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The Ball Assisted Latent Labour trial

Submission date
19/04/2018

Recruitment status
No longer recruiting

Registration date
10/05/2018

Overall study status
Completed

Last Edited
21/08/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hospital admission in the latent phase of labour (or 'early labour') is associated with higher rates of intervention, such as using a hormone drip to speed up labour, breaking waters, continuous electronic foetal monitoring and Caesarean section. These all contribute to increased problems for mothers and babies during and after birth. Women sent home from hospital in early labour to 'await events' feel anxious and say that pain is their main reason for seeking hospital admission in early labour.
Using a birth ball to remain mobile in full labour reduces women's pain perception and their anxiety. However, no research has examined the effect of using birth balls at home in early labour to see if women find their contractions less painful and have less complicated labours. Promoting birth ball use at home in the latent phase of labour may enhance women's confidence and reduce their pain perception. This may help them to delay going into hospital until their labour is established.
This study involves a randomised, controlled, single centre trial with two parallel groups of low risk pregnant women.

Who can participate?
Pregnant women aged over 18 years who plan to give birth in hospital and have a low risk of problems giving birth.

What does the study involve?
Following recruitment and consent at 28 weeks' gestation 332 women will be randomly allocated to two groups. The Intervention Arm will be asked to access an online animated 90-second infomercial and offered the loan of a birth ball to use early labour at home. Control Arm participants will receive normal care provided by the NHS Trust. Participants will be asked to record their pain on a scale from 0-10 when they go into hospital in labour. Both Arms will be followed up 6 weeks' postnatally with an online questionnaire to evaluate how many women used the ball at home in early labour and whether they found it helpful.

What are the possible benefits and risks of participating?
There are no risks to the health of the mother or baby. For example, if the birth plan changes and it is recommended that labour should be induced or that the baby should be born by caesarean section, then participants are free to follow advice. Participants are not required to use the birth ball if they do not wish to do so, or stay on it for a fixed length of time. 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.

Where is the study run from?
St. Mary's Hospital, Newport, Isle of Wight, UK.

When is the study starting and how long is it expected to run for?
Participants will be recruited between February 2018 and October 2018.

Who is funding the study?
Wessex Integrated Clinical Academic Training Programme through Bournemouth University and the Isle of Wight NHS Trust.

Who is the main contact?
Dominique Mylod, dmylod@bournemouth.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
194437

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 194437

Study information

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

Acronym
The BALL trial

Study objectives
Using a birth ball at home in the latent phase of labour reduces pain perception compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central- Hampshire B Research Ethics Committee, 11/12/17, 17/SC/0534

Study design
Single-centre non-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format; please use contact details to request a Participant Information Sheet.

Health condition(s) or problem(s) studied
Pain in the latent phase of labour

Interventions
Following recruitment and consent at 28 weeks' gestation, participants are randomised into Control or Intervention Arms via an online randomisation service (Sealed Envelope 2016). The Control Arm receives usual care. The Intervention Arm accesses a 90-second online animated infomercial 'Having A Ball in Early Labour' at 36 weeks' gestation. They are also offered the loan of a birth ball to use at home in the latent phase of labour. Participants will be asked to record their pain on a scale from 0-10 when they go into hospital in labour. Both Arms will be followed up 6 weeks postnatally with an online questionnaire to evaluate how many women used the ball at home in early labour and whether they found it helpful.

Intervention Type
Mixed

Primary outcome measure
Proportion of participants who show a reduction in visual analogue scale (VAS) pain scores of 1 point or more when women are admitted to hospital in labour.

Secondary outcome measures
1. Changes in Outcome Expectancy and Self-Efficacy Expectancy CBSEI scores in Intervention Arm participants before and after viewing the infomercial
2. Amniotomy, syntocinon augmentation, CEFM, epidural and CS rates will be descriptively analysed as the sample size is too small to detect significant differences
3. Measures of birth ball uptake, acceptability and satisfaction will be descriptively presented

Overall study start date
05/01/2015

Completion date
20/07/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Able to understand, read and speak English
3. Planned hospital labour and vaginal birth
4. Spontaneous labour
5. Singleton cephalic pregnancy >37 weeks gestation
6. Home internet access

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
332

Key exclusion criteria
1. <18 years old
2. Not able to understand, read and speak English
3. Planned home birth

4. Elective Caesarean section (CS)
5. Induction of labour
6. Non-cephalic presentation
7. <37 weeks gestation
8. Body Mass Index >35 kg/m2 at booking
9. Previous CS or other uterine surgery
10. Antenatal diagnosis of foetal anomaly, intrauterine growth restriction, foetal growth <10th centile or intrauterine death
11. Pre-existing maternal medical conditions e.g. cardiac, endocrine
12. Previous stillbirth
13. Obstetric complications e.g. intrahepatic cholestasis
14. Current use of recreational or prescribed analgesic medication

Date of first enrolment
01/02/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Mary's Hospital
Parkhurst Road
Newport, Isle of Wight
United Kingdom
PO30 5TG

Sponsor information

Organisation
Bournemouth University

Sponsor details
Research and Knowledge Exchange M402 Melbury House
1 - 3 Oxford Road
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BH8 8ES

Sponsor type
University/education

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
Not defined

Funder Name
Wessex Integrated Clinical Academic Training Programme

Results and Publications

Publication and dissemination plan
Submission of Literature Review and Protocol imminent. Results and findings to be published in 2019.

Intention to publish date
31/01/2024

Individual participant data (IPD) sharing plan
The BALL Trial deindentified and anonymised data will be stored in the Bournemouth Online Data Repository (BORDaR) https://bordar.bournemouth.ac.uk/ .Data will available for anyone following the conclusion of the researcher's doctorate programme in 2019 and retained for 5 years according to the University Data Management regulations.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No