Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of cognitive restructuring based on therapeutic metaphor on fear of childbirth in primiparous women

Protocol summary

Study aim
Investigating the effectiveness of cognitive restructuring based on therapeutic metaphor on fear of childbirth in primiparous women

Design
This is a randomized clinical trial with a parallel design and control group. This randomized, non-blinded study will be conducted on eligible pregnant women. The randomized block design will be used for randomization, and participants will be assigned to two intervention and control groups.

Settings and conduct
This non-blinded study will be conducted at the Hafezieh Health Center in Kermanshah. At the beginning of the study, a fear of childbirth questionnaire will be provided to primiparous women.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent; Gestational age between 28 and 32 weeks; Obtaining a score of 66-84 on the fear of childbirth questionnaire; Being a firstborn; Having a singleton pregnancy Exclusion criteria: History of underlying disease or complications during pregnancy (preeclampsia, gestational diabetes); History of taking neuroleptic drugs; History of smoking addiction; History of alcohol and drug use; History of recurrent miscarriages (3 or more consecutive miscarriages); History of infertility; Indication for cesarean delivery

Intervention groups
The intervention group, in addition to routine prenatal care, will receive 6 group sessions (one session per week), each session lasting 60-90 minutes, of cognitive restructuring intervention based on metaphor therapy. The control group will receive routine prenatal care according to the national protocol.

Main outcome variables
Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N273**
Registration date: **2026-01-09, 1404/10/19**
Registration timing: **prospective**

Last update: **2026-01-09, 1404/10/19**
Update count: **0**

Registration date
2026-01-09, 1404/10/19

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 1821 4653

Email address
fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-10, 1404/10/20

Expected recruitment end date
2026-02-19, 1404/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of cognitive restructuring based on therapeutic metaphor on fear of childbirth in primiparous women

Public title
Investigating the effectiveness of cognitive restructuring on fear of childbirth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent Gestational age between 28 and 32 weeks Obtaining a score of 66-84 on the fear of childbirth questionnaire Being a first-born Having a singleton pregnancy

Exclusion criteria:
History of underlying disease or complications during pregnancy (preeclampsia, gestational diabetes) History of taking neuroleptic drugs History of smoking addiction History of alcohol and drug use History of recurrent miscarriages (3 or more consecutive miscarriages) History of infertility Indication for cesarean delivery

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a random block. These blocks are created by a computer using the https://www.sealedenvelope.com site, and each individual will be given a unique code to ensure careful concealment of the randomization process. The generation of blocks and assignment of codes will be done by a third party (the person in charge of the selected center) who has no role in the process of assigning individuals to groups. The allocation ratio between the control and intervention groups is considered to be 1:1, meaning that in each block of four, two individuals will be assigned to the control group and two individuals to the intervention group.

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 Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kerrmanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2025-12-06, 1404/09/15

Ethics committee reference number
IR.KUMS.REC.1404.520

Health conditions studied

1

Description of health condition studied
Fear of childbirth

ICD-10 code
F40

ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Fear of childbirth

Timepoint
One week and four weeks after the intervention and during the first week after delivery

Method of measurement
Using the Fear of Childbirth Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group, in addition to routine prenatal care, will receive 6 group sessions (one session per week), each session lasting 60-90 minutes, of cognitive restructuring intervention based on metaphor therapy. Summary of the intervention includes: awareness of the role of thoughts in creating fear of childbirth, replacing rational thoughts with thoughts that cause fear of

childbirth, defining catastrophizing and hasty conclusions of a prophetic nature, and expressing an analogy related to catastrophizing.

Category
Behavior

2

Description
The control group will receive routine prenatal care according to the national protocol.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafeziyeh Health Center

Full name of responsible person
Zahra Zaeri

Street address
Next to Hafeziyeh Girls' Middle School, 45 meters from Hafeziyeh 2nd, Hafeziyeh

City
Kermanshah

Province
Kermanshah

Postal code
671581154

Phone
+98 83 3836 7909

Email
ZahraZaeri8486@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Zohreh Rahimi

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
Zrahimi@kums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Zahra Zaeri

Position
Master's degree student in consulting in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing and Midwifery Dolatabad Blvd, Isar Square

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3826 6429

Email
ZahraZaeri8486@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Mastaneh Kamravamanesh

Position
University faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Faculty of Nursing and Midwifery Dolatabad Blvd, Isar Square

City

Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3826 6429
Email
kamravamanesh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Mastaneh Kamravamanesh
Position
University faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Faculty of Nursing and Midwifery Dolatabad Blvd, Isar Square
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3826 6429
Email
kamravamanesh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information 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