

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Effects of birth ball exercise on labor pain and self-efficacy : A randomised controlled trial in Shahrekord

Protocol summary

Summary

Labour pain and its management remains a primary concern for childbearing women, their families, and their health-care providers. Pharmaceutical and non-pharmaceutical ways be considered for labor pain relief. Many women approach childbirth with a desire to avoid pharmacologic pain relief agents or to minimise their use. Coping strategies can assist in the pain management process. Self-efficacy playing an important role in a woman's ability to cope and indicated that self-efficacy affects childbirth experiences, both in terms of bodily functions and in thoughts and feelings regarding childbirth. If women are highly self-confident, they will be able to cope with childbirth, enjoying a positive childbirth experience. the birth ball has been shown to be a valuable and comfortable tool in clinical practice that have effects on coping ability. This study will be conducted to examine the effects of a birth ball exercise programme during childbirth in terms of childbirth self-efficacy and childbirth pain. Design: randomised controlled trial. Methods: the study will conducted in 60 pregnant women who refere to lajar birth center for prenatal care. participants will be allocated by block randomisation into the two arms of the study(intervention & control). Intervention group will receive the birth ball exercise programme consisted of a booklet and films, with periodic follow-ups during prenatal checks. Both the experimental and control groups received standard midwifery care. Measurements: the women will complete demographic information, the Childbirth Self-efficacy Inventory (CBSEI), and the short form of the McGill Pain Questionnaire (SF-MPQ) in active phase of labor(cervical dilations four and eight centimetres) and at second stage of labor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120631238N2**

Registration date: **2017-03-08, 1395/12/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-08, 1395/12/18

Registrant information

Name

shahnaz Kohan

Name of organization / entity

Isfaha University of Medical Sciences

Country

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+98 31 3792 3078

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of birth ball exercise on labor pain and self-efficacy : A randomised controlled trial in Shahrekord

Public title

Birth ball effect on labor pain and self-efficacy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (1) pregnant women aged between 18-35 years old (2) women are 30–32 weeks of gestation (3) had no major obstetric or medical pregnancy complications according to the maternal booklet (eg hypertention or anemia) (4) a singleton pregnancy (5) ability to undertake activities (6) the ability to speak, read, and write persian, (7) had no conterandiation for normal delivery like placenta previa.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib

City

Isfahan

Postal code**Approval date**

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MUI.REC.1394.2.147

Health conditions studied**1****Description of health condition studied**

Normal delivery

ICD-10 code

080

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes**1****Description**

Pain

Timepoint

In active phase of labor and second stage of labor

Method of measurement

Mcgill pain Standard questionnaire

Secondary outcomes**1****Description**

Self efficacy

Timepoint

In active phase of labor and second stage of labor

Method of measurement

Low self-efficacy Standard questionnaire

Intervention groups**1****Description**

The birth ball exercise programme for 6-8 weeks, consisted of a booklet and films, with periodic follow-ups for home exercise and routine prenatal cares

Category

Other

2**Description**

Routine exercise prenatal care for control group

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hajar Hospital of Shahrekord

Full name of responsible person

Ziba Raeisi Dehkordi

Street address**City**

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar Jarib

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Morvarid Ghasab Shirazi

Position

PhD Candidate Student Reproductive Health

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty