

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of cognitive- behavioral educations on childbirth self-efficacy and maternal role adaptation and fear of childbirth in nulliparous women

Protocol summary

Study aim

Effect of cognitive- behavioral educations on childbirth self-efficacy and maternal role adaptation and fear of childbirth in nulliparous women

Design

Semi experimental study with control group, with two parallel groups design of 70 patients

Settings and conduct

This study will be performed in the prenatal clinic of the Milad hospital. During the weeks 26 to 28 of pregnancy, completed the demographic questionnaire, general health questionnaire, Wijma Delivery Expectancy/ Experience Questionnaire Version A and Child Birth Self-Efficacy Inventory will be collected by the participants from the two groups of intervention and control. Then, the training classes will be started from 28th weeks of pregnancy during 8 sessions of 90 minutes and once a week that their contents are equal to cognitive-behavioral training. In each session, the homework of the previous sessions will be checked and also the specific practice will be given for the next session. at the last cognitive and behavioral training sessions, the questionnaire of fear of delivery and self-efficacy will be completed by the two different groups. In addition, two and eight weeks after delivery, the Maternal Role Adaptation Questionnaire and the Wijma Delivery Expectancy/ Experience Questionnaire Version B will be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-35 years old, Diploma and higher education, Single pregnancy, Nullipara, 28-26 week of gestational age, Scoring 65 and above Fear of Childbirth, Scoring 3 / 5 and less general health questionnaire, No history of infertility

Intervention groups

1. In the cognitive-behavioral education, the classes are conducted from 28 to 35 weeks of gestation during 8 sessions of 90 minutes weekly. 2. In the control group, the sample does not receive any intervention.

Main outcome variables

maternal role adaptation, self-efficacy, Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N3**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cognitive- behavioral educations on childbirth self-efficacy and maternal role adaptation and fear of childbirth in nulliparous women

Public title

Effect of cognitive- behavioral educations in nulliparous women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

18-35 years old Diploma and higher education Single pregnancy Nullipara 28-26 week of gestational age Scoring 65 and above in Fear of Childbirth Scoring 3 / 5 and less in general health questionnaire No history of infertility

Exclusion criteria:**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: **70**

Randomization (investigator's opinion)

Not 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**

Ethics committee of Iran University of Medical Sciences

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Hemat highway next to milad tower, Tehran

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Tehran

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1449614535

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC.1397.346

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

cognitive- behavioral education

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Maternal role adaptation

Timepoint

2 weeks and 2 months after childbirth

Method of measurement

Maternal role adaptation questionnaire

2**Description**

Fear of childbirth

Timepoint

Before intervention at 26-28 week gestation, before and immediately after intervention and 2 weeks and 2 months after childbirth

Method of measurement

Delivery expectancy/ experience questionnaire version A, Fear of childbirth questionnaire version B

3**Description**

Childbirth self-efficacy

Timepoint

Before intervention at 26-28 week gestation, before and immediately after intervention

Method of measurement

Child birth self-efficacy inventory questionnaire

Secondary outcomes

empty

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

The intervention group (cognitive-behavioral educations and childbirth preparation classes in two distinct classes), the beginning of cognitive-behavioral educations classes, is conducted from 28 to 35 weeks of gestation during 8 sessions of 90 minutes, including:

session 1: the importance of classes cognitive and behavioral, emotional disturbances, awareness of fear of childbirth and How to encounter, session 2: familiarity with cognitive- behavioral educations, session 3: familiarity with cognitive distortions and empowering individuals, session 4: solution for an issue, , session 5: training to remember, session 6: familiarity with the concept of childbirth self-efficacy and maternal role adaptation, session 7: definition, principles and action of self-acceptance in person, session 8: an review of past sessions, plans for changing mind and behavior in the future, encouraging to continue exercises, giving feedback and saying goodbye.

Category

Other

2**Description**

Control group: Control (taking part in childbirth classes) does not receive any intervention

Category

Other

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

Milad hospital

Full name of responsible person

Fatemeh Eidozaei

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Eidozaei

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available