitted in the active phase of labour compared to the Control Arm (63.6% versus 55.7%). This held true when recoded as per WHO (2018) guidelines ≥ 5cm cervical dilatation (52.5% versus 42.1%).

These findings should be considered in conjunction with those of Section 6.8.8, where Control Arm respondents reportedly spent longer at home than Intervention Arm participants prior to hospital admission. If more Intervention Arm participants were admitted in active labour, whilst more Control Arm participants postponed their admission, then a feasible explanation is that Intervention Arm participants' labours established more quickly than those of the Control Arm.

This is a significant consideration because despite the limitations of cervical dilatation as a diagnosis of active labour, it is the observable characteristic available to most maternity care systems and the most widely used (Neal et al. 2010; Hanley et al. 2016). A similar finding emerged from the COSMOS trial (Davey et al. 2013) which found that women under midwifery case loaded care were more likely to be admitted to hospital in the active rather than the latent phase. Whilst the benefits of case loaded midwifery care extend far beyond active phase admission, if birth ball use can achieve at least this outcome, then in terms of infrastructure and financial outlay, it becomes a highly cost-effective strategy.

Because latent phase admission is associated with higher rates of obstetric intervention, with the potential for increased maternal and fetal morbidity, as discussed in Chapter 1.0, the savings to maternity services in the reduction in CS by using a birth ball would be considerable and the improvements in perinatal outcomes commensurately large and far-reaching.

7.3.4. Obstetric interventions

With regards to the uptake of CEFM, amniotomy, synthetic oxytocin and regional anaesthesia as obstetric interventions, the differences between the trial arms were small and neither statistically nor clinically significant. It should be borne in mind that the trial was not statistically powered to detect these differences beyond a descriptive analysis.

Nevertheless, both trial arms experienced higher rates of CEFM, amniotomy and regional anaesthesia in comparison to the host Trust background rates, (Sections 6.4.1, 6.4.2 and 6.4.4) This is surprising because the background rates comprise women at high and low risk of obstetric intervention, where higher intervention rates might be anticipated. The exception to these findings was the use of intravenous synthetic oxytocin, which was similar to that of the host Trust. (Section 6.4.3)

These results may be attributable to the increased IOL rates in the trial cohort. Amniotomy and intravenous synthetic oxytocin are accepted components of IOL protocols in the UK (NICE 2008). Although IOL using prostaglandins and amniotomy alone are not primary reasons for using CEFM throughout labour (NICE 2008; NICE 2017), under the local IOL protocol, CEFM was recommended. Additionally, IOL is associated with higher uptake of regional anaesthesia (Carter 2018), therefore this may have been a contributory factor.

It is possible that the increased intervention rates are due to artefact and indicate unintended bias in recruitment. However, the high recruitment and the fact that most women opt for hospital-based labour and birth in the UK (Office for National Statistics 2017), evidence against this. Although each trial arm had slightly more primiparous than multiparous participants (52.7% in the Control Arm and 56.1% in the Intervention Arm), the difference is insufficient to account for the added intervention, even allowing for the known increased interventions associated with primiparity (Dahlen et al. 2014; RCM 2016).

Overall, it may be concluded that the birth ball did not reduce CEFM, amniotomy, the use of synthetic oxytocin or regional anaesthesia as obstetric interventions.

7.3.5 Birth mode

The low rate of elective CS when compared with the host Trust background rate may be attributed to a low risk trial cohort when compared to the background Trust cohort, which was composed of women at all levels of risk of obstetric intervention. Inevitably, the background Trust cohort includes women with more indicators for elective CS, such as maternal request or multiple pregnancy. Comparison of the

trial cohort with the Birthplace cohort in regards to birth mode is not appropriate because the Birthplace data excluded births with IOL and regional anaesthesia (Birthplace in England Collaborative Group et al. 2011). As noted previously, IOL and regional anaesthesia were administered to sizeable proportions of the trial cohort. IOL and regional anaesthesia are associated with higher rates of assisted birth (Middleton et al. 2018), therefore comparison is not equivalent.

Although the trial cohort was inadequately powered to detect a statistically significant difference in the rate of CS, there was a trend towards a reduced rate of emergency CS in the Intervention Arm (7.5%) compared to the Control Arm (17.9%). This cannot be attributed to IOL rates, as in fact, the Intervention Arm had a higher rate of IOL. This is partly offset by higher assisted birth rates in the Intervention Arm, which are more likely to reflect assisted birth as an alternative to CS.

It is possible that Intervention Arm participants who underwent IOL were positively influenced by the infomercial in terms of Outcome Expectancy and Self-efficacy Expectancy and felt more empowered and confident to use the birth ball during the IOL process. Upright positioning and enhanced maternal confidence in the first stage of labour are associated with reduced uptake of pharmacological analgesia and a reduction in CS (Lawrence et al. 2013), so the trial intervention may have had an extended effect, which would be evident through Intention-To-Treat statistical analysis as all IOL data were included.

7.3.6 Maternal satisfaction, acceptability and experience

A total of 140 out of 171 (89%) eligible respondents completed the questionnaire. This high response rate suggests that respondents were highly motivated and engaged with using the birth ball and with the trial. This may partially account for the strongly positive responses; even respondents who had not used the ball or found it helpful themselves, remarked that they would still be willing to try it in a future labour or recommend it to their friends or family. This points to a pool of shared wisdom amongst women that the birth ball is helpful in working positively with their latent labour. Many participants cited personal experience or that of friends and family who had used a birth ball as a reason for entering the trial. This

was acknowledged when constructing the trial design and reinforced the need for an RCT and objective evaluation.

The reported activities while using the ball in the trial matched those reported by Beebe et al. (2007) of rocking, swaying and leaning, with or without the ball. Rhythmic movement is a universal component of normal labour (Gould 2000) and reflects the synchrony with the pulsatile secretion of oxytocin and regular uterine contractions (Moberg 2011). Leaning forward in labour is also a characteristic and innate response, which may facilitate fetal rotation of the denser fetal occiput towards an optimal occipito-anterior position for birth (Simkin 2010; Gizzo et al. 2014).

Whether using a birth ball or not, these facilitating intrapartum movements do not always feature in midwives' advice to women in the latent phase. It may be assumed that women will undertake these movements instinctively; however, anxious and fearful families may be unsure what to do. For example, although the infomercial modelled women kneeling or standing over the ball, comparatively few undertook this, even when they reported fetal descent which made sitting on the ball uncomfortable. Control Arm respondents would not have accessed the infomercial, but some Control Arm respondents who used a ball of their own volition did comment that they were unsure what to do. This demonstrates that families need an educational component and some supportive direction to engage with latent phase strategies, as indeed was provided by Hau et al. (2012) and Leung et al. (2013) in the form of physiotherapist-led group sessions and a leaflet respectively.

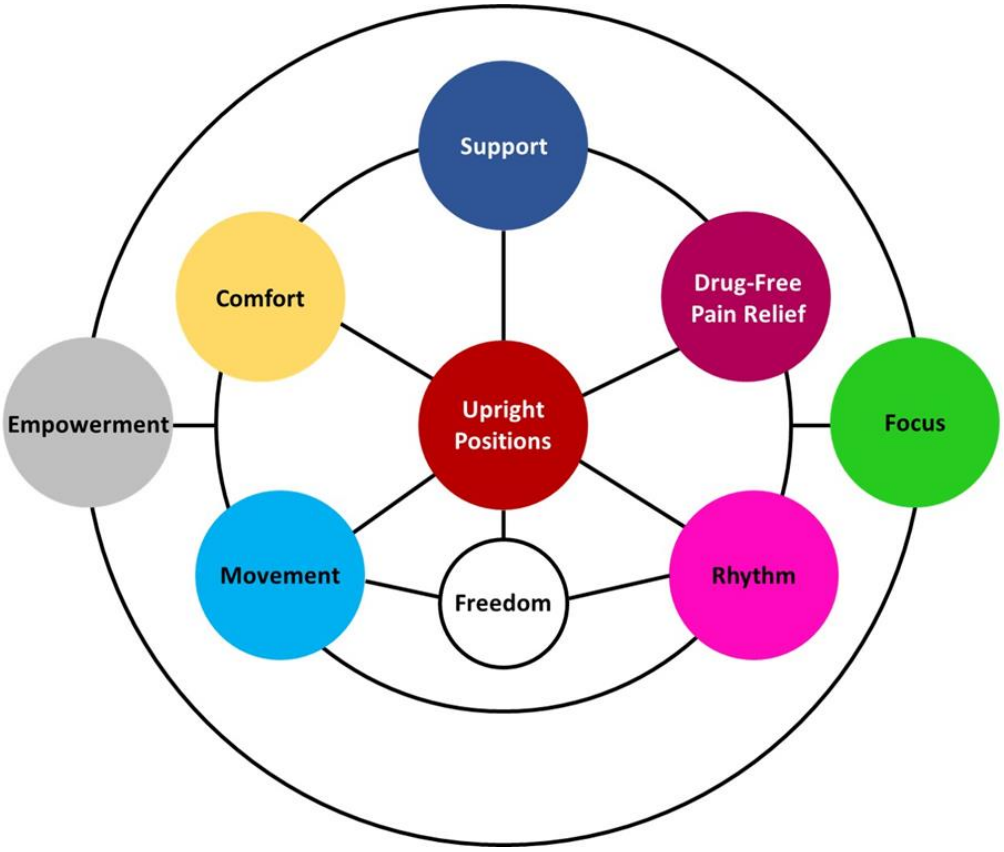
The online infomercial *Having A Ball in Early Labour* demonstrated a significant increase in both Outcome Expectancy and Self-efficacy Expectancy, as detailed in Section 6.2.1. Online maternity resources have increased exponentially since Hau et al. (2012) and Leung et al. (2013) , both of which used more traditional methods of education (paper-based and face-to-face respectively) In addition to offering families greater flexibility and accessibility (Evans 2006), it is the impact of these educational tools on health literacy which is most important. i.e. promoting the ability of individuals to access, understand and use information and services to

make decisions about their health (WHO 2015). Health literacy is closely associated with self-efficacy and empowerment, and is key to improving health outcomes (WHO 2015), which is entirely consistent with the aims of the BALL Trial and midwifery care overall. Thus, it may be concluded that an educational component is an essential component of any health-related intervention and justified the choice of a complex intervention for the BALL Trial.

7.3.6.1 Thematic map

Emergent themes from the postnatal questionnaire as discussed in Section 6.9 allowed the construction of a thematic map, as shown in Figure 7.1 below.

Figure 7.1 Thematic map



The overarching themes of ‘Focus’ and ‘Empowerment’ were notable because respondents reported uniting physical activity with cognitive strategies to drive their labours towards birth. Mastery of the self, the physiological journey and the physical activity to culminate in the birth of the baby are the fundamental components of a woman’s journey to maternity. Self-efficacy is associated with improved perinatal outcomes (Tilden et al. 2016); combined with the enhanced Outcome Expectancy and Self-efficacy Expectancy reported in Section 6.7 after accessing the infomercial, the birth ball also appears to enhance women’s self-efficacy. This suggests that the infomercial (as a cognitive strategy) and the birth ball (as a physical support) as a complex intervention complement each other.

The theme of ‘Comfort’ and its association with ease and relaxation while using the ball was also anticipated to some extent, in view of the recommendations by Perez (2000) the findings of Taavoni (2011) and Makvandi (2015), Hau et al. (2012) and Leung et al. (2013), all of whom concluded that birth ball use reduced pain perception in either the active or latent phase of labour. Moreover, respondents in the BALL Trial highlight their core experience of ‘Upright Positioning’, which promotes their other physical experiences and sensations of ‘Support’, ‘Drug-Free Pain Relief’ and the ‘Freedom’ to express ‘Movement’ and ‘Rhythm’. The centrality of ‘Upright positioning’ is supported not only by the respondents’ experiences, but by the Cochrane review which established upright positioning with reduced analgesia uptake (Lawrence et al. 2013).

These findings are significant because they encapsulate the synergy of women’s cognitive and physical strategies to progress their labours towards birth, which is congruent with the themes from Carlsson et al. where women described ‘maintaining power’ (2012, p.88) as a combination of bodily and mental strength which was fuelled by their desire for motherhood and their sense of autonomy over their own bodies.

In this respect, the empowerment and focus of a trusted strategy to facilitate upright positioning in the latent phase of labour conferred the freedom to move rhythmically and progress labour. Therefore, the complex intervention in the BALL Trial fulfils Eri et al.’s (2015) proposal for a ‘tool kit’ to navigate the challenges of the latent phase of labour.

7.3.7 An unexpected finding

All the participants met either the CI or research midwife face-to-face through recruitment and consent; they all discussed the rationale for the trial with their midwives and the research team. Some participants stated that their motivation for joining the trial was altruistic in order to help other women. Others viewed the trial as prestigious for the community in the research setting, especially because the trial was innovative and would set a precedent for other research. Potential participants often expressed surprise and interest at the number of participants and the ambitious recruitment target. For some participants the trial was as an opportunity to reduce the chance of pharmacological analgesia and intrapartum intervention. Some mentioned that the chance of a free birth ball loan was motivational. In summary, although participants' motivations varied, the trial was considered an attractive opportunity as a 'win-win', i.e. one in which they might gain some benefit personally and help others (McCann et al. 2010). On several occasions, participants contacted friends, relatives and neighbours who they thought might benefit from the trial or be interested.

This was an unexpected, but positive feature of the trial which appeared to generate a degree of social capital and facilitate discussion and experience sharing in the community. The host Trust runs a moderated maternity services Facebook page where the trial was advertised, which also gave rise to discussion amongst pregnant women, their families and their midwives. All participants expressed enthusiasm about receiving an emailed summary of the trial findings. The implications will be discussed in Section 7.6, as 'Impact'.

7.4 Strengths of the BALL Trial

The BALL Trial was the first formal evaluation of the effectiveness of birth balls at home in the latent phase of labour. The trial choice of a woman-centred intervention directly addressed the concerns and needs of women and their families (McCourt et al. 2013) as opposed to maternity care resource appropriation and allocation. The fact that this had not been examined before may be attributed to the fact that until recently, maternity services did not view the latent phase as relevant or requiring more than cursory and generic input. It also directly addressed strategies for the latent phase as an overlooked source of workload and tension between women, families and maternity caregivers (Shallow 2016) and the potential for consequent iatrogenic obstetric intervention.

The trial was based on a rigorous literature search and review which identified a notable gap in the evidence, namely, that using the birth ball in the latent phase of labour had been tested in observational trials in hospital environments where latent phase admission was a sociocultural norm (Hau et al. 2012; Leung et al. 2013) and therefore had a care context which differed markedly from other high-income countries. Therefore, using a birth ball in the latent phase had not been objectively trialled in other high-income care contexts such as the UK, where labouring women are encouraged to postpone hospital admission until labour had established.

The BALL Trial design pre-empted a Cochrane review recommendation to strengthen the evidence base for latent phase interventions (Kobayashi et al. 2017) by using an RCT methodology, which is considered more robust in the ‘hierarchy of evidence’ and more likely to establish a causative link between variables (Cluett 2006). Given the known issues of compliance, deviation from protocol and cross over in maternity trials, a pragmatic approach to the trial design aimed to balance objectivity and the minimisation of bias with determining clinical effectiveness i.e. whether the birth ball reduced women’s pain perception under ‘real life’ conditions, which strengthened external validity (Welsh 2013). Additionally, data analysis by Intention-To-Treat was used because it overcomes the common issues of non-compliance, absent data and protocol deviations (Gupta 2011) and reduced the likelihood of a Type 1 error.

The trial set an ambitious recruitment target, which was 89% fulfilled, with a two month recruitment extension, which evidenced high recruitment and engagement by participants and midwifery care staff. The positive effect for local families has already been described above, which supported interest and recruitment. It should be noted that the trial cohort was eclectic; although not all UK ethnic groups were represented, this was a feature of the local population. By contrast the continuum of the childbearing age (18 to 44 years) and social backgrounds were well-represented. CMWs indicated to the CI where potential participants had additional challenges in order to determine whether the woman could be contacted appropriately after expressing an interest in participating in the trial. For example, one potential participant could not be consented at home due to a moratorium on lone visiting by staff. A substantial proportion of the cohort managed safeguarding issues including young parenthood, mental health issues, low income, vulnerable housing and domestic abuse; these social groups are often under-represented in research (Davaki 2019).

The trial was supported through the award by the Iolanthe Midwifery Trust to fund the birth balls and the assistance of the NIHR and the host Trust Research and Development department. A research midwife assisted in recruitment and data collection and pool cars were made available to allow travel to clinics and participants' homes to recruit and consent. As a result, the trial was highlighted as the highest recruiting trial in reproductive health for the local NIHR Clinical Research Network, which enhanced the trial's standing.

7.5 Limitations of the BALL Trial

The trial's ambitious recruitment target left insufficient margin for participants who would not contribute to the primary outcomes, despite the positive engagement. This would have been better anticipated by piloting / feasibility, which would have detected the attrition in spontaneous labours.

The second limitation was the degree of 'crossover' between the Control and Intervention Arms, where 52% of Control Arm respondents reported using the birth ball at home in the latent phase. Whilst this was offset by a much higher proportion

of Intervention Arm participants using the birth ball (83%) and the fact that Control Arm participants did not have access to the infomercial, some degree of compromise to internal validity must be accepted.

Clinicians often engage with situations over which they have little or no control, such as staff shortages, equipment / resource deficits or sudden increases in workload (Bentley et al. 2014), which inevitably impacts on the quantity and quality of data which can be collected in terms of accuracy and timeliness (Sole et al. 2018). This was particularly evident in the trial, where missed VAS scores could not be completed retrospectively. Whilst these data collection issues may be considered as an inevitable hazard of pragmatic research, albeit ameliorated by the CI's embeddedness within the research context, the key to optimising data collection is by research design which minimises workflow disruption and workload to clinicians as well as the burden to participants. This is discussed in greater detail in Section 7.6.

Three participants were withdrawn for non-compliance, in that they ceased to engage with the trial following consent; this violated the Intention-To-Treat principle of 'once randomised, always analysed' and meant that the pool of outcome data was unnecessarily reduced. Two participants were withdrawn for previously undisclosed medical conditions, which meant that screening procedures had to be tightened.

Lastly, although the response rate to the postnatal questionnaire was high (77%), 23% of data regarding birth ball use, activities and latent phase experience was lost through non-completion. Whilst research participants' rights to respond or not are paramount, a more timely data collection point might have yielded more data from a cohort that had already been reduced due to IOL.

7.6 Challenges and learning

The trial launch on 1 February 2018 coincided with the reconfiguration of the host Trust midwifery teams from an integrated, community-hospital rotation model to discrete Core and Community teams. This meant that midwives were embroiled in handing over caseloads, adapting to new areas and alternately adapting to on-call / shift rotas. In retrospect, recruitment and VAS data collection commenced slowly because the midwives had more immediate and pressing issues to address. Midwives commented that in addition to their new roles, it took longer to incorporate the parameters for data collection and the details of the trial in addition to their new workload. Better liaison and discussion of policy and practice initiatives in the research year would have allowed smoother and more effective trial implementation.

Errors, venal as opposed to mortal, were made by the CI. There was an error in the administration of the CBSEI© Part 1 questionnaire, where only the Before questionnaire was supplied; this cost the trial a substantial number of data pairs for the paired t-test (see Section 5.7). The use of a postal questionnaire for the CBSEI© produced a reasonable response; however, using paper-based questionnaires may be construed as an anachronism and is certainly costly in terms of cost and resources. Since every participant used a smartphone, an online questionnaire at the CBSEI© stage may have generated as good a response as the online postnatal questionnaire and potentially reduced mailing costs.

The single biggest problematic issue for the trial was the introduction of new national and local guidelines regarding IOL for reduced fetal movements and for the GAP whilst the trial was in design. The consequent attrition and the associated effects on the trial cohort have been detailed and evaluated; however, there was little liaison with the host Trust obstetric team and monthly Labour Ward meetings in the months during which the trial design was elaborated. More robust liaison would have highlighted the implementation of these policies and their predicted effect of increased IOL (NHS England 2016). In turn, the trial design could have allowed for the attendant reduction in spontaneous labours or reconsidered the primary outcome in terms of feasibility. The recruitment period was extended by 2

months, which improved both recruitment and offered further potential for spontaneous labours.

An additional attrition factor occurred in data collection; 27% of VAS scores from eligible women were not collected, although 73% of primary data capture may be considered as a testament to high levels of engagement by participants and midwives. Initially, absent data was anecdotally reported as admitting midwives being unsure of the correct data collection point. In order to address this, the VAS was placed at the front of participants' maternity notes and eventually printed on coloured paper, with reminder notices in the Maternity Ward clinical areas and office, which improved collection rates. Additionally, the support and involvement of the Ward Manager contributed to improved data collection.

The challenges of relying on clinicians for data collection are documented across health research, whether in high or low-income settings. Trial design needs to incorporate the lived experience of clinicians, in that their work environment is often one of keeping on track and minimising disruptions to their workflow to prioritise the people in their immediate care (Renden et al. 2018). This means that activities which are perceived as lacking immediate benefit such as research data collection may be subordinated and marginalised whilst clinicians prioritise and develop solutions for unpredictable or unexpected situations. The BALL Trial protocol was developed to minimise the workload and workflow disruption to the admitting midwives, a process which was facilitated by the CI working clinically alongside the midwives, and gaining insight into the clinical context.

Although training, *aides memoires* and information packs were provided, as described in Section .4.2 and as common strategies to support data collection by clinicians (Sole et al. 2018), some staff may have benefited from further training, as they expressed confusion as to when women should provide a VAS score or whether they should be encouraging them to use the birth ball in the hospital. This ongoing need was addressed by further updates and reminders by the CI at shift handovers.

7.7 Impact

The BALL Trial was an innovative trial which directly addressed families' concerns and wishes around care in the latent phase of labour. It offers promising evidence that using the birth ball is acceptable to women and improves their latent phase experience, promoting their comfort and mobility and empowering them to work positively with their contractions. There are indications that the birth ball may help postpone hospital admission in active rather than latent labour and may also improve the likelihood of vaginal birth.

The trial's infomercial, '*Having A Ball in Early Labour*' significantly increased participants' confidence levels, which suggests that the format and content were appropriate and meaningful to women. as well as demonstrating the importance of providing advice and information with any intervention. The online format is accessible and ultimately cost-effective since it is adaptable to different languages and cultural contexts and does not require even basic literacy skills.

There were several positive outcomes for the host Trust and the local population. Firstly, the inclusion of the trial on the NIHR portfolio brought support to the trial and the host Trust Research and Development department. The high recruitment levels meant that the trial became the highest recruiting trial in the region for reproductive health, which enhanced the Trust's research reputation. It also provided significant positive affirmation for the midwifery team who were instrumental in recruitment and data collection. The trial was popular and well-supported in the host Trust because of its innovative approach, the scale and the prestige which it gained for the community, the midwifery team and the Trust.

The generation of social capital is not new in midwifery research, characterised by bonding, linking, participation and trust (Rocco and Suhrcke 2012). The participation, engagement and sharing of information and experience by the trial participants was not anticipated, but may serve as a platform to disseminate shared experience and strategies via relationships and social media.

The birth balls have been gifted to the host Trust to run a birth ball loan scheme for the latent phase of labour. This will be run by the CMWs and offers the opportunity

to broaden and enhance birth preparation and labour triage conversations. A follow-up of the scheme uptake and satisfaction is planned after a year. Although post-trial access to clinical trial treatments generates strong for and against arguments (Doval et al. 2015), the BALL Trial intervention is non-pharmacological and facilitates a course of action which many women pursue of their own volition and with the encouragement of their midwives. The positive experiences of participants and lack of demonstrable adverse effects mean that the birth ball loan scheme is ethically sound and has the potential to positively influence the culture and approach to the latent phase of labour.

The trial findings will be shared with the participants, Trust staff and the public as an infographic (Appendix 20), which can be displayed as a poster and on the Trust website. As stated, it will hopefully pave the way for further midwifery-led research in the area.

7.8 Implications for maternity care research

Firstly, if using a birth ball is effective in helping women navigate the latent phase as indicated, then there are likely to be other physical and cognitive strategies in the shared pool of wisdom which merit investigation. The trial has demonstrated that strategies or tools require an information / educational component to promote their implementation by families. Online resources and data collection are more accessible and cost-effective as opposed to postal / paper-based resources. Moreover, online resources and mobile apps are likely to advancing data collection in health research by reducing the burden on frontline clinicians and facilitating more timely data reports by research participants themselves (Burrows 2018). For example, the VAS scores in the BALL Trial could have been collected by a mobile app, which would have allowed a VAS evaluation before participants left their homes for admission.

The trial was undermined by an attrition bias due to rising rates of IOL and its attendant interventions and possibly to a lesser degree, due to local idiosyncrasies of care practice. As discussed in Chapter 1.0, the UK maternal population and indeed, those of other high-income countries, are now older, with larger body sizes and living with a greater range of health conditions, which places them at higher

risk of obstetric intervention. Unless current trends are reversed, conducting prospective objective research will have to contend with a shrinking pool of potential participants at low risk of obstetric intervention and larger scale trials will be needed to recruit them.

Future research into using the birth ball needs to consider a multi-centre RCT with a larger potential pool of potential participants, which would offset increased obstetric intervention and local care practices and cultures. This may be supported by the adoption of maternity clinical networks (NHS England 2016) as a tactic to share best practice amongst NHS trusts and therefore reduce disparity in maternity care practice.

7.9 Conclusion and contribution to knowledge

The BALL Trial was unable to demonstrate that objectively, women reported less perceived pain on admission to hospital when they used a birth ball at home in labour. Nevertheless, many women reported that they found using the ball provided a sense of comfort, ease and empowerment whilst at home.

The infomercial '*Having A Ball in Early Labour*' exerted a positive effect both on women's Outcome Expectancy and Self-efficacy Expectancy as an 'overflow' effect, in that having received information and a rationale for using a birth ball through the infomercial, they reported increased self-efficacy and confidence in relation to other latent phase strategies. This was reiterated in the postnatal questionnaire where respondents reported empowerment and focus to work with their contractions. Using online resources offers a visually powerful, flexible and cost-effective means of sharing core information and educational support to use the birth ball.

The birth ball may help women postpone hospital admission until labour has established. Using the birth ball appeared to enable women to adopt and maintain upright postures and move as they wished. This did not seem to reduce obstetric intervention, however the findings suggest that the birth ball may increase the likelihood of a vaginal birth as opposed to a CS.

Overall, the BALL Trial was a robust, innovative and pragmatic trial. The birth ball was a popular and acceptable intervention for which women expressed high degrees of satisfaction and would be happy to use in a future labour and to recommend to friends or family. In itself, this represents an improvement in latent phase experience and responds to women's wishes and hopes for non-pharmacological, evidence-based strategies to navigate the latent phase and facilitate normal birth. The birth ball merits further research on a larger scale.

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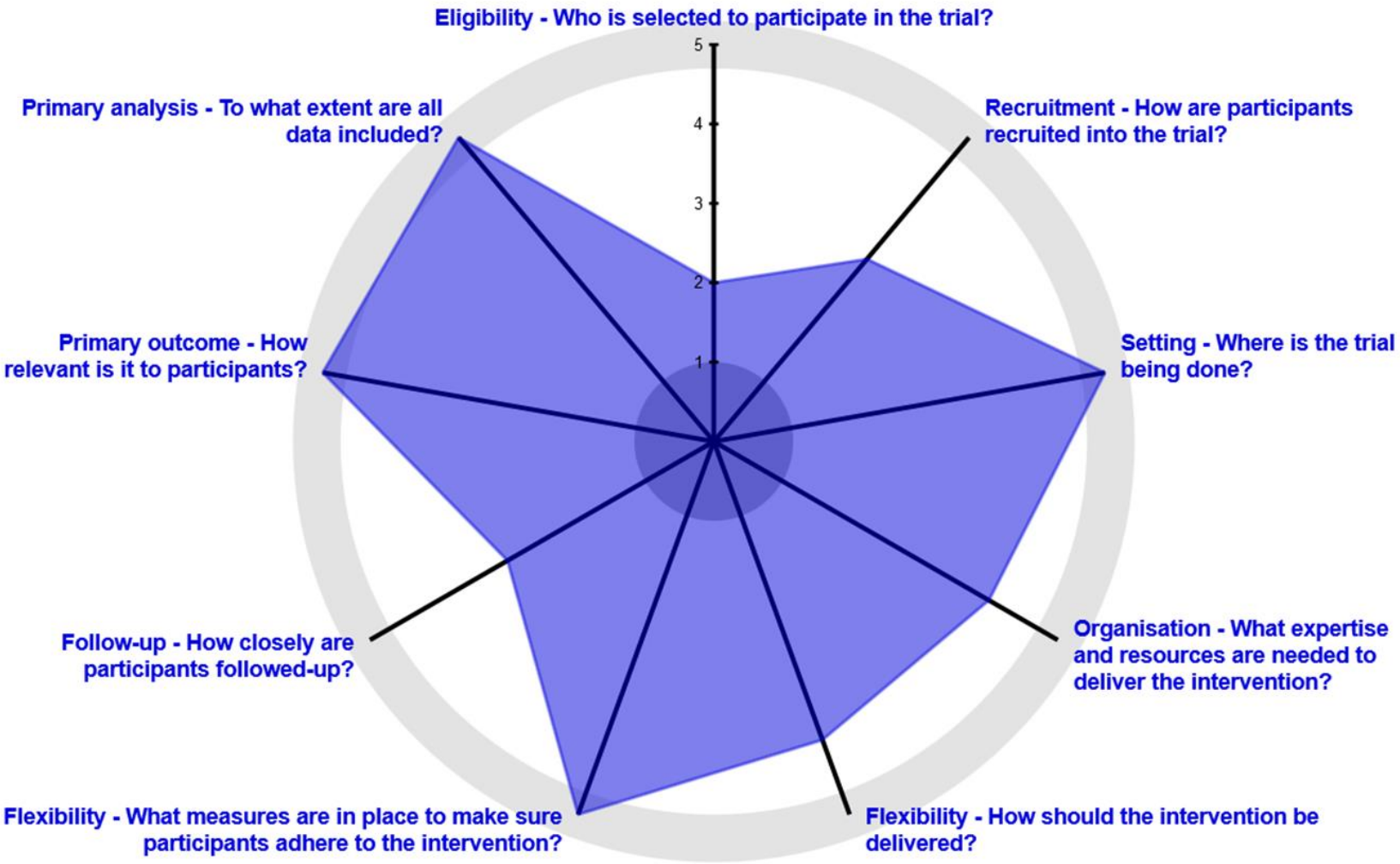
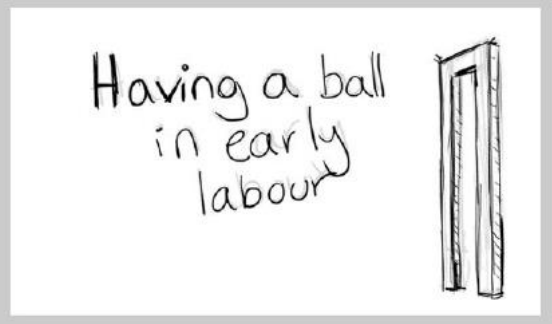
Appendices

Appendix 1 The BALL Trial design on the Pragmatic-Explanatory continuum (Loudon et al. 2015)



Appendix 2 Infomercial storyboard and aesthetic

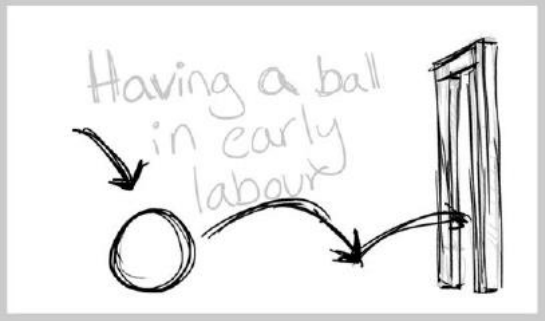
Storyboard



001-1

Description: Blank environment with a door frame. Text introduces the film

VO:None



001-2

Description: Ball bounces into shot and through the door frame

VO: Voice over begins
"Being at home in early labour... "

002-1

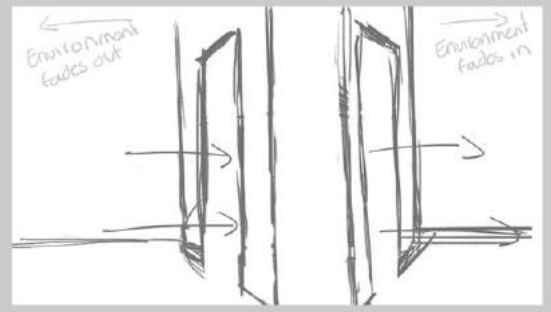
Description: Bathroom. Woman is in clear discomfort

VO: "Early labour can be frustrating .... "

002-2

Description: Ball bounces in and gently bumps into woman. She reacts with a welcoming surprise.

VO: "Woman who use a birth ball in early labour... "



002 transition to 003

Description: Camera tracks to the right as if travelling through the door. The bathroom environment fades out and the bednroom environment fades in. The only object that does not fade is the ball.

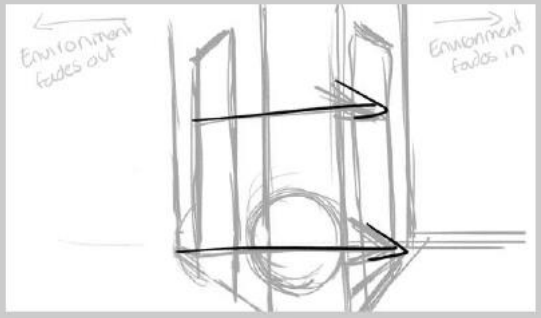
VO:

003-1

Description:Bedroom. Woman is bouncing on ball.

VO: "You can bounce"

Storyboard



003 transition to 004

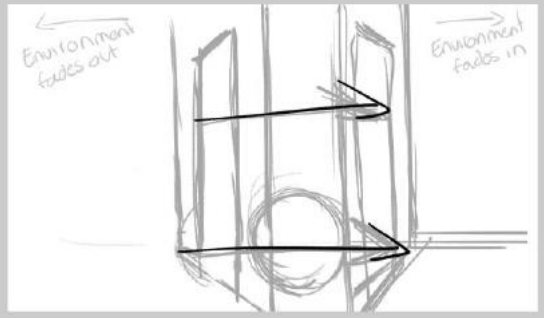
Description: Camera tracks to the right as if travelling through the door. The bedroom environment fades out and the hallway environment fades in. The only object that does not fade is the ball.

VO:None

004-1

Description: Hallway. Woman rocks hips against ball

VO:
"Rock your hips"



004 transition to 005

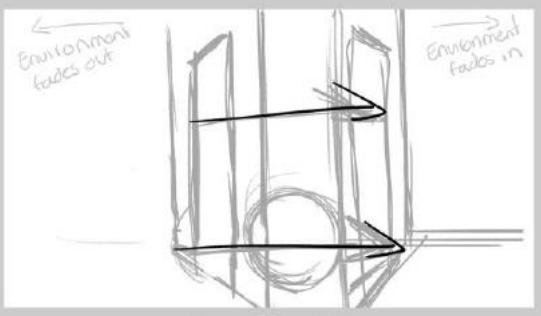
Description: Camera tracks to the right as if travelling through the door. The hallway environment fades out and the kitchen environment fades in. The only object that does not fade is the ball.

VO:None

005-1

Description: Kitchen. Woman circles her hips.

VO: "Circle your hips"



005 transition to 006

Description: Camera tracks to the right as if travelling through the door. The kitchen environment fades out and the office environment fades in. The only object that does not fade is the ball.

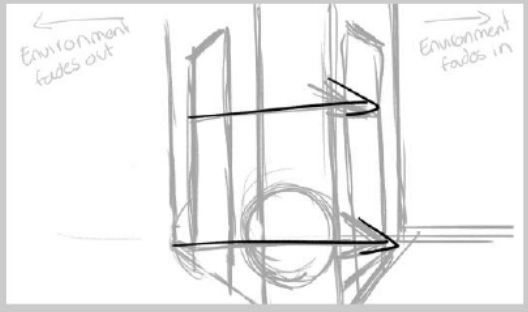
VO:

003-1

Description:Office. Need guidence on what the pose is. At the moment its the scene from the karate kid.

VO: "In whatever position feels right to you"

Storyboard



006 transition to 007

Description: Camera tracks to the right as if travelling through the door. The office environment fades out and the living room environment fades in. The only object that does not fade is the ball.

VO:None

007-1

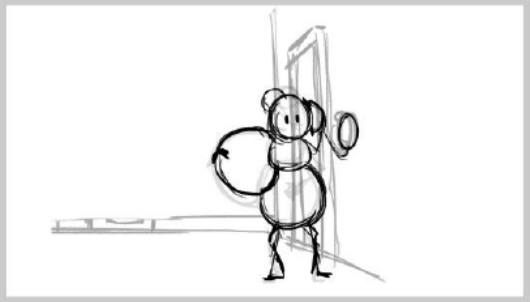
Description: Living Room. Woman is holding ball. Various thumbs up hands pop out from the door frames. She returns the thumbs up.

VO:
"Women report feeling more confident when they use the birth ball, especially when supported by birth partners"

007-2

Description: Woman suddenly shows strong discomfort

VO:None



007-3

Description: Camera tracks right. Woman walks over and picks up the ohone.

VO: "Call the hospital when your contractions are for x, y and z"

007-4

Description: Woman leaves the through door with the ball.

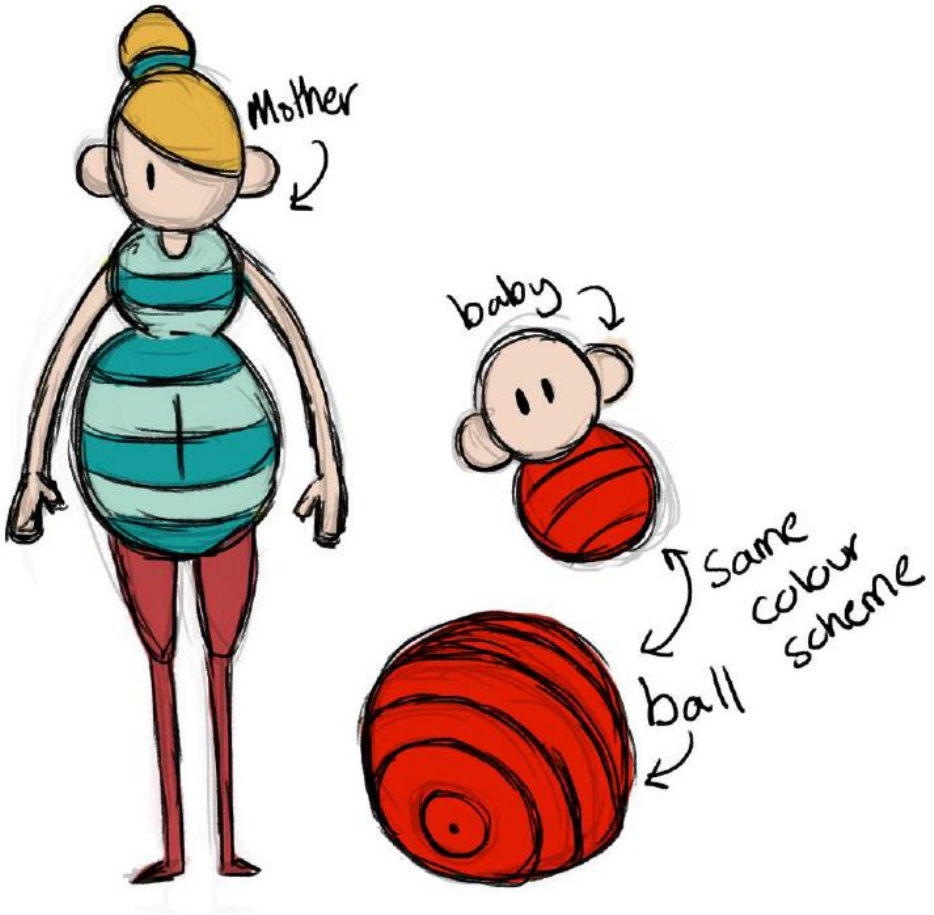
VO: "You can use the ball throught labour if you wish"

008-1

Description: Woman appears through the door no longer carrying a ball but a baby. Final words appear on screen.

VO: "You can ask your midwife if you have any questions"

Current Character Design



Having A Ball In Early Labour Script

by Dominique Mylod

TITLE CARD

Narrator Welcome to *Having A Ball in Early Labour; making early labour work for you.*

FIRST FRAME

Ball bounces into shot and through door frame.

Narrator Being at home in early labour means you are less likely to have a complicated labour, use pain relief or have a caesarean section.

As Eve bends over with her contractions.

Narrator Early labour can be a frustrating and tiring time for you and your birth supporters while your cervix thins and opens up.

Woman 1 It's hard to trust your instincts – your body's doing things. And I didn't know it could go on that long.

Woman 2 It was more painful for him. He spent the whole time pacing about.

The birth ball rolls up to Eve.

Narrator Women who use a birth ball find it easier to work with their contractions and find them less painful.

SECOND FRAME

Eve bounces on the ball.

Narrator You can bounce (bounce noise). Your knees should be about 10cm below your hips.

Woman 1 It really helped with the pain in my hips and back.

THIRD FRAME

Eve kneels over the ball and rocks her hips.

Narrator Or rock your hips with your knees apart to help your baby move down.

Woman 2 I used it to help with the baby's position.

FOURTH FRAME

Eve circles her hips.

Narrator Or circle your hips. Using a birth ball may help you move into active labour more quickly. You can change positions depending on what feels right for you.

FIFTH FRAME

Eve stands and leans on the birth ball on the table.

Narrator Women report feeling more confident on the birth ball especially with birth supporters. .Massage, watching TV or listening to music can help you relax. Peace and quiet helps too.

Woman 1 Everybody's perception is about rushing it.

Woman 2 The pressure about telling so-and-so; have you told so-and-so yet?

SIXTH FRAME

Eve calls on her phone.

Narrator Call the hospital when your contractions are 3 – 4 minutes apart, if your waters break or if you are worried.

FINAL FRAME

'Good Luck' appears on the screen.

Narrator Good luck!

Appendix 3 Infomercial PPI feedback

Friday 17th February 2017

Children's Centre 10:00 – 11:15

Discussion with 15 mothers and babies aged 0 – 12 months

1. What is helpful for a positive early labour experience?

- It is very scary, it's petrifying. It's that reassurance that you need from someone.
- Everyone feels that overwhelming sense of fear.
- It's hard to trust your instincts – your body's doing things.

2. What did you find helpful or unhelpful in your early labour?

- I sat in the bath.
- Everybody's perception is about rushing it.
- I didn't know early labour went on that long.
- It's not just the woman needs to understand; society needs to understand that it does take time.
- The pressure about telling so-and-so; have you told so-and-so yet?
- Dilatation doesn't mean you're going to have a baby there and then.
- It was more painful for him. He spent the whole time pacing about.
- You feel that you can't cope; nothing's going to work.

3. What would you do differently in a future early labour?

- Midwives need to personalise early labour.

4. What do you think about using a birth ball in early labour?

- I don't think there was much really in the antenatal classes about using a ball and stuff.
- My daughter still sits on the ball that I used in labour to watch TV.
- Really helped with the pain in my hips and back.
- I used it to help with the baby's position.

5. What do you think about the project title, '*Having A Ball in Early Labour'?*

- I'd be intrigued by what it actually means.
- Fun

- Some people might not know what it actually means

6. Are there any comments you would like to make about the proposed storyboard for the infomercial?

- Use the neutral colour background
- Better than being inundated with leaflets.
- Fun ….. simple ….. makes the point

Appendix 4 Childbirth Self-Efficacy Inventory Part 1

Childbirth Self-Efficacy Inventory (CBSEI)

The Ohio State University
Columbus, Ohio, USA

Nancy K. Lowe, Ph.D., CNM, FACNM, FAAN
College of Nursing
University of Colorado
13120 E. 19th Ave., Mail Stop C288-18
Aurora, CO 80045 USA
(303) 724-8549; nancy.lowe@ucdenver.edu

Modified and used by kind permission of Professor Nancy Lowe 2017

CBSES: Part I ID_____ BEFORE AFTER

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

	Not at all helpful								Very helpful	
1. Relax my body.	1	2	3	4	5	6	7	8	9	10
2. Get ready for each contraction.	1	2	3	4	5	6	7	8	9	10
3. Use breathing during labor contractions.	1	2	3	4	5	6	7	8	9	10
4. Keep myself in control.	1	2	3	4	5	6	7	8	9	10
5. Think about relaxing.	1	2	3	4	5	6	7	8	9	10
6. Concentrate on an object in the room to distract myself.	1	2	3	4	5	6	7	8	9	10
7. Keep myself calm.	1	2	3	4	5	6	7	8	9	10
8. Concentrate on thinking about the baby.	1	2	3	4	5	6	7	8	9	10
9. Stay on top of each contraction.	1	2	3	4	5	6	7	8	9	10
10. Think positively.	1	2	3	4	5	6	7	8	9	10
11. Not think about the pain.	1	2	3	4	5	6	7	8	9	10
12. Tell myself that I can do it.	1	2	3	4	5	6	7	8	9	10
13. Think about others in my family.	1	2	3	4	5	6	7	8	9	10
14. Concentrate on getting through one contraction at a time.	1	2	3	4	5	6	7	8	9	10
15. Listen to encouragement from the person helping me.	1	2	3	4	5	6	7	8	9	10

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

	Not at all sure									Completely sure
16. Relax my body.	1	2	3	4	5	6	7	8	9	10
17. Get ready for each contraction.	1	2	3	4	5	6	7	8	9	10
18. Use breathing during labor contractions.	1	2	3	4	5	6	7	8	9	10
19. Keep myself in control.	1	2	3	4	5	6	7	8	9	10
20. Think about relaxing.	1	2	3	4	5	6	7	8	9	10
21. Concentrate on an object in the room to distract myself.	1	2	3	4	5	6	7	8	9	10
22. Keep myself calm.	1	2	3	4	5	6	7	8	9	10
23. Concentrate on thinking about the baby.	1	2	3	4	5	6	7	8	9	10
24. Stay on top of each contraction.	1	2	3	4	5	6	7	8	9	10
25. Think positively.	1	2	3	4	5	6	7	8	9	10
26. Not think about the pain.	1	2	3	4	5	6	7	8	9	10
27. Tell myself that I can do it.	1	2	3	4	5	6	7	8	9	10
28. Think about others in my family.	1	2	3	4	5	6	7	8	9	10
29. Concentrate on getting through one contraction at a time.	1	2	3	4	5	6	7	8	9	10
30. Listen to encouragement from the person helping me.	1	2	3	4	5	6	7	8	9	10

Thank you. Please return the questionnaires in the attached Stamped Addressed Envelope.

Appendix 5 Postnatal questionnaire

For the last phase of the BALL Trial, please complete this short questionnaire. It should take approximately 10 minutes of your time. Your answers and information will not be traced to you and your participation in the BALL trial will remain confidential, so please be as frank as possible.

Q.1. I agree to provide information for this postnatal questionnaire for the BALL trial.

I agree

Q.2. What is your Participant Information Number (PIN)? (This should already be filled in below.)

Q.3.**User name (hidden)**

Q.4. Was this your first ever labour?

Yes → Routed to Q.7.

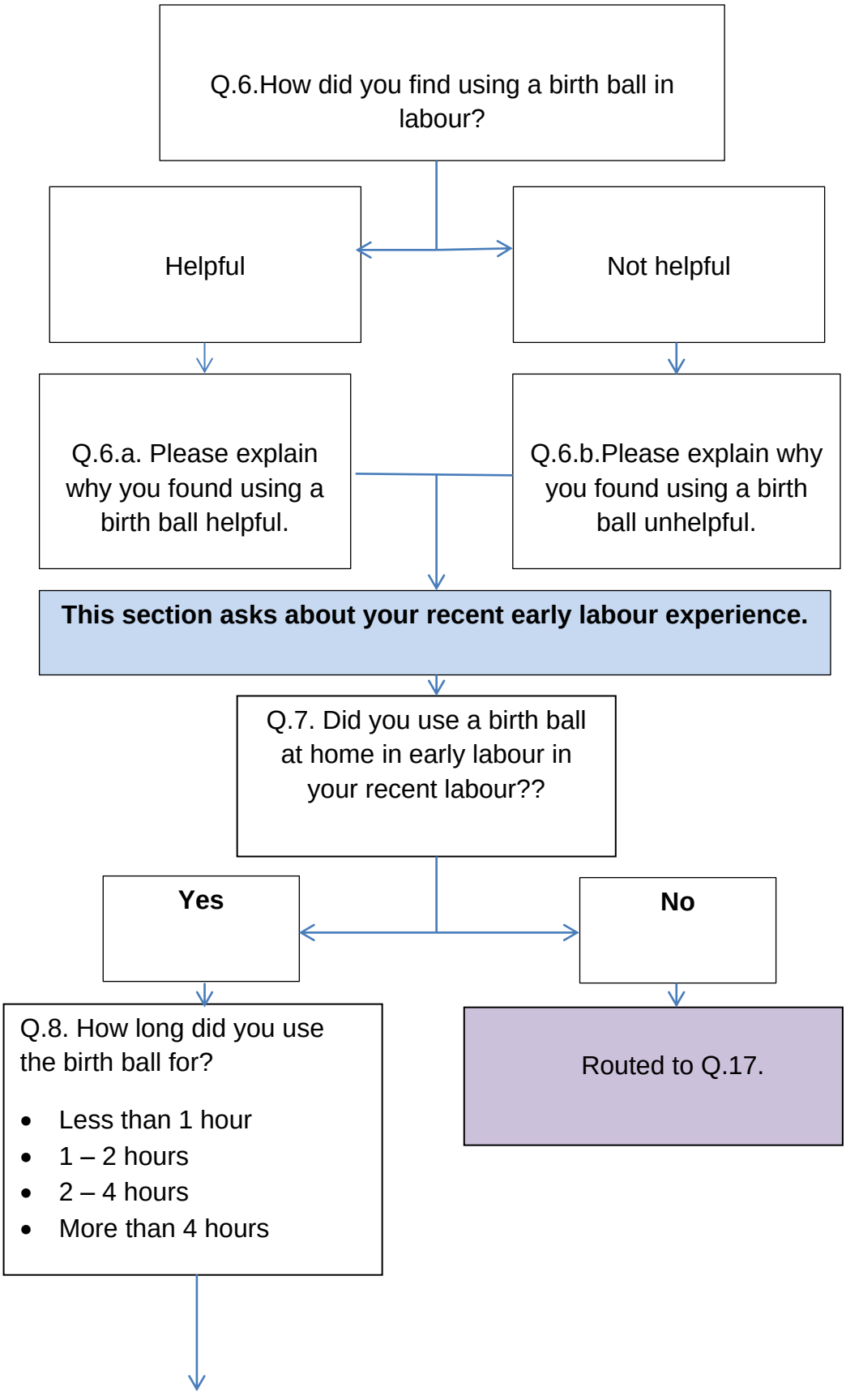
No

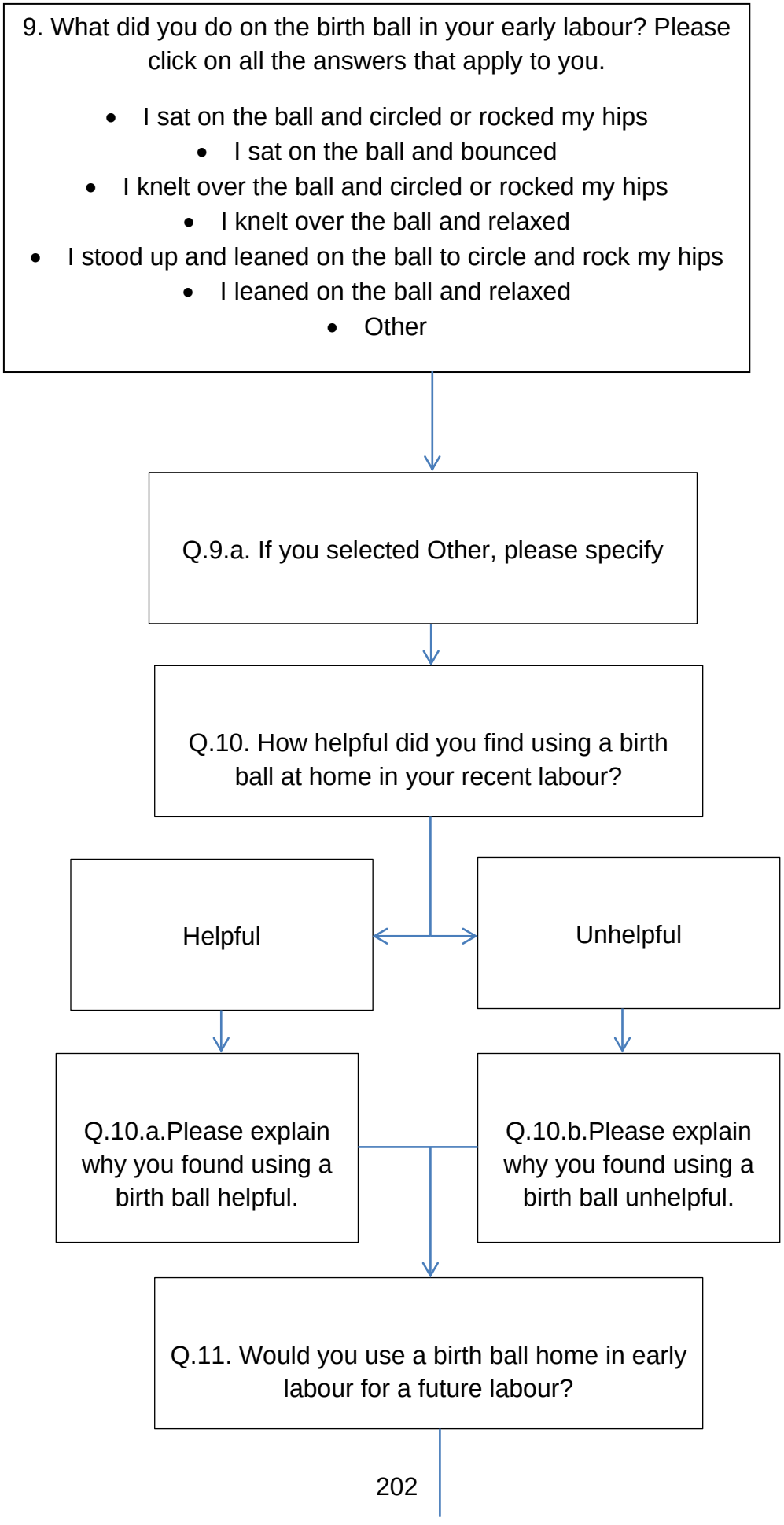
This section asks about your previous experience.

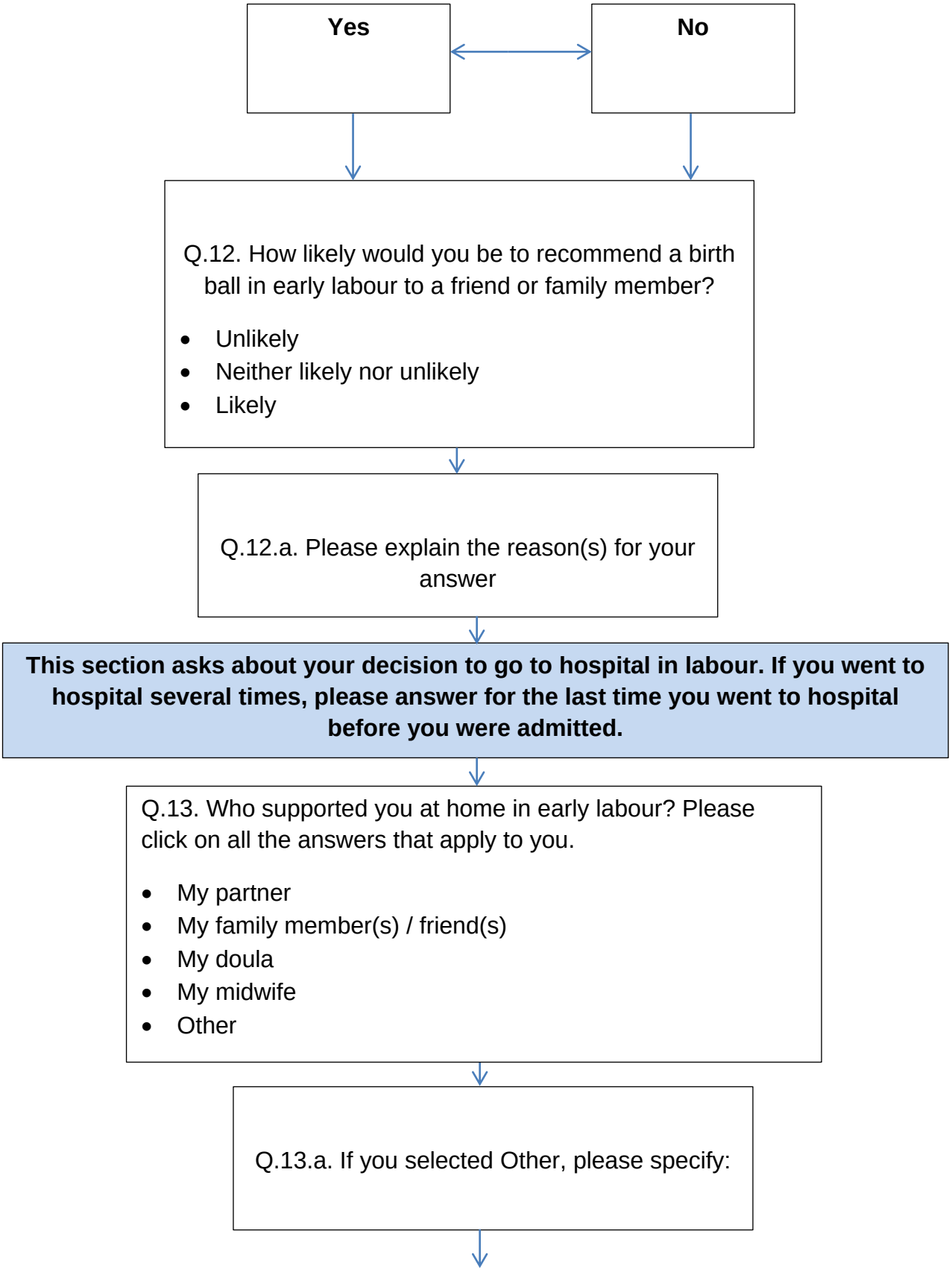
Q.5. Had you used a ball in a previous labour?

200

No → Routed to Q7.


Q.6.How did you find using a birth ball in labour?
Helpful
Not helpful
Q.6.a. Please explain why you found using a birth ball helpful.
Q.6.b.Please explain why you found using a birth ball unhelpful.
This section asks about your recent early labour experience.
Q.7. Did you use a birth ball at home in early labour in your recent labour??
Yes
No
Q.8. How long did you use the birth ball for?
Less than 1 hour
1 – 2 hours
2 – 4 hours
More than 4 hours
Routed to Q.17.


9. What did you do on the birth ball in your early labour? Please click on all the answers that apply to you.
I sat on the ball and circled or rocked my hips
I sat on the ball and bounced
I knelt over the ball and circled or rocked my hips
I knelt over the ball and relaxed
I stood up and leaned on the ball to circle and rock my hips
I leaned on the ball and relaxed
Other
Q.9.a. If you selected Other, please specify
Q.10. How helpful did you find using a birth ball at home in your recent labour?
Helpful
Unhelpful
Q.10.a.Please explain why you found using a birth ball helpful.
Q.10.b.Please explain why you found using a birth ball unhelpful.
Q.11. Would you use a birth ball home in early labour for a future labour?


Yes
No
Q.12. How likely would you be to recommend a birth ball in early labour to a friend or family member?
Unlikely
Neither likely nor unlikely
Likely
Q.12.a. Please explain the reason(s) for your answer
This section asks about your decision to go to hospital in labour. If you went to hospital several times, please answer for the last time you went to hospital before you were admitted.
Q.13. Who supported you at home in early labour? Please click on all the answers that apply to you.
My partner
My family member(s) / friend(s)
My doula
My midwife
Other
Q.13.a. If you selected Other, please specify:

Q.14. When did you go to hospital?

- Less than 4 hours after contractions AND / OR waters breaking
- 4 – 8 hours after contractions AND / OR waters breaking
- 8 – 12 hours after contractions AND / OR waters breaking
- More than 12 hours after contractions AND / OR waters breaking
- Other

Q.14.a. If you selected Other, please specify:

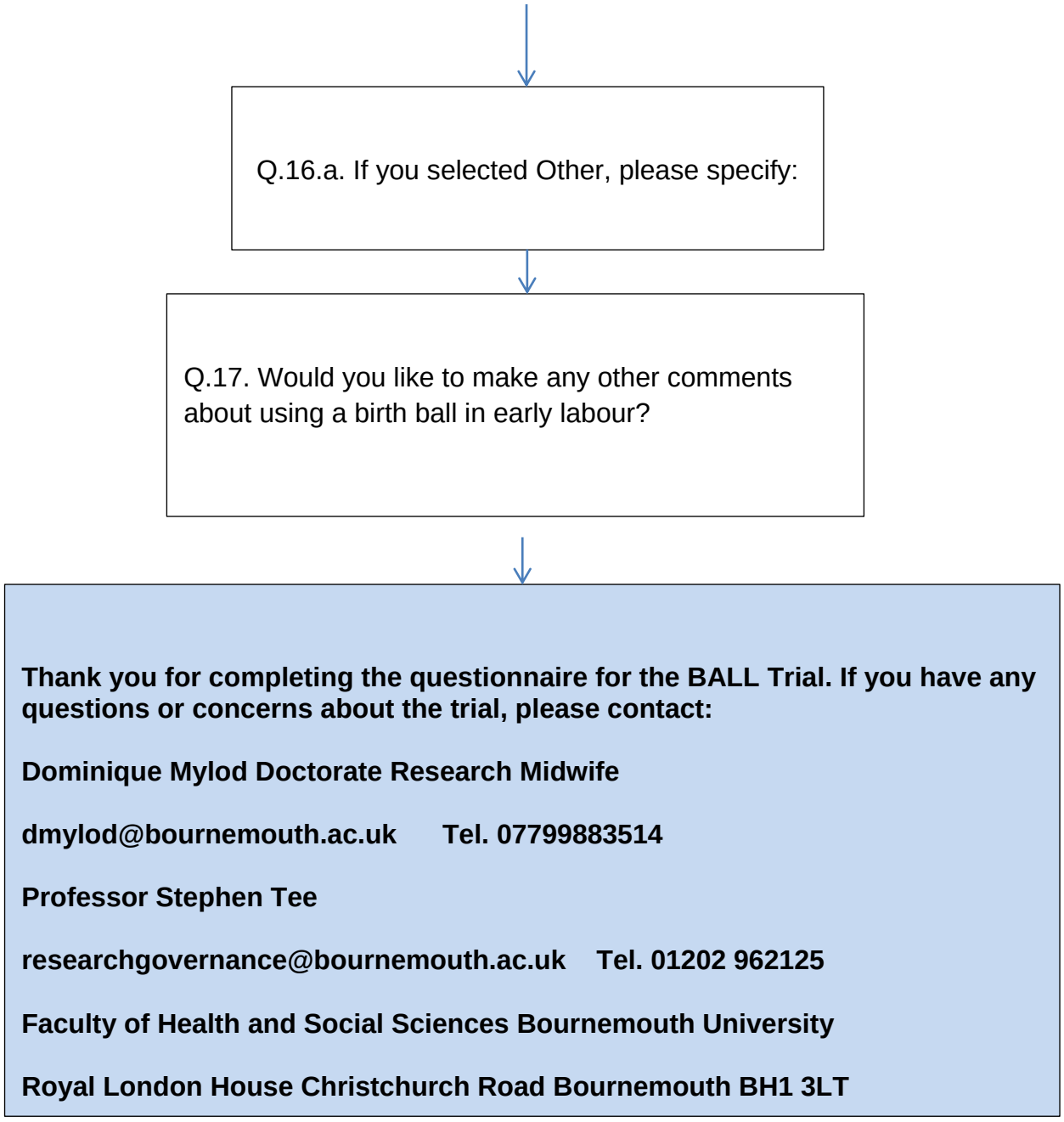
Q.15. Who made the decision to go to hospital?

- I did
- My partner did
- My family member(s) friend(s) did
- My doula did
- My midwife or the hospital midwives advised us to go in
- Other

Q.15.a. If you selected Other, please specify:

Q.16. Why did you go to hospital? Please click on all the answers that apply to you.

- My contractions were more frequent
- My waters broke
- I did not feel well
- I was anxious
- My birth partner(s) was / were anxious
- I wanted pain relief
- Other


Q.16.a. If you selected Other, please specify:
Q.17. Would you like to make any other comments about using a birth ball in early labour?
Thank you for completing the questionnaire for the BALL Trial. If you have any questions or concerns about the trial, please contact:
Dominique Mylod Doctorate Research Midwife
dmylod@bournemouth.ac.uk Tel. 07799883514
Professor Stephen Tee
researchgovernance@bournemouth.ac.uk Tel. 01202 962125
Faculty of Health and Social Sciences Bournemouth University
Royal London House Christchurch Road Bournemouth BH1 3LT

Appendix 6 Midwives' pathway

Approach eligible woman at 28 / 40 AN check

If interested, provide Participant Information Sheet.

Complete Participant Demographic Sheet

Place Participant Information Sheet in box in Community Midwives' Office

↓

Participant admitted in labour

Ask woman to complete Visual Analogue Scale Proforma

Place box in Maternity Ward office

↓

Got a problem or a question?

Dominique Mylod

Tel. 07799883514 (24/7)

dmylod@bournemouth.ac.uk

Appendix 7 Demographic Details Form

Version 2.0 01/12/2017 IRAS ID 194437

The Ball Assisted Latent Labour (BALL) trial

Thank you for your interest in the BALL trial. Please provide the following details. Your information will remain confidential.

1. Contact details

Your first name	
Your surname	
Your year of birth	
Your address	
Your postcode	
Your phone number	
Your mobile phone number	
Your e-mail address	

2. Are you:

A. single and unsupported by a partner

B. single and supported by a partner

C. married

D. living with a partner

E. other …… (please state)

3. What is your highest level of education?

A. secondary education

B. college

C. undergraduate

D. postgraduate

5. How many children do you have (not counting this pregnancy)?

4. What date is your baby due?

Appendix 8 Participant Information Sheet

Version 2.0 01/12/2017 IRAS ID 194437

The BALL Trial Participant Information Sheet

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

The Ball Assisted Latent Labour (BALL) trial

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 carried out 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.

What is the purpose of the project?

Women who are admitted to hospital in the latent phase of labour ('early labour') are more likely to have complicated labours and interventions such as having their waters broken, a hormone drip to speed up contractions, epidural anaesthesia and caesarean sections. There is some evidence to suggest that women who use a birth ball in early labour find labour less painful and are more likely to have a normal birth.

The research team behind the trial has developed a short animated film as an 'infomercial' to explain the possible benefits of using a birth ball in early labour. The trial will also lend birth balls to participants.

Why have I been chosen?

You have been chosen because you are pregnant and you plan to labour and give birth in hospital. You also have on-line access. 332 women will be included in this part of the research.

Do I have to take part?

It is up to you whether or not to take part. If you decide to take part, you will be asked to read and sign a Consent Form Version 2.0 01/12/17. You can withdraw at any time and you do not have to give a reason. Your future care / treatment will not be affected in any way; your GP and Community Midwife will be informed that you are taking part in the study.

What will happen to me if I take part?

The best way to understand if women find that the birth ball makes their early labour less painful or not is to ask randomise pregnant women into two groups. The randomisation process will ensure that there is an equal balance of first time mothers and women who have given birth before in each group. During statistical analysis, the information you provide about your age, marital status and educational level will also be used to compare the two groups. However, you cannot 'choose' which group you are assigned to. You will then be sent an Instructions Pack by post.

The control group will carry on as normal.

The intervention arm will be sent a link to the online infomercial in your Instruction Pack. The infomercial is under restricted access online, so you can watch the infomercial as many times as you wish, but are asked not to show other people apart from yourself and your birth supporters. You will be asked to fill out a short questionnaire before and after looking at the infomercial. The questionnaire assesses your feelings of confidence or 'self-efficacy' about your future labour.

Women in the intervention group will also be offered a birth ball to use at home in early labour. If you decide to borrow a ball, you can either collect the ball yourself from the maternity unit or at your next antenatal appointment. Alternatively it can be delivered to your home. The balls are 65cm diameter. However, if you are 5 foot 8 inches or taller, there are 75cm balls. Each ball comes 'flat packed', with its own hand pump. The ball takes about 5 minutes to inflate and can be deflated again.

All participants will be asked to mark their pain level on a simple pain scale when they decide to go to hospital in labour. If you go into hospital several times in early

labour, you will be asked to complete the pain scale when you and your midwife decide that you should remain in hospital.

When your baby is six weeks old, you will be e-mailed a short questionnaire to complete. The questions will ask you about your early labour and whether you used a birth ball.

The researcher will also ask for permission to look at your maternity notes to record the following anonymous data:

- the length of your pregnancy when you gave birth
- whether your labour was spontaneous or induced
- whether your baby's heart beat was checked with a Sonicaid (intermittently) or by a cardiotocographic machine (continuously)
- whether you had an epidural
- whether your waters were broken (Artificial Rupture of Membranes)
- whether you had a hormone (syntocinon) drip to speed up your labour
- whether your baby was born vaginally, with forceps or Ventouse or caesarean section

What are the possible disadvantages and risks of taking part?

There are no risks to the health of you or your baby. For example, if your birth plan changes and you agree with the maternity team that your labour should be induced or that your baby should be born by caesarean section, then you are free to follow advice. You are not required to use the birth ball if you do not wish to do so, or stay on it for a fixed length of time. If there are problems or concerns in your early labour, you should phone the Maternity Ward and follow their advice.

What are the possible benefits of taking part?

There are no immediate benefits for people taking part in this part of the project. It is hoped that the information from this project will show whether the infomercial is acceptable to families and whether using the birth ball in early labour helps women to have more normal births.

Will my taking part in this project be kept confidential?

All the information that you give will be kept strictly confidential under the General Data Protection Regulations. You will not be identified in any reports or publications.

Bournemouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your maternity records in order to undertake this 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. Bournemouth University will keep identifiable information about you for 5 years after the study has finished.

The researcher at the Isle of Wight NHS Trust will collect information from you and your maternity records for this research study in accordance with our instructions. The Trust will keep your name, NHS number, hospital number, date of birth, and contact details confidential and will not pass this information to Bournemouth University. The Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Bournemouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Bournemouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, hospital number, date of birth or contact details. The Trust will keep identifiable information about you from this study for 25 years after the study has finished. The BALL Trial Participant Information Sheet Version 2.0 01/12/17 IRAS ID194437

Our rights to access, change or move your information are limited, as we 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.

The researcher is also a midwife. If there are safeguarding concerns for you or your baby, the researcher will discuss this with you and share the details with your midwife.

You can find out more about how we use your information by contacting:

James Stevens, Chief Data Officer on researchgovernance@bournemouth.ac.uk or for more general enquiries: DPO@bournemouth.ac.uk

Who is organising and funding this research?

This research is study project in fulfilment of a clinical midwifery doctorate (PhD) programme. It is funded by the Wessex Integrated Clinical Academic Training Programme through Bournemouth University and the Isle of Wight NHS Trust.

Contact for further information

Dominique Mylod Doctorate Midwife Researcher

Maternity Department St. Mary's Hospital

Parkhurst Road

Newport PO30 5TG

Tel. 07799883514 e-mail: dmylod@bournemouth.ac.uk

If you have a concern or a complaint

Professor Stephen Tee

Executive Dean of the Faculty of Health and Social Sciences

R714 Royal London House

Christchurch Road

Bournemouth BH1 3LT

Tel. 01202 962125 e-mail: researchgovernance@bournemouth.ac.uk

Professor Vanora Hundley

Deputy Dean Research and Professional Practice

R703 Royal London House

Christchurch Road

Bournemouth BH1 3LT

Tel. 01202 965206 e-mail: researchgovernance@bournemouth.ac.uk

You will be given a copy of this Participant Information Sheet. If you decide to participate, you will be asked to sign a Consent Form and given a copy.

Thank you for taking the time to read this information.

Appendix 9 Consent Form

Bournemouth University

Version 2.0 01/12/2017 IRAS ID 194437

Participant Identification Number:

CONSENT FORM

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

The Ball Assisted Latent Labour (BALL) Trial

Chief Investigator: Dominique Mylod

Please initial all boxes

Part 1 Main Study

1. I confirm that I have read and understand the information sheet dated **[01/12/17]** (version **2.0**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

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

4. I agree to my Community Midwife and GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When completed:

1 copy for participant

1 copy for Site File

Original to be kept in Maternity Records

Appendix 10 Participant Instructions

Bournemouth University

The Ball Assisted Latent Labour (BALL) Trial

Participant Instructions

Participant Identification Number ……..

Please find enclosed the following:

- **This Participant Instruction Sheet**
- **A Visual Analogue Score (VAS) Pro-forma to put in your hand-held antenatal notes**

1. When you are admitted to hospital in labour, the midwife will ask you to complete the VAS Proforma and collect it.

2. 6 weeks after your baby is born, you will be e-mailed the link to a short on-line questionnaire to complete.

If you have any concerns during your pregnancy, labour or after your baby is born, please call the Maternity Ward on Tel. *******

Contact for further information

Dominique Mylod Doctorate Midwife Researcher

Tel. 07799883514 e-mail: dmylod@bournemouth.ac.uk

Thank you for your participation in the BALL trial.

Bournemouth University

Version 1.0 01/12/2017 IRAS ID 194437

The Ball Assisted Latent Labour (BALL) Trial

Participant Instructions

Participant Identification Number ……..

Please find enclosed the following:

- **These Participant Instructions**
- **A BEFORE Questionnaire**
- **An AFTER Questionnaire**
- **A Stamped Addressed Envelope**
- **A link to an on-line infomercial**
- **A Visual Analogue Scale (VAS) Pro-forma to put in your hand-held antenatal notes**

1. Complete the BEFORE questionnaire when you are 36 weeks pregnant.

2. Access the on-line infomercial at: …….

The password is ……..

You may watch the infomercial as many times as you wish. Your birth partner(s) may watch it too. Please do not share the access code or the infomercial with anyone else.

3. Please complete the AFTER questionnaire **72 hours (3 days)** after watching the infomercial. Do not look at your BEFORE questionnaire while you do this.

4. Post the BEFORE and AFTER questionnaires in the Stamped Addressed Envelope.

5. You may use a birth ball during your early labour at home if you wish. If you would like to borrow a birth ball, please contact the Researcher by text, phone or e-mail (details below). An inflatable birth ball and pump in a box will be made available to you and collected after your baby is born.

6. When you are admitted to hospital in labour, the midwife will ask you to complete the VAS Proforma in your notes and collect it.

7. 6 weeks after your baby is born, you will be e-mailed the link to a short on-line questionnaire to complete.

If you have any concerns during your pregnancy, labour or after your baby is born, please call the Maternity Ward on Tel. (01983) 534392.

Contact for further information

Dominique Mylod Doctorate Midwife Researcher

Tel. 07799883514 e-mail: dmylod@bournemouth.ac.uk

Thank you for your participation in the BALL trial.

Appendix 11 GP / CMW Letter

Bournemouth University

Version 1.0 03/03/2017 IRAS ID 194437

To:

Dominique Mylod Clinical Academic Doctorate Midwife

Faculty of Health and Social Sciences Bournemouth University

Royal London House Christchurch Road Bournemouth BH1 3LT

Tel. 07799883514 e-mail: dmylod@bournemouth.ac.uk

Dear …….

Your patient ……., has consented as a participant in the Ball Assisted Latent Labour (BALL) Trial. Information about the BALL Trial is provided overleaf. You will be informed of any clinically relevant outcomes. Please do not hesitate to contact me should you have any questions or require further information.

Yours sincerely

Dominique Mylod

Clinical Academic Doctorate Midwife

Chief Investigator for the BALL Trial

Can using a birth ball in the latent phase of labour reduce pain perception? The Ball Assisted Latent Labour Trial.

Background

Most births in high-income countries occur in hospital. However, hospital admission in the latent phase of labour is associated with higher rates of obstetric intervention, with the potential for increased maternal and fetal morbidity. Women sent home from hospital in the latent phase to 'await events', frequently feel anxious and unsupported. They also cite pain as their main drive to seeking hospital admission in the latent phase. Confidence in labour is associated with less anxiety, pain perception and obstetric intervention. Using a birth ball to assume upright positions and remain mobile in the latent phase of labour is associated with less pain and anxiety. However, no research has examined the effect of using birth balls at home in the latent phase on pain perception, latent phase hospital admission or obstetric intervention. An antenatal evidence-based intervention to promote birth ball use at home in the latent phase of labour may prove effective in enhancing women's self-efficacy and reducing their anxiety, thereby reducing their pain perception and delaying hospital admission until active labour is established.

Methods / design

A randomised, controlled, single centre trial with two parallel groups. Following recruitment and consent at 28 weeks' gestation 332 women will be randomly allocated to two groups. The Intervention Arm will access an on-line animated 90 second infomercial promoting using a birth ball in the latent phase of labour. They will be asked to complete the Childbirth Self-Efficacy Inventory Part I before and after viewing. They will also be offered the loan of a birth ball to use in the latent phase at home. Control Arm participants will receive standard care. Both groups will assess their pain level on admission to hospital in labour on a Visual Analogue Scale. Both groups will be followed up six weeks' postpartum with an online questionnaire to evaluate birth ball usage and maternal satisfaction.

Discussion

The BALL Trial offers an innovative, evidence-based intervention package to address a key challenge in contemporary maternity care, for both families and maternity services.

Appendix 12 Participant Sticker

Participant

Please complete VAS when admitted in labour

Version 1.0 19/04/17 **IRAS No. 194437**

Bournemouth University

Version 1.0 19/04/2017 IRAS ID 194437

The Ball Assisted Latent Labour (BALL) Trial

Safety Advice

- **Your birth ball can support up to 300kg (47 stone). It is anti-burst, so it cannot burst suddenly.**
- **It has an anti-slip finish.**

✗ **Do NOT puncture it with sharp objects.**

✗ **Do NOT leave it near heat sources.**

✗ **Do NOT let children play with it unsupervised.**

✗ **Do NOT sit or kneel on the birth ball on raised surfaces.**

- **Use the pump provided to inflate the ball.**

✗ **Do NOT over-inflate the ball.**

- **To clean the ball, use hot water and a simple detergent.**

- **If your early labour shows any of the following:**
- Contractions or your waters breaking before 37 weeks
- Your waters broke more than 24 hours ago
- Meconium in your waters (they look brown or dark green)
- Vaginal bleeding (not a 'show')

- Your baby is not in a ‘head down’ position
- Scans have shown that yc

- Your baby has not been moving as much as usual
- Contractions when you have agreed with an obstetrician that your baby should be born by caesarean section
- You do not feel well or are concerned

You should call the Maternity Ward at ********** on:

Tel. ***** or *******

Appendix 14 VAS proforma

Bournemouth University

The Ball Assisted Latent Labour (BALL) Trial

Participant Identification Number …….

Please mark your pain level on this scale when you arrive at the hospital in labour.

---

no pain **worst pain imaginable**

Thank you.

To the admitting midwife: please place the completed pro-forma in the Collection Box in the office.

Appendix 15 The BALL Trial Management Committee Report

Bournemouth University

The BALL Trial Management Committee Report

Wednesday 13th June 2018 11:00 – 11:30 Maternity Unit **** Hospital**

Attended by: Professor Vanora Hundley Dr. Sue Way

Jo Pennell ********** NHS Trust Midwifery Risk Manager

Dominique Mylod Doctorate Midwife Chief Investigator

1. Recruitment

At the time of the meeting **97 participants** had been consented. Representing **29%** of the **332** recruitment required at a stage where **45%** recruitment had been projected. This has been addressed elsewhere and the recruitment has started to improve. An IRAS Amendment has been submitted to introduce an incentive scheme for recruiting midwives.

2. Adverse incidents, near misses and complaints

There have been no adverse events, near misses or complaints arising from the BALL Trial to date.

At the time of the meeting, **58** participants had given birth.

- 79% participants had a normal vaginal birth
- 17% participants had an Induction of Labour
- 12% of participants underwent CS in spontaneous labour; 40% of participants underwent CS following IOL
- 3 babies were admitted to NICU; 2 of these babies were pre-term
- 0 unplanned births occurred outside of the maternity unit
- 0 babies were stillborn or died after birth
- 7 participants were withdrawn from the study – 4 for diagnoses that were either not shared or diagnosed at consent. 1 parous participant accepted an elective CS for an allegedly macrosomic baby, who was born below the 95th centile

Table 1 BALL Trial Participants Birth Modes

Birth Mode	Spontaneous	IOL
Normal birth	40	6
Assisted birth	3	0
CS1	1	0
CS2	4	3
CS3	0	1

Table 2 BALL Trial Participants IOL

IOL	Total
Maternal condition	2
Post-term	1
Reduced fetal growth velocity	2
Reduced fetal movements	5

Table 3 BALL Trial Adverse Events

Adverse Event		
Stillbirths or neonatal deaths	0	
Preterm births < 37 weeks	2	
NICU admission	3	Pre-term birth (2) Tachypnoea (1)
Unplanned birth outside maternity unit	0	

Table 4 Withdrawals from the BALL Trial

Withdrawn	Total
Gave birth before randomisation	1
Elective CS	1
Maternal request	1
GDM diagnosis	1
Opiate analgesia in pregnancy	1
Unknown cardiac condition	1
Unknown thyroid condition	1

3. Conclusions

No adverse events can be directly attributed to the BALL Trial at this stage. There have been no complaints from participants or other stakeholders in the study. Although numbers are small, outcomes for mothers and babies are well within background rates for the host Trust and may even be better, although this must await final analysis.

The decision was made to continue the trial.

Appendix 16 Data Management Plan (Digital Curation Centre 2019)

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

Data Collection

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

Control Arm

1. Demographic details; name; date of birth; address; phone contacts; email address; civil status; educational status; Estimated Date of Delivery (EDD); Trust identifying number; NHS number; GP name and address; Community Midwife

2. Visual Analogue Scale (VAS) pain scores from the woman's perception on admission to the maternity unit either in latent phase or active labour

3. Labour and birth outcomes: amniotomy, Continuous Electronic Fetal Monitoring (CEFM); syntocinon augmentation; epidural anaesthesia; birth mode; gestation; birthweight; sex; Apgars @ 1 & 5 minutes of age; maternal age when gives birth; cervical dilatation on admission; parity

4. Postnatal questionnaire: latent phase activities; satisfaction; acceptability

Intervention Arm

1. Demographic details; name; date of birth; address; phone contacts; email address; ethnic background; marital status; educational status; Estimated Date of Delivery (EDD); Trust identifying number; NHS number; height; GP name and address; Community Midwife

2. Visual Analogue Scale (VAS) pain scores from the woman's perception on admission to the maternity unit either in the latent phase or active labour

3. Labour and birth outcomes: amniotomy; Continuous Electronic Fetal Monitoring (CEFM); syntocinon augmentation; epidural anaesthesia; birth mode; gestation; birthweight; sex; Apgars @ 1 & 5 minutes of age; maternal age when gives birth; cervical dilatation on admission; parity

4. Postnatal questionnaire: latent phase activities; satisfaction; acceptability

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?

1. Quantitative Data

.xlxs on a Case Sheet to collate numerical data

2. Qualitative Data (Postnatal Questionnaire)

Tabulated on .pdf

3. On SPSS

Tabulated on .sav and .spv

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

The University laptop is password protected.

Data will not be stored or transferred onto host Trust systems.

Data will also be stored on EDGE, but is strongly protected.

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.

8 megabytes

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

Not applicable

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

A numerical system for version control with the date. e.g. Current submissions for Ethics are 1.0. Following amendment, they will become 1.1. If they are redrafted, they will become 2.0.

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.

1. Anonymised participant demographic profiles; tabular headings

2. Tabulated data and SPSS calculations of before / after CBSEI scores; tabular headings. Participants Information Numbers (PIN) will not be used as they may identify Intervention Arm participants. Sequential numbering only.

3. Tabulated data and SPSS calculations of VAS scores using PINs

4. Tabulated data of labour and birth outcomes using PINs

5. Tabulated data and metadata from postnatal questionnaire; no PINs needed.

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

Dublin Core.

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

Pre-formulated Casesheet to populate CBSEI / VAS / Intervention outcomes.

Intervention outcomes captured as Yes / No

Application of standardised rounding to numerical data (especially VAS - to one decimal point)

Postnatal questionnaire has been pre-trialled to eliminate ambiguities in responses. Free text responses will be recorded verbatim.

Ethics & Legal Compliance

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

Yes. Consent Form makes this explicit. Participation Information Sheet was modified as per HRA guidance when EU General Data Protection Regulations were enforced on 25 May 2018.

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

Bournemouth University has copyright, intellectual / property rights over the output of this research. An IP statement approved by the Legal Team states this overtly in the concluding frames of the infomercial intervention.

For publication submissions, conformity with the accepting journal's copyright policies will be followed.

Storage & Backup

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

Only the Chief Investigator has access to the Case Sheet, which remains within the University IT system on the Chief Investigator files. On conclusion of the trial, the data will be stored in the University for 5 years and then destroyed.

Participants' details are uploaded onto EDGE NHS, as per R&D requirement.

Following contact, for any participants who decline to participate, their hard copy contact will be shredded promptly. On conclusion of the trial, with all participants' details on EDGE, contact details will shredded and disposed of as Confidential Waste. During the trial, the Site File will be stored in a locked filing cabinet in a locked office in the maternity unit. The University laptop will not be stored in the office.

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

As above.

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.

This will be a straightforward procedure for the Case File as participant identity will be secured on EDGE NHS. The data will be de-identified by leaving the PIN

initially. Data cleaning and normalisation (as per Excel) will then be undertaken. The resulting data base will then be stored.

For the postnatal questionnaire, respondent order will not be in sequential PIN order and the Online Surveys software will collate responses as a data set.

How long do you need to store your data?

5 years (as per University guidelines).

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

Final, cleaned and anonymised.

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. I will require all the resources cited above.

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.

N/A

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

Cleaned, anonymised data will be available from the end of 2019 as soon as the trial is closed.

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https://creativecommons.org/licenses/by-nd/4.0/legalcode

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.

Dominique Mylod Chief Investigator GCP completed

Dr. Eleanor Jenkins Research Midwife GCP completed

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

The trial is restricted to the CI. The data will be retained for 5 years, as per University policy.

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.

Jose Lopez Blanco, HSS Faulty Librarian, Bournemouth University

Suzy Wignall, Clinical Governance Advisor, 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)?

Extra costs not incurred.

Appendix 17 Thematic analysis of questionnaire free test responses

Q6a. [If you used a birth ball in a previous labour] Please explain why you found using a birth ball helpful. (27 responses)

	Initial codes
1. The soft, rhythmic bouncing up and down and side to side movements helped with lower back pain relief as labour progressed. I recall I rotated as well. It was my first labour and I had to be induced so I was just going through the motions and listening to the midwife (P1; Control Arm; used ball in trial). 2. I found it relaxing to bend over it in the early stages of contractions. My babies were quite big and bending over it seemed to relieve some pressure (P1; Intervention Arm; used ball in trial).	Movements; bouncing, movements, rotated, Rhythm; rhythmic Release, soft, helped, relief Movements / position; bend over Release; release from pressure
3. Definitely helped managing my contractions (P1; Control Arm; used ball in trial).	Dealing; managing
4. Helpful during the very 1st stage of labour. When I wasn't sure if I was having contractions or hicks. Bouncing on it gave me something to focus on! And was comfortable on my hips (P2; Intervention Arm; used ball in trial).	Movements; bouncing Cognitive; focus on Easing; comfortable
5. I found it helpful being sat upright and found that the slight bouncing motion aided in my early contractions. I felt that I either wanted to be walking or bouncing and not sitting on something solid helped (P1; Intervention Arm; used ball in trial).	Position; sat upright Movements; bouncing; motion, walking Ease; not something solid
6. It was more comfortable that sitting on a bed or standing (P1; Control Arm; did not use ball in trial).	Easing; comfortable
7. Good for bouncing on at home (P1; Intervention Arm; used ball in trial).	Movements; bouncing
8. Keeping active and moving (bouncing) through contractions. Preparing for the next one (P2; Control Arm; used ball in trial).	Movements; moving, bouncing, Dealing; preparing for the next one
9. It took the edge off the pain slightly, eased pain to hips (P1; Control Arm; used ball in trial).	Easing; took the edge of the pain slightly, eased pain to hips
10. Kept me moving and eased the pain when I was too tired to stand (P1; Control Arm; used ball in	Movements; moving

trial).	Easing; eased the pain
11. Being able to move freely without having to stand up (P2; Control Arm; did not use ball in trial).	Movements; to move Easing; freely
12. Helped ease the pain in early labour and to help baby down (P1; Intervention Arm; did not use ball in trial).	Easing; ease the pain Dealing; to help the pain
13. It helped ease the pain (P1; Intervention Arm; used ball in trial).	Easing; ease the pain
14. Moving on the ball helped to give me a focus away from the pain and concentrate on breaths as I moved. I think may have helped my baby into position too (P1; Control Arm; did not use ball in trial).	Movements; moving on Cognitive; focus away, concentrate on,
15. I was able to sit on the birth ball and help ease the pressure I was feeling in my lower stomach. Being able to roll the ball around in a circle helped ease my back pain and my hips between contractions (P2; Control Arm; did not use ball in trial).	Position; to sit Easing; ease the pressure, helped ease my back pain Movements; roll the ball around in a circle
16. Helped to make pain more manageable (P1; Intervention Arm; used ball in trial)	Easing; make the pain more manageable Dealing; manageable
17. Gave a more comfortable seat (P1; Intervention Arm; did not use ball in trial).	Easing; comfortable Release comfortable
18. Using the birthing ball helped me keep moving, bouncing on the ball gave me something to concentrate on whilst having contractions. I also used it to sit on as it was more comfortable (P1; Intervention Arm; used ball in trial).	Movement: moving, bouncing, Cognitive; concentrate on Upright; sit on Easing; comfortable
19. In my recent labour I found the ball very useful in early labour. It eased pain and made me comfortable (P1; Intervention Arm; used ball in trial).	Dealing; useful Easing; eased pain, comfortable
20. It helped in early labour whilst at home (P1; Intervention Arm; used ball in trial).	Dealing; helpful
21. Because it helped keep me moving (P1; Control Arm; used ball in trial).	Movement; moving
22. Helps to have something to do, to distract from pain, and I found moving helped with pain (P1; Control Arm; did not use ball in trial).	Dealing; helps to have something to do Cognitive helps to have something to do; to distract, Movements, moving

23. During my first pregnancy as I did a pregnancy yoga course which involved a lot of ball use. During my first labour I bounced and rocked on a ball at home and in hospital. It helped having something to focus on and it felt good to knowing that it would help progress labour. In my first and second labours I used my ball to lean on to rest on and to encourage my back-to-back baby to turn the right way (P2; Control Arm; did not use ball in trial).	Easing; helped with pain Movement; bounced, rocked Rhythm, rocked Cognitive; focus on Dealing; knowing that it would help progress labour – self-efficacy?, to encourage
24. I found it helped me cope with the contractions better. Everytime i felt one coming i sat on the ball and rocked backwards and forwards (P1; Intervention Arm; used ball in trial).	Rhythm, rocked
25. The bouncing gave me something to do and took the strain off my back and hips in the fist [sic] hours, as labour progressed the rhythm really helped (P2; Control Arm; used ball in trial).	Movement; bouncing Cognitive; gave me something to do Easing; took the strain off Rhythm; rhythm Dealing; as labour progressed
26. Helped when in pain (P2; Intervention Arm; did not use ball in trial).	Cognitive; helped Easing; helped when in pain
27. It's more comfortable than a bed when you are in labour, it helps things move along quicker and bouncing on it gives you something to focus on (P4; Intervention Arm; used ball in trial).	Easing; comfortable Progress/ ; helps things move along Movement; bouncing Cognitive; helps move things along (self-efficacy), focus on

Note: parity (P) is stated as antenatally

Box 17.1 Themes identified in responses to Q.6.a.

Bouncing, rocking and rhythm

Movement, and bending

Focus away from the pain and onto the strategies

Comfort and easing the pain

Cognitive empowerment and useful to help progress

Upright

Q.6.b. [If you used a ball in a previous labour] Please explain why you found the birth ball unhelpful. (14 responses)

1. Contractions were felt in my hips and legs, the ball made the pain worse (P1; Control Arm; used ball in trial).	Intensified; made the pain worse ,
2. I could only get comfortable sitting on it. I felt very uncomfortable leaning on it ect [sic] (P1; Intervention Arm; used ball in trial).	Uncomfortable; very uncomfortable
3. As my labour progressed I found sitting really uncomfortable as baby's head lowered (P1; Intervention Arm; used ball in trial).	Uncomfortable; I found sitting really uncomfortable as baby's head lowered
4. No reasons why it was unhelpful (P1; Control Arm; did not use ball in trial).	
5. It hurt my back (existing problem) when sitting on it and it felt more uncomfortable on it than on the sofa/chair (P1; Control Arm; did not use ball in trial).	Intensified; it hurt may back when sitting on it Uncomfortable; more uncomfortable on it than on the sofa / chair (unsteady)
6. I found it hurt my tummy (P2; Intervention Arm; used ball in trial).	Intensified; it hurt my tummy
7. While having a contraction I needed to lean/push against something that could hold my weight. As I did this, my husband had to steady me as I nearly fell off! (P2; Control Arm; did not use ball in trial).	Unsteady; my husband had to steady me as I nearly fell off
8. n/a (P1; Control Arm; did not use ball in trial).	
9. As labour progressed, it was not comfortable any more (P1; Intervention Arm; used ball in trial).	Uncomfortable; not comfortable Labour progressed; as labour progresses
10. In my first labour I was induced and the ball was introduced too late so wasn't beneficial (P1; Intervention Arm; used ball in trial).	Labour progressed; the ball was introduced too late
11. Im [sic] not sure if it was helpful or not, i used it during my first labour but not my second, my first was a lot longer (P1; Control Arm; did not use ball in trial).	Unsure; not sure if it was helpful or not.
12. Not helpful for me once labour was established as I was too uncomfortable and wanted to stand (P1; Intervention Arm; used ball in trial).	Labour progressed; I was too uncomfortable and wanted to stand Uncomfortable; I was too uncomfortable
13. In my second labour I did not sit on a ball as was too painful to sit down - I had bad PGP which was exacerbated when baby's head became engaged (P2; Control Arm; did not use ball in trial).	Intensified; I had bad PGP which was exacerbated when baby's head became engaged … it was too painful to sit down Uncomfortable; it was too painful to sit down
14. I didn't (P2; Control Arm; used ball in trial).	N/A

Box 17.2 Themes identified in responses to Q.6.b.

N/A Unsure or not applicable.

Uncomfortable or painful

Labour progressed

Intensified pain

Unsteady

Q.10.a. Please explain why you found using a birth ball helpful (80 responses)

1. It helped my hips and took my mind off labour (P0; Intervention Arm).	Easing. helped my hips Cognitive; took my mind off labour
2. The ball helped to keep me focused and comfortable. I was able to remain at home from when my waters broke, 12.15am until 5pm when I went to hospital, where my baby was born less than an hour later (P1; Control Arm) .	Easing; helped, comfortable Cognitive; focused, Dealing; I was able to
3. It helped me to relax (P2; Control Arm).	Cognitive; helped Easing; to relax
4. It helped with initial lower back pain but when it became stronger I needed to physically massage the area. When I felt labour was progressing I wanted to get to hospital and didn't focus on the ball. I was in the control group but I am self motivated so I researched online what I needed to do. (P1; Control Arm).	Dealing; helped, labour was progressing, self-motivated, researched online
5. It helped to relieve the pressure I was feeling (P0; Control Arm).	Cognitive; helped Easing; relieved the pressure
6. It moulds to your frame and the extra weight and takes a bit of pressure off your body in the early stage (P1; Intervention Arm).	Support; it moulds to your frame and the extra weight Easing; takes a bit of pressure off
7. It helped relieve pain and also found moving on the ball a distraction from the pain rather then [sic] standing or sitting in one place (P0; Intervention Arm).	Cognitive; helped Easing; relieve Cognitive; helped; a distraction Movement; moving on the ball
8. Comfortable (P1; Intervention Arm).	Easing; comfortable
9. Sitting in [sic] the ball gave me a focus (to stay on the ball) taking me away from the pain (P0; Intervention Arm).	Upright; sitting Cognitive; gave me a focus, taking me away from the pain

10. Gave me something to do. Possibly helped speed up labour as it allowed me to be active and upright (P1; Control Arm).	Cognitive; gave me something to do, Dealing; helped speed up labour; allowed Upright; to be active and upright
11. Definitely helped dealing with my contractions (P1; Control Arm).	Dealing; dealing with
12. As well as using the birth ball to tempt my baby to go into the correct position it also helped a lot with contractions pushing the contraction pain though my birthing ball (P0; Intervention Arm).	Dealing; tempting my baby into the correct position, helped, pushing the contraction through my birthing ball
13. I found it made the contractions less painful and made it easier to power through the pain (P0; Intervention Arm).	Easing; made the contractions less painful (cognitive)
14. It helped with the pressure of the baby pushing down on my pubic area. Also, rocking around on the ball created a distraction from the contractions (P1; Intervention Arm).	Easing; it helped with the pressure of the baby Movement; rocking Cognitive; created a distraction
15. Comfortable to sir [sic] on. Helped me believe it would get my pelvis ready and I found this mentally comforting. I sat playing a game on the computer while I had small contractions (P2; Intervention Arm).	Cognitive; helped me believe it would get my pelvis ready, mentally comforting
16. It helped ease contraction pain and also helped me focus on my breathing (P0; Control Arm).	Easing; ease contraction pain Cognitive; helped me focus
17. I found the light bouncing/rocking helped ease some of the pain, and perhaps took my mind off the pain too! (P0; Control Arm).	Movement; bouncing / rocking Easing; ease some of the pain Cognitive; took my mind off the pain
20. It was a very comfortable position on the ball either bouncing or rocking - more comfortable than sitting or lying. It was good to intersperse a bit of walking with using the ball in different positions. Using the ball eased the pain in my back (P1; Intervention Arm).	Easing; comfortable, more comfortable, eased the pain Movement; bouncing or rocking Upright; a bit of walking; more comfortable than sitting or lying
21 Good support for the position I wanted to be in to help with pain. And possibly as a distraction from the pain too (P0; Control Arm).	Support; good support Easing; to help with pain Cognitive; help, a distraction from the pain
22. It kept me busy and took my mind off of things (P1; Intervention Arm).	Cognitive; it kept me busy and took my mind off things

23. It helped me to concentrate on something else when I started to feel contractions as I had to focus on rocking and keeping balance. Made me think of something else rather than the pain. I didn't feel I needed pain relief. I spent at least 6 hours in labour at home before needing to go into hospital (P0; Intervention Arm).	Cognitive; to concentrate on something else, focus on, made me think of something else, I didn't feel I needed pain relief Movement; rocking Support; keeping balance
24. It relieved the feeling of pressure and made it more comfortable to keep moving. It was comfortable to sit on (P0; Control Arm). 26. It helped me to relax and gain focus on my breathing (P0; Control Arm). 27. Great position for managing contractions, felt more relaxed and in control (P1; Intervention Arm) 28. It provided stability for me to lean, and at just the right height (P0; Intervention Arm). 29. I found moving and rocking on the ball helpful and helped ease contraction pain (P2; Control Arm). 30. Bouncing on the ball took the edge off the pain whist having contractions (P1; Control Arm) 31. It helped keep me relaxed [sic] during contractions with breathing as well (P0; Control Arm). 32. Moving around helped to "ride out" the contractions (P0; Intervention Arm). 33. Helped me relax and focus on something. Helped and distracted me with the contractions (P0; Intervention Arm).	Easing; it relieved the feeling of pressure, comfortable Movement; to keep moving Easing; comfortable Upright; to sit on Easing; it helped me to relax Cognitive; to gain focus Upright position; great position Cognitive; managing contractions, in control Easing; relaxed Support; stability for me to lean Movement; moving, rocking, Rhythm; rocking Easing; helped ease contraction pain Movement; bouncing Rhythm; bouncing Easing; took the edge off the pain Easing; relaxed Cognitive; helped Movement; moving around Cognitive; helped to 'ride out' the contractions Easing; helped me relax Cognitive; focus, helped, distracted

34. Relaxing position and slight movement helped (P0; Control Arm).	Easing; relaxing Movement; slight movement Cognitive; helped Upright / position
35. Circling on the ball helped ease the pain (P1; Control Arm)	Movement; circling Cognitive; helped Easing; ease the pain
36. I had to have antibiotics so did early labour at hospital on a birth ball and walking around. It helped ease pain by giving me something else to focus on. It also supports your back nicely when your [sic] in pain (P0; Control Arm).	Movement; walking around Upright; walking Easing; ease pain Cognitive; helped, focus on Support; supports your back
37. Gave me something to focus on (P0; Control Arm)	Cognitive; to focus on
38. Found it the most comfortable place to sit whilst in labour (P0; Control Arm).	Easing; comfortable Upright / positions; to sit
39. It helped me bounce to my breathing (P0; Intervention Arm).	Cognitive; helped Rhythm; bounced to my breathing Movement; bounced
40. It made me think about staying relaxed (P1; Intervention Arm) .	Cognitive; it made me think about Easing; staying relaxed
41. This was during the very early stages so the pain wasn't too bad yet, it helped me focus on Something [sic] else and it felt good to move the lower body (P0; Intervention Arm).	Cognitive; it helped me focus on Something Easing; it felt good Movement; to move the lower body
42. It eased the discomfort of early labour (P0; Intervention Arm).	Easing; it eased the discomfort of early labour
43. Distracted me from the pain I was feeling (P0; Intervention Arm).	Cognitive; Distracted me from the pain
44. It helped me relax and ease the pain (P1; Intervention Arm).	Cognitive; helped me Easing; relax and ease the pain

45. It not only eased my pain of contractions but also helped stretch my back which I found helped, but it also gave me something [sic] to focus on or take my attention off the pain (P0; Intervention Arm).	Easing; eased my pan of contractions, helped stretch my back, Cognitive; gave me something to focus on or take my attention off the pain
46. Relieved pain, helped me relaxed [sic], made me feel like it was helping to progress labour. Helped me stay active and mobile (P1; Intervention Arm).	Easing; relieved pain, helped me relaxed[sic] Cognitive; made me feel like it was helping to progress labour Movement; to stay active and mobile
47. It was comfortable to sit on and lean on and being comfortable helped me to stay relaxed and calm, I found the motion of circling and rocking therapeutic (P0; Intervention Arm).	Easing; comfortable, being comfortable, to stay relaxed and calm Upright and positions; to sit on Support; lean on Cognitive; helped me Movement; I found the motion …. therapeutic Rhythm; circling and rocking
48. It felt like a distraction from the contractions (P0; Control Arm).	Cognitive; it felt like a distraction from
49. I found that using a birthing ball brang [sic] on my labour quicker and also think it made my labour easier. I found the contractions more painful than the labour it's [sic] self (P0; Control Arm).	Cognitive; a birthing ball brang [sic] on my labour quicker Easing; it made my labour easier
50. The ball helped with pain management and put me in a comfortable position (P0; Control Arm).	Cognitive; helped Upright / position
51. I found the birth ball helpful because it gave me something to concentrate on during contractions and helped me feel light and relaxed during the early stages of labour (P1; Intervention Arm).	Cognitive; helpful, gave me something to concentrate on; Easing; light and relaxed
52. It helped with early nausea (bending over the ball). It helped me remain focused and calm during contractions as I kept a rhythm throughout (P1; Intervention Arm).	Cognitive; helped, remain focused and calm Movement; bending over the ball Rhythm; I kept rhythm throughout
53. It kept me moving and distracted me from the pain of contractions (P1; Intervention Arm).	Movement; kept me moving Cognitive distracted me from the pain

54. It was the only place I was comfortable (P1; Intervention Arm).	Easing; it was the only place I was comfortable (movement)
55. It was the only thing that helped, as I could lean over it, hug it tight during contractions, it took my weight so took the pressure off and could move it as I wanted (P1; Intervention Arm).	Cognitive; it was the only thing that helped. Movement; lean over it, could move it as I wanted Support, hug it tight, took my weight Easing; took the pressure off
56. It took the weight off my legs and hips (P1; Control Arm).	Support; it took the weight off my legs and hips
57. Yes, very helpful …. Very easy delivery of my baby (P0; Intervention Arm).	Cognitive; very helpful
58. The motion of movement on the ball was relaxing (P1; Intervention Arm).	Movement; motion of movement Easing; relaxing
59. Using a Ball [sic] made me feel more comfortable during contractions (P0; Control Arm).	Easing; made me feel for comfortable
60. Helped to focus attention on something whilst having contractions (P0; Intervention Arm).	Cognitive; helped to focus attention on something
61. It helped take the pain off my hips as all my contractions was [sic] in the front. Also the bouncing help [sic] take my mind off the pain while talking to my partner (P3; Intervention Arm).	Cognitive; helped, take my mind off the pain while talking to my partner Easing; take the pain off my hips,
62. I felt it kept me calm and found contractions were more bearable on the ball (P2; Intervention Arm).	Dealing; found contractions were more bearable while on the ball Cognitive; kept me calm
63. The time leading up to the labour I used the ball a lot as it relieved the pressure of the baby, who was engaged. I had a very quick labour (2 hours) so could only use it slightly when having contractions. This still helped me keep mobile and focused (P1; Intervention Arm).	Easing; relieved the pressure of the baby Movement; keep me mobile Cognitive; keep me ….. focused
64. It helped me to focus on what I was doing rather than what was going on around me. I felt that it was a comfortable way to help my baby get into a good position. I used it up until the point where she was so low down the ball became to [sic] hard feeling for me to sit on it (P0; Intervention Arm).	Cognitive; helped me, a comfortable way to help my baby into a good position, focus on what I was doing rather than what was going on around me

65. It gave me something else to think about and take my mind away from the discomfort (P0; Intervention Arm).	Cognitive; gave me something else to think about and take my mind away from the discomfort
66. It really took the edge off the contractions. They came very thick and fast as I had a short labour this time (P1; Intervention Arm).	Easing; really took the edge off the contractions
67. Great pain relief and distraction (P0; Intervention Arm).	Easing; great pain relief Cognitive; distraction
68. The rhythmic movement helped the pain and helped me focus my breathing. I could vary the movement depending on whether I was having a contraction or not (P0; Control Arm).	Rhythm; rhythmic Movement; movement, I could vary the movement (freedom?) Easing; helped the pain, Cognitive; helped me focus my breathing
69. I found that bouncing on the ball during contractions eased the pain (P0; Intervention Arm).	Movement; bouncing on the ball Rhythm; bouncing Easing; eased the pain
70. It was comfortable to sit on (P1; Intervention Arm).	Easing; comfortable Upright / positions; to sit on
71. Was the only way to sit comfortably (P0; Intervention Arm).	Easing; comfortable Upright / positions; to sit on
72. I went over my due date and used the ball regularly to excersize [sic] and to help move baby along. During my contractions, bouncing on the ball helped me through the pain (P0; Control Arm).	Cognitive; to help move baby along Moving; bouncing on the ball Rhythm; bouncing on the ball Easing; helped me through the pain
73. The motion and the fact that there was no real pressure if I was to sit on it (not like a hard seat) gravity from the bouncing could of [sic] been a plus as well (P2; Control Arm).	Movement; motion, bouncing Easing; there was no real pressure Rhythm; bouncing
74. It helped me focus on something when I was having contractions (P0; Intervention Arm).	Cognitive; helped me focus on something
75. The bouncing motion helped to relieve uncomfort [sic], relax my body and help move baby down for labour (P0; Intervention Arm).	Movement; bouncing Rhythm; bouncing Easing; to relieve uncomfort [sic] relax my

76. Quickened my labour (P0; Control Arm). 77. I found it relaxing, it made me feel more comfortable. (P1; Control Arm).	body Cognitive; help move baby down Cognitive; quickened my labour Easing; I found it relaxing, it made me more comfortable
78. It gives you something to focus on and makes labouring more of a process rather than just a pain (P4; Intervention Arm). 79. It was the only way I could get comfortable however it did not help me dilate even though I had been using it for months before (P0; Intervention Arm). 80. More comfortable to sit on than a chair or bed as it has more give but still supportive. The movement of the ball keeps you a little looser through the pain rather than tensing up quite so much (P1; Intervention Arm).	Cognitive; it gives you something to focus on, makes labouring more of a process than a pain Easing; it was the only way I could get comfortable

Q.11.a Would you use a birth ball at home in early labour for a future labour? (88 responses)

1. The bouncing was great and stopped my hips hurting so much (P0; Intervention Arm).	Movement; bouncing Rhythm; bouncing Easing; stopped my hips hurting so much
2. The birthing ball was a great comfort and a focus during strong contractions (P1; Control Arm).	Easing; a great comfort Cognitive; a focus during strong contractions
3. It helped me to birth beyond what I thought I could cope with (P3; Control Arm).	Cognitive / dealing; it helped me beyond what I thought I could cope with
4. Because it's a drug free pain relief which is important for me as I try to avoid medication where necessary (P1; Control Arm).	Drug free pain relief, to avoid medication
5. It was relaxing (P0; Control Arm).	Easing; relaxing
6. Because it was a helpful distraction and I felt it helped relieve the pain (P0; Intervention Arm).	Cognitive; a helpful distraction Easing; relieve the pain
7. Yes, even though pain wasn't reduced it was still quite comfortable in between contractions (P1; Intervention Arm).	Easing; quite comfortable Not working; pain wasn't reduced
8. I could use the movement of me on the ball as a focus and try and stay balanced on it as I was moving my hips took my mind off the contraction [sic] (P0; Intervention Arm).	Movement; of me on the ball, I was moving my hips Cognitive; as a focus, took my mind off the contractions Support; try and stay balanced on it
9. I'm not having any more children (P1; Control Arm).	No intention of future pregnancy
10. Relieving pain with contractions (P1; Control Arm).	Easing; relieving pain
11. Yes and no, don't think I used it long enough before the contractions had got stronger, so I don't think I've given it a fair judgement (P0; Intervention Arm).	Equivocal response
12.	
13. I would have been a mess on the floor without it (P0; Intervention Arm).	Cognitive; firmly positive response, belief in the birth ball

14. It really helped me especially when I was in pain I would highly recommend using one (P0; Intervention Arm).	Cognitive; it really helped me
15. For the same reasons I've mentioned above (Response: 10.a.14) (P1; Intervention Arm).	Already coded
(It helped with the pressure of the baby pushing down on my pubic area. Also, rocking around on the ball created a distraction from the contractions)	
16. For the very start of my contractions the ball was a good distraction from contractions, but I wouldn't use the ball in active labour (P0; Intervention Arm).	Cognitive; a good distraction from contractions
17. As a comfortable seat only (P2; Intervention Arm).	Easing; a comfortable seat (only – not for anything else)
18. Helped with the pain! (P0; Control Arm).	Easing; helped with the pain
19. The same reasons I found it helpful. Also being mobile helped ease the pain, and the ball can assist in this, even if it's just a gentle bounce / rock (P0; Control Arm).	Movement; mobile, bounce / rock Easing; helped ease the pain Rhythm; bounce / rock
20. I found it helpful in the early stages to aid me through my contractions, ease my back pain and because you could use it in multiple positions you could keep changing positions as needed (P1; Intervention Arm).	Cognitive; to aid me through my contractions Easing; ease my back pain Upright / positions; in multiple positions, you could keep changing positions as needed (freedom?)
21. I was pleased with how my labour went and would attempt to repeat it (P0; Control Arm).	Cognitive; firmly positive response
22. I didn't find the ball very helpful (P2; Intervention Arm).	Negative response
23. Kept me upright and busy (P1; Intervention Arm).	Upright / positions Cognitive; busy
24. I found that Using [sic] the birthing ball whilst in labour was more painful (P0; Intervention Arm; used ball in trial).	Negative response
25. I used the birth Ball at home in early labour and then continued to use a birth ball whilst in the hospital for many hours into established labour without having any pain relief as I found focusing on using the ball helped me get through the contractions. I only stopped using the ball when I was instructed the midwife would need to intervene and break my waters as contractions started to slow down late in labour (P0; Intervention Arm; used ball in trial)	Cognitive;' focusing on the ball helped me get through contractions

26. I think it's a useful tool to have at home to help manage contractions. I found it helpful the first time so will use again! (P0; Control Arm; used ball in trial).	Cognitive; to help manage contractions, helpful
27. It made me feel settled and comfortable (P0; Intervention Arm; used ball in trial).	Easing; settled and comfortable
28. Made me much more comfortable (P2; Intervention Arm; used ball in trial).	Easing; comfortable
29. It really helped and even now my baby loves being bounced on the ball! (P0; Control Arm; used ball in trial).	Cognitive; helped Movement; bounced Movement; bounced
30. Great height to lean over and ease of rocking motion (P1; Intervention Arm; used ball in trial).	Movement; lean over Support; lean over
31. Early labour it was comfy to sit and bounce on. It provided comfy seating during late pregnancy when baby was sitting very low. I'd use it to lean on again (P0; Intervention Arm; used ball in trial).	Easing; comfy, comfy seating Movement; bounce, Rhythm; bounce Support; to lean on again
32. It really does help (P2; Control Arm; used ball in trial).	Cognitive; help
33. Same reason as above (Response 10.a.30) (P1; Intervention Arm; used ball in trial). *(Bouncing on the ball took the edge off the pain whist having contractions)*	Already coded
34. I found it to be very relaxing and went well with hypnobirthing breathing I was doing (P0; Control Arm; used ball in trial).	Easing; relaxing
35. I found it helpful and therapeutic in early labour (P0; Intervention Arm; used ball in trial).	Cognitive; helpful Easing; therapeutic
36. Was needed, when I got to hospital I realised how dependent on it I was (P0; used ball in trial).	Cognitive; dependent on it
37. I didn't find it eased the pain as effectively as getting on my hands and knees did (P0; Control Arm; used ball in trial).	Negative response
38. Comfortable to lean on and relax, and bouncing helped with the pain (P0; Control Arm; used ball in trial).	Easing; comfortable, relax Movement; bouncing Rhythm; bouncing Cognitive; helped with the pain Support; to lean on
39. The movement really helped manage the pain and steady [sic] at home as long as possible (P1; Control Arm; used ball in trial).	Cognitive; helped manage the pain

40. Helps distract the pain (P0; Control Arm; used ball in trial).	Cognitive; helps, distract
41. I felt it helped alot [sic] (P0; Control Arm; used ball in trial).	Cognitive; helped
42. Because I found it comfortable (as can be) (P0; Control Arm; used ball in trial).	Easing; I found it comfortable
43. To help me regulate my breathing (P0; Intervention Arm; used ball in trial).	Cognitive; regulate my breathing
44. I think it helped me (P1; Intervention Arm; used ball in trial).	Cognitive; it helped me
45. Because it was relaxing to move the lower body (P0; Intervention Arm; used ball in trial).	Easing; relaxing Movement; to move the lower body
46. It was a useful tool to ease discomfort. I also understand it gets the baby in the correct position (P0; Intervention Arm; used ball in trial).	Cognitive; a useful tool, it gets the baby in the correct position
47. Found it very helpful and distracted me from the pain (P0; Intervention Arm; used ball in trial).	Cognitive; very helpful, distracted me
48. I felt that it was very helpful and relaxing (P1; Intervention Arm; used ball in trial).	Cognitive; helpful Easing; relaxing
49. I'm unsure of what I would do for another labour as hoping if I labour again baby will not be back to back (P0; Intervention Arm; used ball in trial).	Equivocal response
50. I just didn't find it helpful (P2; Intervention Arm; used ball in trial).	Negative response
51. I found it very useful (P0; Intervention Arm; used ball in trial).	Cognitive; very useful
52. Same as above (10.a.46) (P1; Intervention Arm; used ball in trial). *Relieved pain, helped me relaxed [sic], made me feel like it was helping to progress labour. Helped me stay active and mobile.*	Already coded
53. I definitely think it helped me stay at home longer as it helped me to manage the contractions I was having (P0; Intervention Arm).	Cognitive; helped me to manage the contractions
54. I feel more prepared for what's to come now so would be able to be more controlled (P0; Control Arm).	Cognitive; more prepared, more controlled
55. It helped the first time I used it by offering distraction from the contractions. I hope next time I will be able to spend more time using a ball to help me dilate quicker (P0; Control Arm).	Cognitive; helped, by offering distraction
56. Found it helped a lot (P0; Control Arm).	Cognitive; it helped a lot
57. I found it helped control pain (P0; Control Arm).	Cognitive; it helped control pain
58. I think using the birth ball enabled me to stay at home a lot longer than I did in my previous labour where I didn't use a birth ball. During this labour I spent 6 hours at home whereas during my previous labour I spent 3 hours at home (P1; Intervention Arm).	Cognitive; the birth ball enabled me
59. Although labour was long, it was very manageable at home right up until contractions were close	Cognitive; (labour) … was very

together and the most painful part of labour (in the hospital) lasted much less than with my first baby (P1; Intervention Arm).	manageable
60. I feel it helped me, so I would use it again (P1; Intervention Arm).	Cognitive; it helped me
61. It really eased the pain (P1; Intervention Arm).	Easing; it really eased the pain
62. I tried everything whilst at home to keep comfortable and the ball was the only thing that helped. I think as I was able to move position and the ball as I liked and being able to put all my weight on to / over it and squeeze it really helped (P1; Intervention Arm).	Easing; keep comfortable …. Cognitive; the ball was the only thing that helped, really helped Movement; move Upright / position; move position as I liked (freedom) Support; put all my weight onto it
63. It helped with the weight off of my legs and hips and I could relax over the ball (P1; Control Arm).	Support; with the weight off my legs and hips Cognitive; helped Easing; relax
64. It was comfortable between contractions to be on the ball (P1; Control Arm).	Easing; comfortable
65. Very helpful for me (P0; Intervention Arm).	Cognitive; very helpful for me
66. The movements helped keep me focused and relaxed (P1; Intervention Arm).	Movement; the movements Cognitive; helped keep me focused Easing; relaxed
67. Most comfortable thing to sit on during contractions (P0; Control Arm).	Easing; comfortable Upright / positions; to sit on
68. I found it helped with staying in the right position for helping baby to move down (P0; Intervention Arm).	Cognitive; helped, helping baby to move down Upright / position; staying in the right position
69. It really helped with my pain and gave me something to think about instead of the pain (P1; Intervention Arm).	Cognitive; helped with my pain, gave me something to think about instead of the pain

70. Helped keep me active (P1; Control Arm). 71. The ball supports the body by keeping it mobile (P1; Intervention Arm). 72. As it didn't help me (P0; Control Arm).	Cognitive; helped Movement; keep me active Support; supports the body Movement; by keeping it mobile Negative response
73. I really feel like it gets things moving and you're able to move more freely and comfortably during the early stages (P0; Intervention Arm).	Cognitive; it really gets things moving Movement; you're able to move freely (freedom?) Easing; comfortably
74. I found it beneficial and helped to ease some of the pain and discomfort (P0; Intervention Arm).	Cognitive; beneficial Easing; to ease some of the pain and discomfort
75. Because I found it helped me cope better with the contractions (P1; Intervention Arm).	Cognitive; it helped me cope better
76. It helped me remain nearly pain free and stay at home until 8cm (P0; Intervention Arm).	Cognitive; it helped me Easing; remain nearly pain free
77. It helped me focus, kept me moving and improved my posture and positioning (P1; Control Arm).	Cognitive; helped me focus Movement; kept me moving Upright / positions; improved my posture and positioning
78. As above (10.a.69) (P0; Intervention Arm). (*I found that bouncing on the ball during contractions eased the pain.)*	Already coded
79. It was comfortable to sit on (P1; Intervention Arm).	Easing; comfortable
80. It helps when your [sic] uncomfortable (P0; Intervention Arm). 81. When I arrived at the hospital I was fully dilated and ready to push. I firmly believe that the ball helped move baby along and took my mind off the pain (P0; Control Arm).	Cognitive; I firmly believe that the ball helped move baby along, took my mind off the pain
82. I see only benefits from using it (P2; Control Arm).	Cognitive; I see only benefits from

	using it
83. It helped with my early contractions and helped me to stay focused (P0; Intervention Arm).	Cognitive; helped, helped me to stay focused
84. The birth ball really worked for me, I would definitely use it again (P0; Intervention Arm).	Cognitive; the ball really worked for me.
85. Helped with pressure relief (P0; Control Arm).	Cognitive; helped Easing; pressure relief
86. If I had another I would use again as I found it kept me moving and took my mind of [sic] feeling uncomfortable (P1; Control Arm).	Cognitive; If I had another I would use again, took my mind of [sic] feeling uncomfortable Movement; kept me moving
87. It gives you something to focus on. Previous labours I've just hung around at home in pain waiting to go to hospital, it's hard, horrible and makes you panic (P4; Intervention Arm).	Cognitive; something to focus on
88. I found it useful to lean over (P0; Intervention Arm).	Cognitive; useful Support; lean over
89. Something more comfortable to sit on, bouncing is a distraction to the pain (P1; Intervention Arm).	Easing; comfortable Upright / positions; to sit on Movement; bouncing Rhythm; bouncing Cognitive; a distraction to the pain

Q.12. a. How likely would you be to recommend using a birth ball in early labour to a friend or family member? (79 responses)

.1. My labor was calm and relaxed which I feel was down to the ball. I have passed on my birthing ball and recommendations to my pregnant friend (P1; Control Arm).	Easing; calm and relaxed Cognitive; which I felt was down to the ball
2. It really helped early on, I'd never used one before (P2; Control Arm).	Cognitive; It really helped early on.
3. It is fun. Helps relieve pain. Helps you understand the progression of labour (more so I guess if it's your second birth. Drug free pain relief. (P1; Control Arm).	Cognitive; It is fun, helps you understand the progression of

	labour. Analgesia; drug free pain relief
4. I would definitely recommend this to other people, I found it was a comfy place to sit in the latter stages of pregnancy and early labour (P1; Intervention Arm).	Easing; a comfy place Upright / positions; to sit
5. Because it was a handy distraction and felt helped with the pain (P0; Intervention Arm).	Cognitive; a handy distraction, helped with the pain
6. Comfortable in between contractions (P1; Intervention Arm).	Easing; comfortable
7. I found it very helpful and think others would benefit from it (P0; Intervention Arm)	Cognitive; I found it very helpful
8. Useful for the above reasons (10.a.10) (P1; Control Arm). (*Gave me something to do. Possibly helped speed up labour as it allowed me to be active and upright).*	**Already coded**
9. Helped me with my labour (P1; Control Arm).	Cognitive;
10. Not used it enough to comment, likely or not. But I get a lot of positive information about the ball (P0; Intervention Arm).	Equivocal response
11. As it helped me so much I would definitely recommend all to use it (P0; Intervention Arm).	Cognitive; as it helped me so much
12. Some have said it helped in active labour but in my opinion, it didn't help at all (P0; Intervention Arm).	Negative response
13. As u believe it helped open up my pelvis and gave me something to focus on (P2; Intervention Arm).	Cognitive; it helped open up my pelvis, gave me something to focus on
14. Great means of pain relief without drugs (P0; Control Arm).	Easing; pain relief Drug-free; without drugs
15. I found it provided some relief in early labour so would always recommend anyone to try it out (P0; Control Arm).	Easing; some relief
16. Reducing back pain, helping through initial contractions - enabling me not to have to take any analgesia. It felt comfortable and I knew that there was research that it was beneficial for baby's position	Cognitive; enabling me, I knew that there was research that it

(P1; Intervention Arm). 17. Nice to share positive birth experiences that don't involve/delay drug use (P0; Control Arm). 18. Don't think it helps but everyone is different! (P2; Intervention Arm). 19. Some people may find it easier as I'm not very good with pain as it is (P0; Intervention Arm).	was beneficial for baby's position Drug-free; not to have to take any analgesia Drug-free; don't involve / delay drug use Equivocal response Equivocal response
20. I thought it was brilliant and comfortable to use and keeps you moving and not stationery, it's a great focus tool for something that can be so overwhelming. I like it because you can use it in so many different positions to support so it can be used in a way that's personal to your needs (P0; Intervention Arm). 21. Because it can provide extra comfort and it is an easy thing to get hold of at home. **You can also use it in the run up to labour (during pregnancy)** (P0; Control Arm). 22. Made my latest labour much more bearable than the first two (P2; Intervention Arm). 23. It helps to relieve pain and gain focus (P0; Control Arm). 24. Very helpful for managing contractions. Also great towards end of pregnancy for bouncing and pelvic circling to encourage labour and good baby position (P1; Intervention Arm). 6. As stated above (Response 11.a.30) (P0; Intervention Arm).	Cognitive; I thought it was brilliant, it's a great focus tool Easing; comfortable Movement; keeps you moving and not stationery Upright / positions; so many different positions Easing; it can provide extra comfort Easing; made my labour much more bearable Easing; relieve pain Cognitive; gain focus Cognitive; very helpful for managing contractions, encourage labour and good baby position Movement; bouncing and pelvic circling Rhythm; bouncing and pelvic circling

(Early labour it was comfy to sit and bounce on. It provided comfy seating during late pregnancy when baby was sitting very low. I'd use it to lean on again.)	**Already coded**
26. I strongly believe they help and to keep active/moving through labour and contractions (P2; Control Arm).	Cognitive; I strongly believe they help Movement; to keep active / moving
27. I would recommend it as I found it to help with the contractions and a great pain relief (P0; Control Arm).	Cognitive; I found it to help Easing; a great pain relief
28. Although my labour was quick I found it helped to ride out the contractions. More beneficial than pacing or moving around generally (P0; Intervention Arm).	Cognitive; I found it helped to ride out the contractions.
29 Might not work for everyone, but everyone should give it a try (P0; Intervention Arm).	Equivocal response
30. Although it didn't work for me, it could work for someone else (P0; Control Arm).	Equivocal response
31. Keeping still didn't help with the pain, being able to relax over the ball and bounce and rock was relaxing (P0; Control Arm).	Easing; being able to relax over the ball, was relaxing Support; over the ball Movement; bounce and rock Rhythm; bounce and rock
32. I feel it made a difference to me so would recommend it as an option to friends etc. (P1; Control Arm).	Cognitive; I feel it made a difference to me
33. It's a nice way to positively manage pain. I used it with hypnobirth (P0; Control Arm).	Cognitive; to positively manage pain
34. It's worth trying (P0; Control Arm).	Cognitive; it's worth trying
35. As above (Response 11.a.41) (P0; Control Arm).	**Already coded**
(Because I found it comfortable (as can be).	
36. I would recommend to help with breathing and comfort (P0; Intervention Arm).	Cognitive; to help with breathing Easing; comfort
37. I think it helped me stay relaxed so it may help others as well (P1; Intervention Arm).	Cognitive; I think it helped me Easing; to stay relaxed
38. Because it helped me loosen up (P0; Intervention Arm).	Cognitive; because it helped me

	Easing; loosen up
39. As above (Response 11.a.45) (P0; Intervention Arm). *(It was a useful tool to ease discomfort. I also understand it gets the baby in the correct position).*	**Already coded**
40. Distracted me from the pain. Also very entertaining as I was eating whilst using the ball (P0; Intervention Arm).	Cognitive; distracted me from the pain, entertaining
41. I would recommend it to friends/ family because it gave me something to focus on and helped with the pain (P1; Intervention Arm).	Cognitive; gave me something to focus on, helped with the pain
42. I would recommend that a friend do whatever makes them feel comfortable (P0; Intervention Arm).	Equivocal response
43. I know it can help. Just because I didn't find it useful, doesn't mean someone else won't (P2; Intervention Arm).	Cognitive; I know it can help Equivocal response
44. I think it helps with relieve [sic] the pain (P0; Intervention Arm).	Easing; relieve the pain
45. Same as above (Response 10.a.46) (P1; Intervention Arm). *(Found it very helpful and distracted me from the pain).*	**Already coded**
46. I know that it was beneficial during pregnancy so I would think it would be during early labour if circumstances allowed for it (P0; Control Arm).	Cognitive; I know that it was beneficial during pregnancy
47. Maybe it is not for everybody, but I think it helped me so it could help somebody else as well (P0; Control Arm).	Cognitive; I think it helped me Equivocal response
48. I found it helped me a lot and made my labour a bit easier and less painful so may make others the same (P0; Control Arm).	Cognitive; I found it helped me a lots Easing; a bit easier and less painful
49. Found very helpful (P0; Control Arm).	Cognitive; found very helpful
50. Because it really helped me during early labour so sure it could be helpful for someone else (P1; Intervention Arm).	Cognitive; it really helped me during early labour
51. This labour was much smoother than my first as I was calmer and more focused, and I believe the ball played a big part in achieving that (P1; Intervention Arm).	Cognitive; calmer and more focused, I believe the ball played a big part in achieving that
52. I would recommend using a birthing ball as I felt it helped me through the contractions and helped my labour progress (P1; Intervention Arm).	Cognitive; I would recommend …..I felt it helped me through the contractions and helped my labour progress

53. I would highly recommend it for comfort and counting the circles of my hips helped through the contractions (P1; Intervention Arm). 54. Would recommend as a possible option for early labour relief (P1; Intervention Arm).	Cognitive; I would highly recommend it Easing; comfort, counting Movement; the circles of my hips Rhythm; the circles of my hips Easing; a possible option for early labour relief
55. It takes your mind off of the pain a little bit and can relax in between contractions (P1; Control Arm). 56. I didn't think it helped with the early labour (P1; Control Arm). 57. Helpful (P0; Intervention Arm). 58. Hopefully it will help relax and keep them calm (P1; Intervention Arm). 59. As above (Response 11.a.66) (P0; Control Arm). *(Most comfortable thing to sit on during contractions.)* 60. I found it quite helpful and would suggest to anyone else to try if it would possibly help them (P1; Intervention Arm) 61. Definitely recommend it. It's [sic] really was helpful (P1; Intervention Arm). 62. For reasons stated above (Response 11.a.70) (P1; Intervention Arm). *(The ball supports the body by keeping it mobile).* 63. I think they would appreciate the advice and it would be more helpful to them than sitting on a sofa etc. which doesn't allow them to move. Also the help and advice you get from the midwives involved with birthing balls is brilliant (P0; Intervention Arm). 64. Same as above (Response 11.a.73) (P0; Intervention Arm). *(I found it beneficial and helped to ease some of the pain and discomfort.)* 65. Because of my experience (P1; Intervention Arm). 66. Easiest form of intervention for pain relief (P0; Intervention Arm). 67. I found it very beneficial and feel it made for a mouth [sic] better labour than my previous one (P1; Control Arm)	Cognitive; takes your mind off the pain a little bit Easing; can relax between the contractions Negative response Cognitive; helpful Easing; relax and keep them calm **Already coded** Cognitive; I found it quite helpful **Already coded** Movement; sitting on a sofa … doesn't allow them to move (freedom?) **Already coded** Equivocal response Easing; pain relief Cognitive; very beneficial, mouth [sic] better labour than my previous one

68. As above (Response 10.a.69) (P0; Intervention Arm). *(Helped keep me active.)*	**Already coded**
69. Depends on if they were looking for things to help them or not (P1; Intervention Arm)	Equivocal response
70. It's helped me a lot (P0; Intervention Arm).	Cognitive; it's helped me a lot
71. As above, the ball helped me with a really quick labour and I had the comfort of my own surroundings until I needed the delivery suite (P0; Control Arm)	Cognitive; helped me with a really quick labour Easing; I had the comfort of my own surroundings
72. It could help someone else feel the relief I felt (P2; Control Arm).	Easing; fell the relief I felt
73. It's easy to use and helped speed along the labour (P0; Intervention Arm).	Cognitive; helped speed along the labour
74. Yes, I highly recommend the birth ball and feel it was a great influence in my relatively quick labour (P0; Intervention Arm).	Cognitive; it was a great influence on my relatively quick labour
75. Very helpful (P0; Control Arm).	Cognitive; very helpful
76. I didn't know I was experiencing contractions as my labour was very fast but when I did feel sore it helped to relax me (P1; Control Arm).	Easing; when I did feel sore it helped to relax me
77. It was my best birth experience yet (P4; Intervention Arm).	Cognitive; it was my best birth experience yet
78. I found it helped so recommended other friends (P0; Intervention Arm).	Cognitive; I found it helped
79. Although it's not an essential item, it's a nice to have. Allows you to have a little more movement through the contractions and somewhere a bit more comfortable to sit or lean on (P1; Intervention Arm).	Movement; allows you to have a little more movement Easing; comfortable Upright / positions; to sit Support; lean on

Q.17. Would you like to make any other comments about using a birth ball in early labour? (65 responses)

1. Such a lovely experience for the birth of my baby. It was calming and natural (P1; Control Arm; used ball in trial).	Easing; calming and natural
2. Didn't have time to use it liked planned my labour was very fast. My water broke at 1 am. Tried to go to sleep but contractions where 2 mins apart so took a bath to see if it would slow. Stayed in the bath for an hour. Contractions stayed the same so we call the hospital and they told us to come in (P0; Intervention Arm; did not use ball in trial).	**No time**
3. Can't believe how much it helped, I was able to continue up to 8cm without pain relief and continued to use it on labour ward (P2; Control Arm; used ball in trial).	Cognitive; can't believe how much it helped, I was able to continue up to 8cm Drug-free; without pain relief
4. I wish you all the best for your study (P1; Control Arm; used ball in trial).	**Good wishes**
5. No (P0; Intervention Arm; used ball in trial).	**No**
6. **I think if I used it more before in the few weeks before due date, probably would have got more out of it** (P0; Intervention Arm; used ball in trial).	**Use in pregnancy**
7. I was 3cm for over 24 hours and the ball helped so much during this time. As soon as my waters broke (45mins later) I was 9cm and ready to push - I'm convinced the ball helped me get to this point! (P0; Intervention Arm; used ball in trial).	Cognitive; and the ball helped so much in this time, I'm convinced the ball helped get me to this point
8. My contractions started at 2pm that day... I really believed it was false starts. The ball worked to give me something to be comfy on and that was it. By 8pm I was tired with not progress and contractions had dropped from 10mins apart to 10 to 15. I woke up at around 11pm as they got back to every 10 mins and called the mat unit as I didn't know what to do and was advised to go in. I think if I knew i was in labour... or had a longer slower active labour I would have tried to use the ball more (P2; Intervention Arm; used ball in trial).	Easing; comfy
9. I found it very beneficial and stayed at home longer this time using the ball than sitting did during my first labour (P1; Intervention Arm; used ball in trial)	Cognitive; I found it very beneficial and stayed at home longer this time using the ball than sitting did during my first labour

10. No (P1; Control Arm; did not use ball in trial).	**No**
11. It's an easy and cheap alternative to drugs during early labour (P0; Control Arm; used a ball in trial).	Drug-free; it's an easy and cheap alternative to drugs
12. I decided not to use it for the reasons given (caused back pain when used when not in labour) (P1; Intervention Arm; did not use ball in trial).	Negative response
13. It was definitely worth a try! Hope someone got a good use out of it (P0; Intervention Arm; used ball in trial).	Cognitive;
14. I think it really helped me, I would certainly use a birth ball again as I wanted to go through labour and the birth as natural as possible without too much medical pain relief intervention as possible and the ball helped to stop that from happening until I had to due to my baby taking too long to arrive (P0; Intervention Arm; used ball in trial).	Cognitive; the ball helped to stop (medical pain relief intervention) Analgesia; without too much medical pain relief intervention
15. I was not given a birth ball so didn't have one (P0; Control Arm; did not use ball in trial).	**No**
16. The combination of birth ball and using a tens machine were very effective for me and enabled me to manage my contractions and have a natural birth without the need for additional pain relief (P0; Control Arm; used ball in trial).	Cognitive; enabled me to manage my contractions Analgesia; without the need for additional pain relief
17. Surprised at the difference (P2; Intervention Arm; used ball in trial).	Cognitive; surprised at the difference
18. **I used the ball during my pregnancy for core strengthening and comfort**. I had a relatively short labour (6 hours) and the ball really helped! (P0; Control Arm; used ball in trial).	Cognitive; I had a relatively short labour (6 hours) and the ball really helped **Used in pregnancy**
19. **I used the birth ball the evening before labour started** in order to encourage baby to move into the correct position. I did not use the birth ball once labour had started (P2; Intervention Arm; did not use ball in trial).	**Used in pregnancy**
20. Thank you for proving [sic] one! (P1; Intervention Arm; used ball in trial).	**Thanks**
21. Use one! Without a birth ball I would have needed pain relief. My third labour using one and with all labours no pain relief needed just the ball and a focused mind! (P2; Control Arm; used ball in trial).	Drug-free; without a birth ball I would have needed pain relief
22. No (P0; Intervention Arm; used ball in trial).	Cognitive; Use one!, needed just the ball and a focused mind
23. Baby born less than 3 hours later. **I used a ball every evening in the weeks prior to labour** (P2; Intervention Arm; did not use ball in trial).	**Used in pregnancy**

24. I unfortunately didn't use the ball as my contractions were very strong and frequent. I also had to go into hospital early as my waters weren't clear. And in the end I gave birth 2 hours later (P0; Intervention Arm; did not use ball in trial).	**No**
25. No thanks (P1; Control Arm; did not use ball in trial).	**No**
26. I found it useful in early labour. I did not know how to use it in the later stages of labour. If I had more knowledge on using a birthing ball I could have used it for longer in labour (P0; Control Arm; used ball in trial). 27. I would of [sic] used a birth ball in early labour if i got the chance as **I used it while pregnant and loved it** but my labour was so fast I didn't get the time! (P0; Control Arm; did not use ball in trial).	Cognitive; I found it useful in early labour **Used in pregnancy**
28. My contractions were infrequent for over a week, and stopping when I sat down, for this reason I stayed on my feet and did not use the ball. I had my waters broken and gave birth 2 hours later... so I am not sure that I actually had early labour this time? (P2; Control Arm; did not use ball in trial).	**No**
29. N/A (P0; Intervention Arm; used ball in trial).	**No**
30. N/A (P0; Control Arm; did not use ball in trial).	**No**
31. I think I was a lot more relaxed at home I think I could have had a home birth (P1; Intervention Arm).	Easing; I think I was a lot more relaxed at home; I could have had a home birth.
32. I wasn't selected to use it so no (P0; Control Arm; did not use ball in trial),	**No**
33. I feel I would have found the ball beneficial again if I'd had opportunity to labour at home (P1; Control Arm; did not use ball in trial).	**No**
34. I feel it may have been more effective if baby was not back to back (P0; Intervention Arm; used ball in trial).	Equivocal
35. I didn't use one (P6; Control Arm; did not use ball in trial).	**No**
36. **I used the birth ball when I arrived at hospital for an hour at 4cm dilated** and was very helpful in helping me feel more comfortable. I was unable to use at home due to contractions waking me and being 4 mins apart and into hospital within an hour and a half (P2; Control Arm; did not use ball in trial).	**Used ball in active labour** **No time at home**

37. I was not required to try the ball and found my best pain relief without the assistants of medicine or gas and air was to walk around, concentrate on my breathing and push against something (like a chair, wall etc.) either on all fours or standing up. I found when I was on the ball I was in discomfort, although I wasn't educated on proper use of a ball and am sure I didn't get the best out of it. I felt I needed to be more mobile and fluid and instead it created more pressure on my pelvic region. My contractions where between 2-4 minutes apart from when I was aware I was having my first one which is why I went to hospital the first time, also to find out if my waters had broke, which they had not at that point. I then returned home where the pain increased quickly with barely a break between contractions. I then went back into hospital an hour or so after my waters broke (about 6/7 hours into latent labour) as by that point I was in a lot of pain**. I would be keen to learn about the birth ball more and give it a better and more fair try next time** (P0; Control Arm; did not use ball in trial).	Equivocal **Would like to know more about ball**
38. I have no other labour experience to compare to but I definitely think the ball was helpful in allowing me to stay relaxed and able to manage my pain during contractions. I was able to stay at home until 8cm dilated (P0; Intervention Arm); used ball in trial).	Cognitive; I definitely think the ball was helpful, I was able to stay home until 8cm dilated, able to manage my pain, allowing me to stay relaxed Easing; stay relaxed
39. Unable to use the ball as I was not at home when I went into labour. The baby was early (P1; Intervention Arm; did not use ball in trial).	**Not at home**
40. I found when I sat on the ball I was very uncomfortable and in more pain. I found standing up or sitting back with my legs up more comfortable (P0; Control Arm; used ball in trial).	Negative response
41. I felt it made my contractions stronger (more painful) but I wish I could have used it more because I imagine labour could have been quicker because of that (P0; Control Arm; used ball in trial).	Equivocal response (regret)
42. I found the ball more helpful in early labour than when contractions became quite unbearable towards the end (P1; Intervention Arm; used birth ball).	Cognitive; I found the ball more helpful in early labour Negative
43. Highly recommend the use of a birth ball (P1; Intervention Arm; used birth ball).	Cognitive; highly recommend the use of a birth ball
44. I was not at home when my waters broke so did not have my ball with me, my contractions were 5 minutes apart within 1 hour of my waters breaking and they only got closer and closer. I asked for a ball when I got to hospital and I used it up until pushing. I truly believe I could not have got through my labour without the ball and I didn't use any pain relief. Dom is amazing and I thank her for introducing me to the ball (P0; Intervention Arm; did not use ball in trial).	**Used ball in active labour**

45. We were set up to use the birth ball at the hospital but by the time we were set up my labour had advanced quite quickly **and so there was no time to use the ball in the end (**P0; Control Arm; did not use ball in trial).	**No time to use the ball**
46. I did not really have a latent phase: SROM at 3pm, contractions started soon after and rapidly became strong and frequent and by 9pm when I got to hospital I was 5cm dilated. I think if I had had more of a latent phase I would have coped better and used the ball. As it was I panicked a bit because I was alone and I wasn't expecting things to happen so quickly and so didn't cope very well with the pain. Once I got to hospital, had support and went in the pool I coped much better (P0; Intervention Arm; did not use ball in trial).	**No time to use ball**
47. Very helpful ..every pregnant lady should use this (P0; Intervention Arm; used ball in trial).	Cognitive; very helpful
48. Would highly recomend [sic] using a Ball in early labour. Would definately [sic] use it again (P0; Control Arm; used ball in trial).	Cognitive; would highly recommend [sic]
49. Thanks for letting me be part of the programme (P0; Intervention Arm; used ball in trial).	
50. **The labour was very rapid** and my waters turned green rather than a straw colour so we were advised if this happened we should go to hospital straight away (P1; Intervention Arm; used ball in trial).	**Used ball in active labour** **No time to use ball**
51. In my third labour I did not use a ball at home. I did use one in hospital to try and encourage my waters to break (they had to be broken manually in the end) and to rest on when I got exhausted (P2; Control Arm; did not use ball in trial).	
52. In early labour it is amazing, I got through so much of it just using the ball and concentrating on it (P0; Intervention Arm; used ball in trial).	Cognitive; In early labour is amazing. I got through so much of it using the ball and concentrating on it.
53. No (P0; Intervention Arm; used ball in trial).	**No**
54. Would definitely use one again**,** i didn't get much use this time **as my labour was about 2 hours from start to finish** but i feel it would of helped had i had a longer labour (P1; Intervention Arm; used ball in trial).	Cognitive; would definitely use one again. **No time to use ball**
55. I think the positioning may have made for a quicker labour (P1; Control Arm; used ball in trial).	Upright / positions; the positioning Cognitive; may have made for a quicker labour

56. I found the ball the most helpful method of pain relief that I tried in early labour (P0; Intervention Arm; used ball in trial). 57. Thank you for letting me borrow it :-) (P1; Intervention Arm; used ball in trial). 58. I laboured with just gas and air (plus suction cap) because I'd stayed at home through the majority of the pain. Being in my own surroundings, a calm environment and using the ball, helped me cope with the process (P0; Control Arm; used ball in trial). 59. No (P2; Control Arm; used ball in trial). 60. I highly recommend! (P0; Intervention Arm; used ball in trial) 61. I didn't have a birth ball (P1; Control Arm; did not use ball in trial). 62. This was my 5th baby, every other labour I've arrived at hospital at 3cm dilated, this time I was 7-8cm, i think the ball helped speed things up, and helped me stay in control for longer (P4; Intervention Arm; used ball in trial). 63. It helped to relax me at the beginning but once my contractions were every 2 minutes the bell [sic] did not help, I never dilated past 3cm and still needed an epidural then emergency c section (P0; Intervention Arm; used ball in trial).	Cognitive; the most helpful method Analgesia; method of pain relief **Thanks** Analgesia; with just gas and air Easing; a calm environment Cognitive; helped me cope with the process **No** Cognitive; I highly recommend **No** Cognitive; I think the ball helped speed things up and helped me stay in control for longer Easing; it helped me at the beginning Negative
64. I continued with the birthing ball at hospital for a little while with gas and air (P1; Intervention Arm; used ball in trial).	**Used in hospital**
65. I had moved home 2 weeks before I went into labour, therefore I didn't have access to my ball. I feel I would have used it in early labour had this not been the case (P0; Control Arm; did not use ball in trial).	**No (regret)**

Box 17.3 Themes identified in Q.10.a, Q.11.a, Q.12. and Q.17.

Bouncing, rocking and rhythm

Movement,

Upright / positions

Physical support and leaning

Focus away from the pain and onto the strategies

Comfort and easing the pain

Cognitive empowerment and progress

Drug free

Negative / equivocal response

Other comments and trends

Appendix 18 Criteria for excellent qualitative research (adapted from Tracey 2010)

Criterion	Means, practices and methods	The BALL trial contribution
Worthy topic	**Relevant** **Timely** **Significant** **Interesting**	• Some qualitative research had previously explored women's experience of the latent phase at home, but none had explored women's experience of using a birth ball at home in the latent phase. • The latent phase was identified as a priority for research by a focus group
Rich rigor	**The study uses sufficient, abundant, appropriate and complex:** **Theoretical constructs** **Data and time in the field** **Sample(s)** **Context (s)** **Data collection and analysis processes**	• Theoretical constructs discussed in Section 4.12 • 90% of trial participants met CI personally over 10 month recruitment period. • High response rate to questionnaire and high response rate to invitation to provide free text responses from respondents (see above), with thick descriptions of labour experience and decision making.
Sincerity	**The study is characterised by:** **Self-reflexivity about subjective values, biases and inclinations of the researcher(s)** **Transparency about the methods and the challenges**	• Researcher embedded in the data and research context, however, perspectives balanced by objective findings . • Methods and challenges discussed in detail in Sections 4.12 and 5.9.
Credibility	**The research is marked by:** **Thick description, concrete detail, explication of tacit (nontextual) knowledge, and showing rather than telling**	• Thick description often provided by respondents' expanded answers • Findings triangulated with those of RCT • Mutivocal – high response to questionnaire and free text

	Triangulation or crystallisation **Multivocality** **Member reflections**	components provides multivocality • Member reflections – not incorporated, but respondents provided written responses
Resonance	**The research influences, affects or moves particular readers or a variety of audiences through:** **Aesthetic, evocative representation** **Naturalistic generalizations** **Transferable findings**	• Respondents chose to offer their own labour and birth experiences, particularly in Q.17; these are moving and compelling, all the more so because they were given spontaneously with little prompting. • Findings are not presented as case studies, so naturalistic generalization is not applicable here. • The wide range of experiences and the similarity of coding between prior ball experience (Q.6a & Q.6b) and experience during the trial (Q.10a and Q.10b) suggests that the findings are transferable to other labouring women in other contexts.
Significant contribution	**The research provides a significant contribution:** **Conceptually** **Practically** **Morally** **Methodologically** **Heuristically**	The findings from the BALL trial and their impact are discussed in detail in Chapters 5.0 and 6.0. However, the findings have practical and heuristic implications for clinical care and as a basis for future research.

Appendix 19 Distribution histograms

Figure 19.1 . VAS score distribution by trial arm

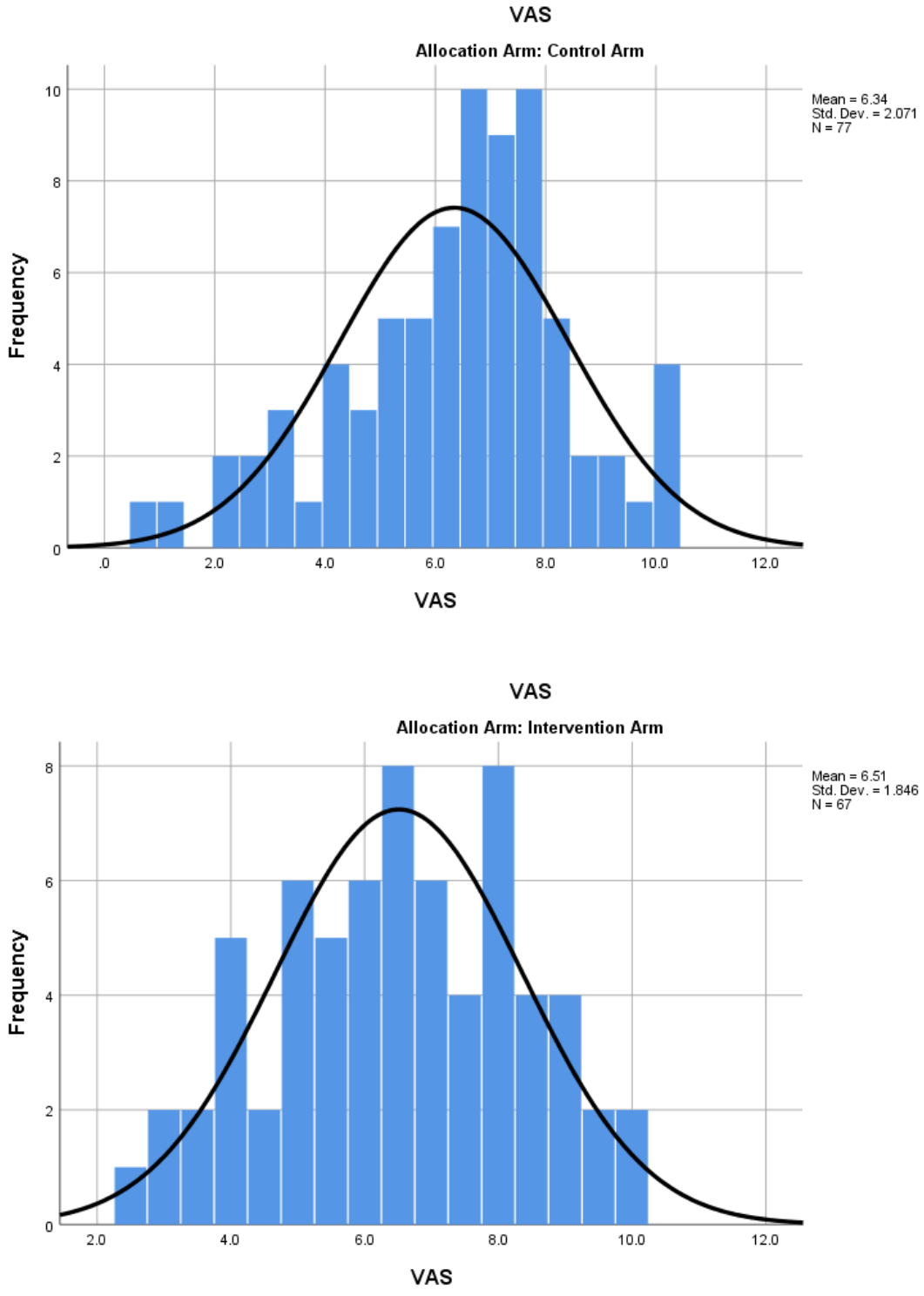
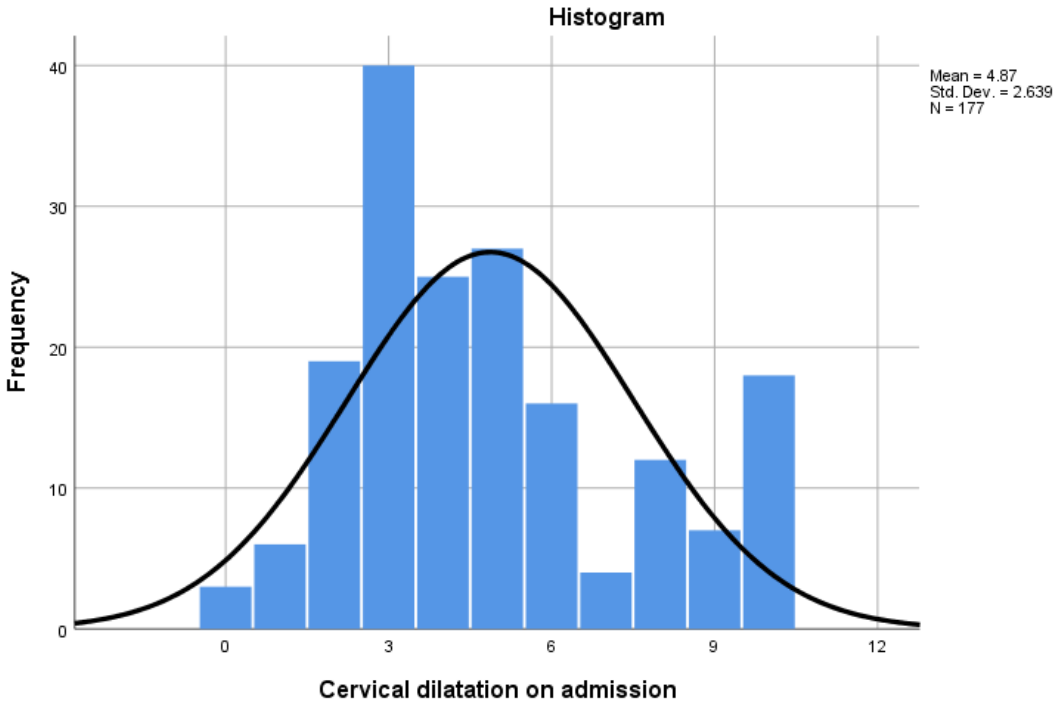
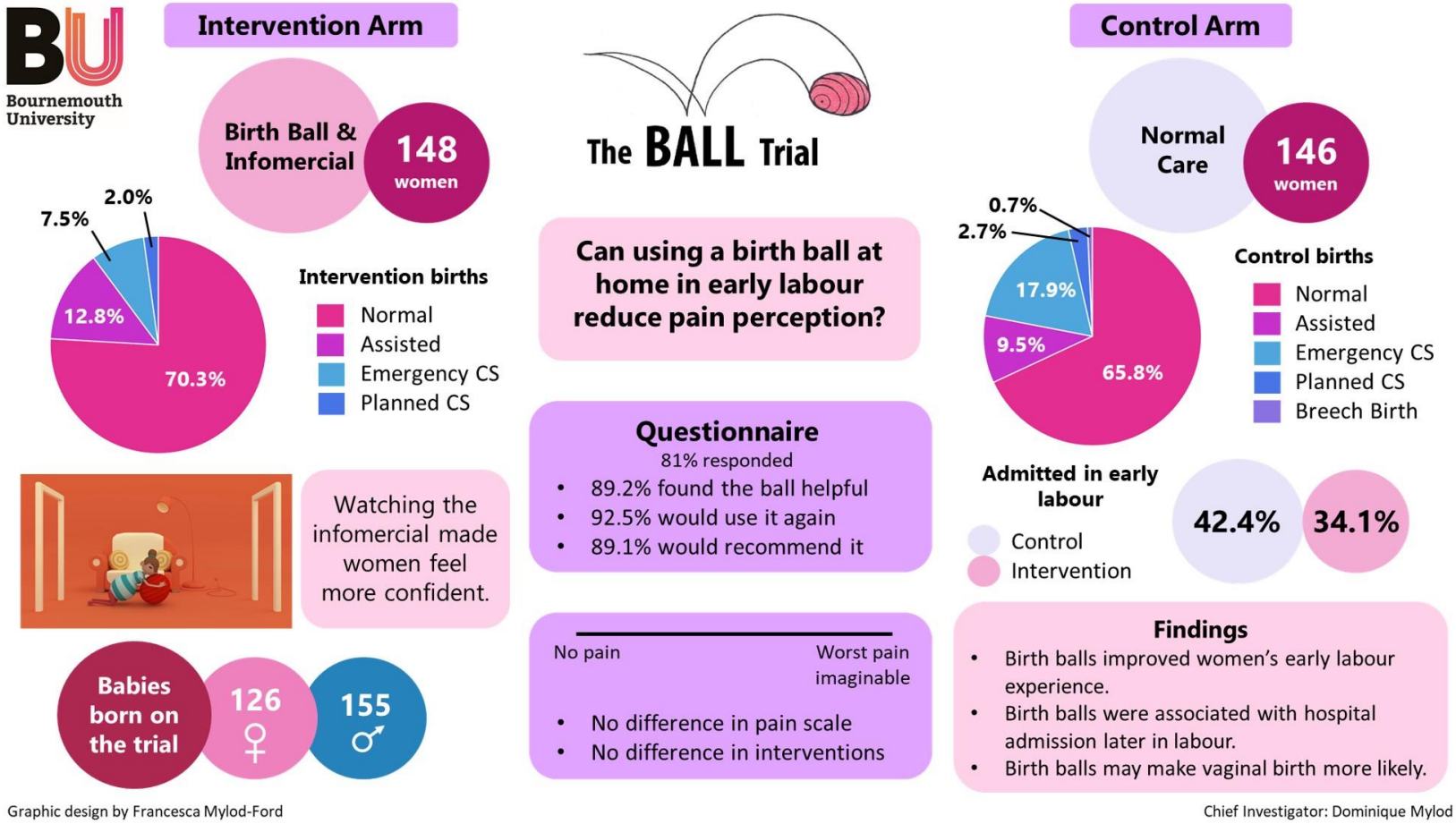


Figure 19.2 Cervical dilatation on admission distribution



Appendix 20 Infographic



Glossary

active labour

The period of time when progressive cervical dilatation is expected to occur in normal labour towards full dilatation at 10 cm. Within current UK guidelines, this is defined as from 4 cm cervical dilatation (NICE 2017).

amniotomy

A procedure undertaken by a midwife or obstetrician to insert an amnihook through the dilated cervix to puncture the membranes and release the amniotic fluid surrounding the fetus. This stimulates uterine contractions to induce or augment labour.

assisted birth

The delivery of a baby following 10cm cervical dilatation using forceps or a Ventouse (vacuum device) applied to the fetal head to expedite a vaginal birth.

augmentation

A care pathway which refers either to performing an amniotomy / administering intravenous synthetic oxytocin in order to stimulate uterine contractions for a diagnosed labour dystocia or for a Prolonged Release of Membranes.

birth ball

Also known as a Swiss, Pezzi, gym or fit ball. Vinyl inflated ball, typically 65cm in diameter, used in rehabilitation, fitness and maternity care.

caesarean section (CS)

The delivery of a fetus through a surgical incision, usually in the lower abdomen either as an elective (planned) or emergency procedure.

catecholamines

A group of neurotransmitters, which include epinephrine (adrenaline) and norepinephrine (noradrenaline) secreted by the adrenal medulla in response to physiological or psychological stress.

epidural / regional anaesthesia

An anaesthetic technique used in maternity care. It typically involves the insertion of a fine catheter into the epidural space around the spinal cord. A mixture of medium duration local anaesthetic and opioid drugs are then administered to achieve a temporary sensory block, although some degree of motor block is inevitable (Obstetric Anaesthetists Association 2013).

induction of labour

A care pathway which involves utilising pharmacological products to artificially stimulate cervical effacement and dilatation as well as uterine contractions to initiate labour. Amniotomy and intravenous synthetic oxytocin are also used to stimulate contractions.

Intrauterine Growth Restriction (IUGR)

A fetus that grows more slowly *in utero* than the projected Growth Assessment Programme growth curve, as determined by ultrasound biophysical measurement.

labour ward / delivery suite

A unit in which obstetricians take primary professional responsibility for women at high risk of complications during labour and birth. Midwives offer care to all women in these units, whether or not they are considered at high or low risk, and take primary responsibility for women with straightforward pregnancies during labour and birth. (Midwifery Services Liaison Committee 2013)

latent phase of labour

Sometimes referred to as ‘early’ or ‘prodromal’ labour.

‘…….. a period of time, not necessarily continuous, when:

- there are painful (uterine) contractions **and**
- there is some cervical change, including effacement and dilatation up to 4cm’ (NICE) 2017, p.24).

For this research project and as a reflection of the guidelines in the research context, the NICE (2017) definition and parameter of a cervical dilatation of 4cm will be adopted, to reflect the context of current guidelines within the research setting.

To reflect contemporary usage, the term ‘latent phase’ is used in this thesis; the term ‘early labour’ is used in communicating with trial participants and the public.

Large for Gestational Age (LGA)

There is no current consensus of an LGA fetus, which varies from an estimated fetal weight of 4000 – 4500g or at or above the 90^{th} – 95^{th} projected weight at a given gestation from 28 weeks onwards and as determined by ultrasound biophysical measurement.

multip / multiparous

A woman who is pregnant and has previously given birth. Denoted by P1, P2, P3 and so on, depending on the number of previous births at or above 24 weeks’ gestation. Note: on rare occasions, a woman may have given birth to a live baby at the edge of viability at less than 24 weeks’ gestation.

oxytocin

A nonapeptide hormone produced in the posterior pituitary gland. The hormone of ‘calm and connection’, oxytocin mediates uterine contractions and lactation as well as parenting behaviours and social bonding (Moberg 2011).

post-term

A fetus / pregnancy beyond 40 weeks' gestation.

pre-term

An infant born before 37 weeks' gestation.

primip / primiparous

Also referred to as '**nullip / nulliparous'**. A woman who is either pregnant for the first time, or with her first ongoing pregnancy / birth. Denoted by P0.

prostaglandins

A group of physiologically active lipids which exert localised hormonal effects. They are significant chemical mediators in the latent phase for cervical effacement and dilatation as well as stimulating uterine contractions.

Small for Gestational Age (SGA)

A fetus / infant who may be constitutionally small but otherwise healthy. In the Growth Assessment Programme, an SGA fetus is below the 10^{th} centile of their projected weight at a given gestation from 28 weeks onwards and as determined by ultrasound biophysical measurement.

synthetic oxytocin

An artificial analogue of oxytocin. Marketed as Syntocinon® in the UK or Pitocin® in the USA. It is administered intravenously to stimulate uterine contractions in order to induce or augment labour.

Abbreviations

antenatal(ly)	AN
Awareness of Fetal Movements and Care Package to Reduce Fetal Mortality	AFFIRM
Ball Assisted Latent Labour trial	BALL trial
Body Mass Index	BMI
Bournemouth Online Research Data Repository	BORDaR
Bournemouth University Research Online	BURO
British Nursing Index	BNI
caesarean section	CS
centimetres	cm
Chief Investigator	CI
Childbirth Self-Efficacy Inventory	CBSEI
Community Midwife	CMW
Continuous Electronic Fetal Monitoring	CEFM
Copyright	©
Cumulative Index of Nursing and Allied Health	CINAHL
Database of Abstracts and Reviews	DARE
degrees of freedom	df
Detection of the Small for Gestational Age Neonate trial	DESiGN trial
Elton B. Stephens Company	EBSCO

Estimated Date Birth / Delivery	**EDB / EDD**
General Practitioner	**GP**
Growth Assessment Programme	**GAP**
Hands On Or Poised trial	**HOOP trial**
Health Research Authority	**HRA**
Induction of labour	**IOL**
International Association for the Study of Pain	**IASP**
International Standard Randomised Controlled Trial Number	**ISRCTN**
Information Technology	**IT**
Intrauterine Growth Retardation	**IUGR**
Intrauterine death	**IUD**
Large for Gestational Age	**LGA**
Maternity Services Liaison Committee	**MSLC**
Medical Research Council	**MRC**
millimetre	**mm**
National Health Service	**NHS**
National Institute of Health and Care Excellence	**NICE**
National Institute for Health Research	**NIHR**
Not Applicable	**N/A**
Open System for Information on Grey Literature	**OpenSIGLE**
Outcome Expectancy	**OE**

Patient-Public-Interaction	**PPI**
Population-Intervention-Comparison-Outcome	**PICO**
postnatal(ly)	**PN**
Pragmatic-Explanatory Continuum Indicator Summary 2	**PRECIS-2**
Preferred Reporting Items for Systematic Reviews and Meta-Analyses	**PRISMA**
Pre-term Prolonged Release of Membranes	**PPROM**
Prolonged Release of Membranes	**PROM**
Randomised Controlled Trial	**RCT**
Registered Trade Mark	**®**
Research Ethics Committee	**REC**
Royal College of Midwives	**RCM**
Royal College of Obstetricians and Gynaecologists	**RCOG**
Self-efficacy Expectancy	**SE**
Short Message System	**SMS**
Small for Gestational Age	**SGA**
Spontaneous Release of Membranes	**SROM**
Standard deviation	**SD**
Standard protocol Items: Recommendations for International Trials	**SPIRIT**
Statistical Package for Social Sciences	**SPSS**

Uniform Resource Location	**URL**
United Kingdom Database of Uncertainties about the Effects of Treatments	**UK DUETS**
United Kingdom	**UK**
United States of America	**USA**
Visual Analogue Scale	**VAS**
World Health Organization	**WHO**