

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effectiveness of physiological childbirth education on pregnant women's stress and their mental health

Protocol summary

Summary

This randomized clinical trial study was conducted on 50 pregnant women referring to Motazedi hospital in Kermanshah in 2015. The purpose of this study is evaluation of physiological childbirth education effectiveness on pregnant women's stress and mental health. Inclusion criteria include: Gestational age at least 20 weeks; Not suffering from anxiety and depression; Lack of warning signs during pregnancy; Do not suffering from abnormal stress due to adverse events and exclusion criteria include: Dissatisfaction from the continued cooperation with the research; being absent three session or more of classes; occurrence of any problems during the study (pre-eclampsia, placenta previa, preterm labor symptoms of multiple pregnancy, PROM, etc.); Abnormalities and fetal death. The subjects were randomly divided into intervention and control groups. In the first meeting, before the start of classes, the questionnaires were completed by samples. In intervention group samples took part in educational classes that were 8 sessions and each sessions lasted ninety minutes. But women in control group remained untrained. The instruments used in this study are: self-made questionnaire of demographic characteristic, stress anxiety depression scale (DASS-21), Goldenberg mental health questionnaire (GHQ-28) which held in pretest and posttest on experimental and control groups. Fetal heart rate and blood pressure were controlled before the start of each session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100427633N2**

Registration date: **2016-10-17, 1395/07/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-17, 1395/07/26

Registrant information

Name

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Name of organization / entity

Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Kermanshah Branch

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of physiological childbirth education on pregnant women's stress and their mental health

Public title

Effectiveness of physiological childbirth education on pregnant women's stress and their mental health

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Lack of anxiety and depression; do not using psychotropic drugs before and during pregnancy; Lack of warning signs during pregnancy; Do not suffering from abnormal stress due to adverse events. Exclusion criteria:Dissatisfaction from continued cooperation with the research; being absent three session or more of classes; occurrence of any problems during the study (pre-eclampsia, placenta previa, preterm labor symptoms of multiple pregnancy, PROM, etc.); Abnormalities and fetal death.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Islamic Azad University of Imam Khomeini Complex

Street address

Ferdowsi Square,The end of town of experts

City

Kermanshah

Postal code

Approval date

2015-11-16, 1394/08/25

Ethics committee reference number

19220701941020

Health conditions studied

1

Description of health condition studied

stress and mental health

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Stress

Timepoint

Before the first training session and at the end of the eighth session (last session)

Method of measurement

Depression Anxiety Stress Scale questionnaire

2

Description

mental health

Timepoint

Before the first training session and at the end of the eighth session (last session)

Method of measurement

General Health Questionnaire

Secondary outcomes

1

Description

Fetal heart rate

Timepoint

Before the start of each session

Method of measurement

Hearing with Sonokids

2

Description

Blood pressure of mother

Timepoint

Before the start of each session

Method of measurement

Blood pressure measurement

Intervention groups

1

Description

Control group: lack of education

Category

Prevention

2

Description

Intervention group :physiological childbirth education,number of eight sessions, each session for 90 minutes. Control group: lack of education

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Moatazedi hospital Kermanshah
Full name of responsible person
Shohreh Ayoubi
Street address
Moatazedi hospital Kermanshah, Ferdowsi Square
City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University Kermanshah Branch
Full name of responsible person
Mokhtar Arefi
Street address
End of town of experts, Ferdowsi Square
City
Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Kermanshah Branch

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
Kermanshah Medical Sciences
Full name of responsible person
Shohreh Ayoubi
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah Medical Sciences
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Frozan Sharifipour
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MSc in Midwifery
Other areas of specialty/work
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unit of 12, Mahestan building, Alley 23, Kashani Street, Town of Elahiyeh
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Postal code
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00
Fax
Email
Web page address

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