Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Clinical trial to compare the effect of the participate and not participate in courses of the physiologic delivery on pregnant woman self-efficacy

Protocol summary

Summary

Objectives: This clinical trial has been designed to evaluate the effect of educational course of the physiologic delivery on pregnant woman self-efficacy. Design: The study population will be pregnant woman who refer to selected Isfahan health centers. Mothers randomly will be divide into two groups, one group is control (without training) and another be intervention (with 8 sessions training). Sample size is thirty six women in each group. This study is a single blind clinical trial for participants in the intervention and control groups. Setting and conduct: With available sampling, gradually selected pregnant women eligible inclusion criteria and randomly placed in the intervention and control groups. Inclusion criteria: mothers with age 18-32 years; ability to read and write. Exclusion criteria: multipara pregnancy with CS history; PROM; preterm delivery in the current pregnancy; gestational hypertension; cervical failure; IUGR; multiple pregnancy; placenta previa after 27 weeks of pregnancy; two and three trimester persistent bleeding. Intervention: For intervention group, eight educational sessions (benefits of vaginal delivery, exercise for pregnancy and childbirth, relaxation exercise during labor and physiologic delivery) will be held during pregnancy. The control group will not receive any training. Main outcome measures: Before, one week and one month after intervention, pregnant woman self-efficacy will be evaluated by the questionnaire in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112223657N2**
Registration date: **2016-02-06, 1394/11/17**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

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Zeinab Heidari
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-08-24, 1394/06/02

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare the effect of the participate and not participate in courses of the physiologic delivery on pregnant woman self-efficacy

Public title

Survey the effect of educational course of the physiologic delivery on pregnant woman self-efficacy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: mothers with age 18-32 years; ability to read and write. Exclusion criteria: multipara pregnancy with CS history; PROM; preterm delivery in the current pregnancy; gestational hypertension; cervical failure; IUGR; multiple pregnancy; placenta previa after 27 weeks of pregnancy; two and three trimester persistent bleeding

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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, Hezarjerib St.

City

Isfahan

Postal code

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

IR.MUI.REC.1394.4.092

Health conditions studied

1

Description of health condition studied

Self-efficacy

ICD-10 code

075.5

ICD-10 code description

Maternal distress during labour and delivery

Primary outcomes

1

Description

Pregnant woman self-efficacy

Timepoint

Before, one week and one month after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For intervention group, 8 educational sessions (benefits of vaginal delivery, exercise for pregnancy and childbirth, relaxation exercise during labor and physiologic delivery) will be held during pregnancy.

Category

Behavior

2

Description

The control group will not receive any training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Navab Health and Treatment Center

Full name of responsible person

Street address

Bozorgmehr St. Ahmad Abad Sq.

City

Isfahan

2

Recruitment center

Name of recruitment center

Eighteen Khajo Health and Treatment Center

Full name of responsible person

Street address

Sharif Vaghefi St.

City

Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mahdi Neamatbakhsh
Street address
Isfahan University of Medical Sciences, Hezarjerib St.
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
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00
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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