Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness-based stress reduction counseling on stress and anxiety in women with positive results of prenatal screening tests

Protocol summary

Study aim
To determine the effect of mindfulness-based stress reduction (MBSR) counseling on stress and anxiety in women with positive results in prenatal screening tests.

Design
This is a parallel-group randomized controlled clinical trial involving 54 participants. Randomization will be performed using a random number table, and the study will be conducted without blinding.

Settings and conduct
Sampling will be conducted at prenatal clinics of the hospital or hospitals affiliated with Tehran University of Medical Sciences, and the childbirth preparation classes will be held at the hospital or health centers of the same university. Participants will be selected using convenience sampling, and allocation will be carried out using block randomization. Participants will complete self-administered questionnaires before the intervention, immediately after the completion of the counseling sessions, and four weeks after the last session.

Participants/Inclusion and exclusion criteria
Pregnant women with a positive result on first-trimester prenatal screening tests, with no history of substance abuse and no diagnosed physical or psychological disorders, who are willing to participate in the study.

Intervention groups
The intervention group will receive eight 120-minute MBSR sessions (once per week). The effects of the intervention will be assessed before the start, immediately after the completion of the counseling sessions, and four weeks after the end of the intervention. The control group will receive routine prenatal care, and at the end of the intervention, counseling will be offered to the control group if they wish to receive it.

Main outcome variables
Stress and Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160608028352N15**
Registration date: **2025-12-02, 1404/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-02, 1404/09/11**
Update count: **0**

Registration date
2025-12-02, 1404/09/11

Registrant information

Name
Roghieh Kharaghani

Name of organization / entity
Zanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-11, 1404/08/20

Expected recruitment end date
2026-02-24, 1404/12/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mindfulness-based stress reduction counseling on stress and anxiety in women with positive results of prenatal screening tests

Public title
The effect of mindfulness-based stress reduction counseling on stress and anxiety in women with positive results of prenatal screening tests

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Providing consent to participate in the study Pregnancy of less than 14 weeks Positive result in the first-trimester screening test Residency in Tehran Having at least basic reading and writing skills

Exclusion criteria:
Presence of medical or psychological disorders Substance abuse Having a history of miscarriage or stillbirth in previous pregnancies

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher will recruit participants from women's clinics. After explaining the study objectives and obtaining written informed consent, participants will be selected using convenience sampling. Once the samples are collected, participants will be assigned using random block allocation. Four-member blocks will be created, with half assigned to the intervention group and half to the control group. Participants will be coded from 01 to 54, and blocks will be selected using a random number table with six possible arrangements, continuing until the target sample size is reached (27 participants in the control group and 27 in 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 Zanjan University of Medical Sciences

Street address
North Side Azadi Boulevard

City
Zanjan

Province
Zanjan

Postal code
4525613113

Approval date
2025-10-27, 1404/08/05

Ethics committee reference number
IR.ZUMS.REC.1404.186

Health conditions studied

1

Description of health condition studied
Stress

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Stress

Timepoint
Before the intervention, immediately after the completion of the counseling sessions, and four weeks after the last counseling session

Method of measurement
Stress questions of the DASS-42 questionnaire (Depression, Anxiety, Stress Scale), which consists of 14 items.

2

Description
Anxiety

Timepoint
Before the intervention, immediately after the completion of the counseling sessions, and four weeks after the last counseling session

Method of measurement
Anxiety questions of the DASS-42 questionnaire (Depression, Anxiety, Stress Scale), which consists of 14 items.

Secondary outcomes

1

Description
Mindfulness
Timepoint
Before the intervention, immediately after the completion of the counseling sessions, and four weeks after the last session
Method of measurement
FFMQ (Five Facet Mindfulness Questionnaire)

Intervention groups

1

Description
Intervention group: MBSR sessions, conducted once a week. The researcher will participate in an MBSR training course and obtain a certification. In addition, the researcher will receive in-person supervision and training from the academic advisor, who is a psychologist.
Category
Behavior

2

Description
Control group: Participants in the control group will receive only the routine prenatal care, and no interventions or counseling sessions will be conducted for them during the study period. After completion of the intervention phase, similar counseling sessions will be offered to the control group participants if they wish.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University Of Medical Science
Full name of responsible person
Niloufar Jafari
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Tehran University of Medical Sciences, 16 Azar Street, Keshavarz Boulevard, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
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Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanjan
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Niloufar Jafari
Position
Master’s student in Midwifery Counseling
Latest degree
Bachelor
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After the completion of the study, information regarding the primary and secondary outcomes will be shared.
When the data will become available and for how long
The access period will begin in mid-2026
To whom data/document is available
The data and documentation will be made available to researchers in the field of medical sciences.
Under which criteria data/document could be used
The data can be used for conducting studies, providing documentation, developing new ideas, and practical applications in educational centers.
From where data/document is obtainable
Send an email to niloufar.jafari1996@gmail.com
What processes are involved for a request to access data/document
The data, after review and approval of the request, will be made available to the applicant within one month.
Comments