Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-based stress reduction counseling on maternal-fetal attachment in women with fear of childbirth

Protocol summary

Study aim
The effectiveness of mindfulness-based stress reduction (MBSR) counseling on maternal-fetal attachment in women with a fear of childbirth

Design
This randomized clinical trial is non-blindeda with a parallel design and control group. This randomized study will be conducted on 60 eligible pregnant women with a fear of childbirth. A randomized block design will be used for randomization, and participants will be assigned to two intervention and control groups.

Settings and conduct
This study, which will be conducted at the Hafezieh Health Center in Kermanshah, is non-blinded. Coordination for the implementation of the study will be done during morning administrative hours in coordination with the relevant officials at the health center. At the beginning of the study, a demographic information form and a childbirth fear questionnaire will be provided to participants to identify pregnant women who have a fear of childbirth

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent; Pregnant mothers with a gestational age of more than 20 weeks with singletons; Obtaining a score of 66-84 on the fear of childbirth questionnaire; Wanting to get pregnant
Exclusion criteria: History of known mental disorders; History of taking neuroleptic drugs; History of addiction; History of infertility

Intervention groups
The intervention group will receive 8 mindfulness group counseling sessions based on stress reduction in person, and for 60-90 minutes. The control group will receive only routine care according to national guidelines.

Main outcome variables
Mother's attachment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N254**
Registration date: **2025-06-16, 1404/03/26**
Registration timing: **prospective**

Last update: **2025-06-16, 1404/03/26**
Update count: **0**

Registration date
2025-06-16, 1404/03/26

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 1821 4653

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fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based stress reduction counseling on maternal-fetal attachment in women with fear of childbirth

Public title
The effectiveness of mindfulness on maternal-fetal attachment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent Pregnant mothers with a gestational age of more than 20 weeks with singletons Obtaining a score of 66-84 on the fear of childbirth questionnaire Wanting to get pregnant

Exclusion criteria:
History of known mental disorders History of taking neuroleptic drugs History of addiction History of infertility

Age
No age limit

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
Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.

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
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2025-05-31, 1404/03/10

Ethics committee reference number
IR.KUMS.REC.1404.161

Health conditions studied

1

Description of health condition studied
Childbirth of fear

ICD-10 code
F40

ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Using the Maternal Attachment Questionnaire

Timepoint
Before the start of the intervention, after the intervention and four weeks after the end of the intervention

Method of measurement
Using the maternal-fetal attachment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 8 mindfulness group counseling sessions based on stress reduction in person and for 60-90 minutes.

Category
Treatment - Other

2

Description

The control group will receive only routine care according to national guidelines. Routine treatment includes at least 8 periodic visits from the beginning of pregnancy until delivery, during which the mother's physical and psychological condition is assessed, vital signs are monitored, fetal growth is measured, laboratory screenings and necessary ultrasounds are performed, nutritional counseling, and childbirth preparation classes are provided.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafeziyeh Health Center

Full name of responsible person

Zahra Shokoohi

Street address

Next to the Girls' School, Hafeziyeh Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Zohreh Rahimi

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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

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

Dr. Mastane Kamromanesh

Position

University faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Faculty of Nursing and Midwifery, Dolatabad Blvd, Isar Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mastaneh Kamrvamanesh

Position

Faculty member of the university

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Kermanshah University of Medical Sciences
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Latest degree
Ph.D.
Other areas of specialty/work
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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
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