Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Mindfulness-Based Stress Reduction on Anxiety Sensitivity and Problem-Solving Ability of Students

Protocol summary

Study aim
This study aims to evaluate the effectiveness of mindfulness-based stress reduction (MBSR) on anxiety sensitivity and problem-solving ability in university students.

Design
This is a randomized, double-blind, parallel-group clinical trial with pre- and post-test design.

Settings and conduct
The study will be conducted at Mashhad University of Medical Sciences, involving volunteer students recruited via announcements. The intervention will be administered by a trained clinical psychologist.

Participants/Inclusion and exclusion criteria
Participants are university students aged 18–35. Inclusion criteria: willingness to participate, moderate to high anxiety sensitivity, and availability. Exclusion criteria: psychiatric medication, psychotherapy, or major psychological disorders.

Intervention groups
Intervention group will receive 8 weekly MBSR sessions (90 minutes each). Control group will receive no intervention during the study but will be offered training afterward.

Main outcome variables
Primary outcomes include anxiety sensitivity (measured by ASI) and problem-solving ability (measured by SPSI-R) assessed at baseline and post-intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250523065853N3**
Registration date: **2025-06-28, 1404/04/07**
Registration timing: **prospective**
Last update: **2025-06-28, 1404/04/07**
Update count: **0**

Registration date
2025-06-28, 1404/04/07

Registrant information
Name
zahra saedi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-31, 1404/06/09

Expected recruitment end date
2026-03-29, 1405/01/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Mindfulness-Based Stress Reduction on Anxiety Sensitivity and Problem-Solving Ability of Students

Public title
The Impact of Mindfulness-Based Stress Reduction on Anxiety and Problem-Solving in Students

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
University students aged between 18 and 35 years Willingness to participate in the study and provide informed consent Having moderate to high anxiety sensitivity based on the Anxiety Sensitivity Index (ASI) Availability to attend all mindfulness sessions Not currently participating in other psychological or psychiatric interventions Basic literacy and ability to complete self-report questionnaires
Exclusion criteria:
Current diagnosis of severe psychiatric disorders (e.g., psychosis, bipolar disorder) Use of psychiatric medication during the intervention period Participation in other psychological treatment programs concurrently Absence from more than two mindfulness sessions Any physical condition that prevents regular attendance or participation Incomplete response to pre-test questionnaires

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to the intervention or control group using a computer-generated random sequence created by block randomization with a 1:1 allocation ratio. Block sizes will be fixed and generated in advance to ensure balanced group sizes throughout recruitment. Allocation concealment will be ensured using sealed, opaque, and sequentially numbered envelopes. The randomization list will be prepared and maintained by an independent researcher who is not involved in participant recruitment or assessment. This process aims to minimize selection bias and maintain allocation integrity.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. Participants are informed that the study involves two different educational programs and are not told which group is considered the intervention or the control. The sessions are presented as potentially beneficial stress management trainings. Outcome assessors, who administer pre- and post-intervention questionnaires, are not involved in delivering the sessions and are unaware of group assignments. Group codes are used during data collection and analysis to maintain blinding and minimize assessment bias.

Placebo
Not used

Assignment
Parallel

Other design features
This study includes repeated measures with pre- and post-intervention assessments to evaluate changes over time. Random allocation is applied using block randomization to ensure group balance. The study also follows the intention-to-treat principle to maintain the integrity of statistical analysis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Medicine, Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
91778-99191

Approval date
2025-05-26, 1404/03/05

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1404.133

Health conditions studied

1

Description of health condition studied
This study focuses on anxiety sensitivity, a psychological trait characterized by the fear of anxiety-related sensations due to beliefs that these sensations have harmful consequences. It is commonly associated with anxiety disorders, especially panic disorder.

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
The primary outcome is the change in anxiety sensitivity levels among students after undergoing mindfulness-based stress reduction (MBSR) intervention. Anxiety sensitivity will be measured using a validated questionnaire.

Timepoint

Anxiety sensitivity will be measured at baseline (before the intervention), immediately after the intervention, and at 3 months follow-up.

Method of measurement

Anxiety sensitivity will be assessed using the Anxiety Sensitivity Index (ASI), a validated self-report questionnaire.

2

Description

The secondary outcome is the change in problem-solving ability among students after mindfulness-based stress reduction intervention.

Timepoint

Problem-solving ability will be measured at baseline, immediately after the intervention, and at 3 months follow-up.

Method of measurement

Problem-solving ability will be assessed using a standardized and validated problem-solving inventory questionnaire.

Secondary outcomes

1

Description

The secondary outcome is the change in problem-solving ability of students following the mindfulness-based stress reduction intervention.

Timepoint

Measured at baseline, immediately after the intervention, and 3 months after the intervention.

Method of measurement

Problem-solving ability will be assessed using a validated problem-solving inventory questionnaire.

2

Description

The secondary outcome is the change in perceived stress levels of students after mindfulness-based stress reduction intervention.

Timepoint

Measured at baseline, immediately after the intervention, and at 3 months follow-up.

Method of measurement

Perceived stress will be assessed using the Perceived Stress Scale (PSS), a validated self-report questionnaire.

Intervention groups

1

Description

Intervention group: Participants in this group will attend an eight-week Mindfulness-Based Stress Reduction (MBSR) program. The program includes weekly 90-minute group sessions. The content involves practical training in mindfulness practices such as body scan, breathing awareness, seated meditation, and mindful movement. Participants are instructed to perform daily home practice for 45 minutes. Audio files and written educational materials are provided. The sessions will be delivered by a trained and experienced instructor in mindfulness-based interventions.

Category

Behavior

2

Description

Control group: Control group: Participants in this group will not receive any psychological intervention during the study period. They will be placed on a waiting list and offered the same MBSR training program after completing the post-intervention assessment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Saedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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School of Medicine, Department of Psychology, Mashhad University of Medical Sciences, Azadi Square, Mashhad, Razavi Khorasan, Iran

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Grant name

Mashhad University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Saedi

Position

Principal Investigator

Latest degree

Subspecialist

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the deidentified individual participant data, along with the study protocol, statistical analysis plan, informed

consent form, clinical study report, analytic code, and data dictionary will be shared with qualified researchers upon reasonable request. Data will be available after publication of main results for a period of 3 years. Requests should be sent via email to the principal investigator at. Data will be provided via institutional secure file-sharing platforms under appropriate ethical and legal agreements.

When the data will become available and for how long

The deidentified individual participant data (IPD) and related documents will be made available 6 months after publication of the main study results. The data will be available for a period of 3 years after that.

To whom data/document is available

The data will be shared with qualified researchers working in academic institutions, governmental organizations, or non-profit research centers. Researchers affiliated with industry may also apply under specific conditions.

Under which criteria data/document could be used

Data may be used only for scientific research purposes, such as secondary analysis, meta-analysis, and validation studies. Applicants must submit a research proposal, ethical approval, and sign a Data Use Agreement (DUA). All requests will be evaluated by a Data Access Committee (DAC).

From where data/document is obtainable

Requests should be sent to the following contact: Dr. Zahra Saeedi Mashhad University of Medical Sciences School of Medicine, Department of Psychology Mashhad, Razavi Khorasan, Iran Phone: +98 916 604 6877 Email: darya2674@gmail.com

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

Applicants must submit: A detailed research proposal Ethical committee approval A signed Data Use Agreement (DUA) Requests will be reviewed by the Data Access Committee (DAC) within 4–6 weeks. If approved, data will be shared via secure digital transfer.

Comments