

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8144

Email address

r.kharaghani@zums.ac.ir

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

Street address

Tehran University of Medical Sciences, 16 Azar Street, Keshavarz Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

۷۶۱۶۹۱۳۵۵۵

Phone

+98 21 8893 3766

Email

tumspr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mehrdad hamidi

Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3315 6141

Email

hamidim@zums.ac.ir

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

Other areas of specialty/work

Midwifery

Street address

Zanjan University of Medical Sciences, Gavazang Road

City

Zanjan

Province

Zanjan

Postal code
4515613191
Phone
098 24 33148300
Email
niloufar.jafari1996@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Roghieh Kharaghani
Position
PhD in Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
جاده گاوزنگ، دانشگاه علوم پزشکی زنجان
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3314 8144
Fax
+98 24 3314 8319
Email
r.kharaghani@zums.ac.ir

Person responsible for updating data

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
Other areas of specialty/work
Midwifery
Street address
Zanjan University of Medical Sciences, Gavazang Road

City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
098 24 33148300
Email
niloufar.jafari1996@gmail.com

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