Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effect of mindfulness training on the childbirth experience in pregnant Women with Fear of childbirth

Protocol summary

Study aim
Investigation the effect of mindfulness training on the childbirth experience in pregnant Women with Fear of childbirth

Design
This study is a randomized clinical trial with a parallel design and a control group. This randomized, unblinded study will be conducted on 60 pregnant women with fear of childbirth. Simple randomization will be used for randomization, and participants will be assigned to two groups: intervention and control.

Settings and conduct
This study, which will be conducted at the Hafizieh Health Center in Kermanshah, is non-blinded. In order to prepare, the researcher, in addition to prior knowledge and skills in mindfulness training, will also draw on the experience of professors. At the beginning of the study, the questionnaires will be given to the participants

Participants/Inclusion and exclusion criteria
Inclusion criteria:Informed consent; Pregnant mothers aged 15 to 45 years with a singleton pregnancy of 24 to 28 weeks of gestation (based on ultrasound information; Pregnant mothers with fear of childbirth, scoring above 66 and below 85 on the Fear of Childbirth Questionnaire. Exclusion criteria:Individuals with a known diagnosis of mental disorders; History of using psychiatric medications, psychoactive substances, and narcotics; History of infertility; Unintended pregnancy; History of underlying diseases or conditions that developed during pregnancy (preeclampsia, gestational diabetes, uterine bleeding; History of giving birth to an infant with (IUGR), etc.

Intervention groups
The intervention group will receive 8 sessions of group counseling with mindfulness training, delivered in person, each lasting 60–90 minutes, according to the study's implementation protocol. The control group will not receive any intervention and will only receive routine care according to the national guidelines

Main outcome variables
Childbirth experience

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130812014333N277**
Registration date: **2026-04-27, 1405/02/07**
Registration timing: **prospective**

Last update: **2026-04-27, 1405/02/07**
Update count: **0**

Registration date
2026-04-27, 1405/02/07

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
2026-05-05, 1405/02/15

Expected recruitment end date
2026-07-06, 1405/04/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of mindfulness training on the childbirth experience in pregnant Women with Fear of childbirth

Public title

The effect of mindfulness training on the childbirth experience

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Pregnant mothers aged 15 to 45 years with a singleton pregnancy of 24 to 28 weeks of gestation (based on ultrasound information Pregnant mothers with fear of childbirth, scoring above 66 and below 85 on the Fear of Childbirth Questionnaire

Exclusion criteria:

Individuals with a known diagnosis of mental disorders History of using psychiatric medications, psychoactive substances, and narcotics History of infertility Unintended pregnancy History of underlying diseases or conditions that developed during pregnancy (preeclampsia, gestational diabetes, uterine bleeding History of giving birth to an infant with (IUGR), etc.

Age

From **15 years** old to **45 years** old

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

Simple random method. 60cards are selected and numbers from 1-60 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control 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

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2026-01-26, 1404/11/06

Ethics committee reference number

IR.KUMS.REC.1404.611

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

Childbirth experience

Timepoint

Immediately after delivery and four weeks after delivery

Method of measurement

Using the Childbirth Experience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 8 sessions of group counseling with mindfulness training, delivered in person, each lasting 60–90 minutes, according to the study's implementation protocol.

Category

Treatment - Other

2

Description
The control group will not receive any intervention and will only receive routine care according to the national guidelines
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafeziyeh Health Center
Full name of responsible person
Mahnaz Hojatimanesh
Street address
Faculty of Nursing and Midwifery Dolatabad Blvd, Isar Square
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3826 6429
Email
mahnaz.hojjatimanesh@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
Mahnaz Hojatimanesh
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
mahnaz.hojjatimanesh@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
Isfahan
Province
Isfehan
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
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