Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Association the effect of mindfulness-based stress reduction (MBSR) intervention on fear of childbirth in first-time pregnant women referring to comprehensive health centers in Sabzevar city

Protocol summary

Study aim

Determination of effect of mindfulness-based stress reduction (MBSR) intervention on fear of childbirth in first-time pregnant women referring to comprehensive health centers in Sabzevar city

Design

A randomized, blinded, control clinical trial on 60 first-time pregnant women.

Settings and conduct

People who fear score between 38 to 84 would be entered to the study. Then 60 participants divided two groups (intervention or control) by using of random allocation table or reliable online software. Results' assessors (clinical psychologist and statistic advisor) and participants are blinded. Intervention group attend both preparation classes for childbirth and MBSR classes. Program is based on John Cabat Zin protcol for pregnant women and location is Mobini Shahidan Hospitan in Sabzevar.

Participants/Inclusion and exclusion criteria

18-35 years old 2.Desire to attend in research; Score of fear of childbirth<85 based on Wijma Questionnaire; First-time pregnancy and without history of abortion and ectopic pregnancy; Gestational age between 26 to 30 weeks; Literate of reading and writing; Single pregnancy; Sonography that shows fetus is normal; Available to groups meeting; No history of mental substance during last 6 months; No history of mental disease during last 6 months

Intervention groups

Women 18 to 35 years old with gestational age between 26 to 30 weeks.

Main outcome variables

1- Determination of score of Fear of childbirth in intervention group before and after study 2- Determination of score of Fear of childbirth in control group before and after study 3- Determination of score of Fear of childbirth, 4 weeks after intervention in intervention and control groups 4- Comparison of score of Fear of childbirth, before, immediately after and 4 weeks after intervention in intervention and control groups

General information

Reason for update

Since the sampling for this study was conducted at Shahidan Mobini Hospital in Sabzevar, and the clinical trial registration took place during the last week of Esfand (mid-March) when the relevant authorities were unavailable, only the hospital name was listed in the sampling location field, while the rest of the address was entered based on the originating university (North Khorasan). We now need to correct the university listed (Sabzevar)for the sampling site.

Acronym

IRCT registration information

IRCT registration number: **IRCT20091229002924N4**
Registration date: **2026-03-15, 1404/12/24**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **1**

Registration date

2026-03-15, 1404/12/24

Registrant information

Name

Maryam Hassanzadeh Bashtian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3151 1206

Email address

m.h.bashtian@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-04-19, 1405/01/30
Expected recruitment end date
2026-08-21, 1405/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Association the effect of mindfulness-based stress reduction (MBSR) intervention on fear of childbirth in first-time pregnant women referring to comprehensive health centers in Sabzevar city

Public title
The effect of mindfulness-based stress reduction (MBSR) intervention on fear of childbirth in first-time pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1.18-35 years old 2.Desire to attend in research 3. Score of fear of childbirth<85 based on Wijma Questionnaire 4. First-time pregnancy and without history of abortion and ectopic pregnancy 5. Gestational age between 26 to 30 weeks 6. literate of reading and writing 7. Single pregnancy 8. Sonography that shows fetus is normal 9. Available to groups meeting 10. No history of mental substance during last 6 months 11. No history of mental disease during last 6 months
Exclusion criteria:
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants divided to two groups (intervention and control) based on random allocation table or online reliable software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Allocation process to study groups is secret and results assessors (clinical psychologist and statistic advisor) and participants will be blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethical committee of North Khorasan University of Medical Sciences.
Street address
Department of Midwifery, School of nursing and midwifery, Shahriar Street, Bojnord, North Khorasan, Iran
City
Bojnurd
Province
North Khorasan
Postal code
96786-94176
Approval date
2026-02-24, 1404/12/05
Ethics committee reference number
IR.NKUMS.REC.1404.190

Health conditions studied

1

Description of health condition studied
First-time pregnant women during 26 to 30 weeks pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fear of childbirth in FOC Wijma questionnaire
Timepoint
Foear of childbirth in first (before intervention), after 8 mindfulness sessions and 4 weeks after that
Method of measurement
FOC Wijma questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First-time pregnant wonen recepiant 8 weeks mindfulness sessions
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobini Shahidan Hospital in Sabzevar
Full name of responsible person
Amir Masrour Naeemi
Street address
Mobini Shahidan Hospital in Sabzevar, North Kashefi street, Sabzevar, Razavi Khorasan, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613856776
Phone
+98 51 4144 6500
Email
Dr.masrour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Omid Toopchian
Street address
Research and Technology Deputy, After Imam Ali (A.S.) Special Clinic, Shahriar Street, Bojnord, North Khorasan, Iran
City
Bojnurd
Province
North Khorasan
Postal code
9417694780
Phone
+98 58 3151 1420
Email
modiriat.pajoheshi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Maryam Hassanzadeh Bashtian
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Hassanzadeh Bashtian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Since article result in study would be published. so, the datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

When the data will become available and for how long

Start for datasets available would be 6 months after article publish.

To whom data/document is available

Datasets would be available for researchers in Universities and Scientifice institutions.

Under which criteria data/document could be used

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

From where data/document is obtainable

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

What processes are involved for a request to access data/document

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request after one month from written requset by email.

Comments