Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of mindfulness training based on stress reduction on sleep quality and anxiety in students with generalized anxiety disorder

Protocol summary

Study aim
The main aim of this study is to determine the effectiveness of mindfulness training based on stress reduction on quality of sleep and anxiety in students with generalized anxiety disorder.

Design
Clinical trial with control group with parallel groups, no blinding. Non-random assignment to intervention and control groups with a sample size of 40 people.

Settings and conduct
The MBSR training sessions will be held at the Islamic Azad University, Tonekabon Branch. This training will be an eight-week course, with one session per week, and the duration of each session will be 30 to 45 minutes. The fixed order of each session will include reviewing the homework assignments from the previous session, feedback on resolving existing questions and problems, teaching the intended materials and techniques, meditation skills, discussing stress and coping methods, and assigning homework.

Participants/Inclusion and exclusion criteria
Entry criteria: All individuals who are currently studying in the nursing field at the Islamic Azad University, Tonekabon Branch, at the undergraduate level. Those who achieve the quorum score on the Spitzer et al. Generalized Anxiety Disorder Test. Written consent to participate in the study. Exclusion criteria: No psychiatric medication in the past 6 months until the time of the study No psychotherapy in the past 6 months until the time of the study No consent to participate in the study

Intervention groups
The intervention group consists of students with generalized anxiety disorder who receive a mindfulness-based stress reduction intervention. The comparison group consists of students with generalized anxiety disorder who receive no intervention.

Main outcome variables
sleep quality, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250827067020N2**
Registration date: **2026-05-01, 1405/02/11**
Registration timing: **prospective**

Last update: **2026-05-01, 1405/02/11**
Update count: **0**

Registration date
2026-05-01, 1405/02/11

Registrant information

Name
MOBINA SADEGHIFAR

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 5422 7267

Email address
mobina.sadeghifarr@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-10, 1405/02/20

Expected recruitment end date
2026-07-11, 1405/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of mindfulness training based on stress reduction on sleep quality and anxiety in students with generalized anxiety disorder

Public title
The effectiveness of mindfulness training based on stress reduction on sleep quality and anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All individuals are studying at the undergraduate level in the nursing department of Islamic Azad University, Tonekabon Branch Those who achieve a quorum score on the Spitzer et al. Generalized Anxiety Disorder Test Written consent to participate in the study
Exclusion criteria:
No psychiatric medication in the past 6 months up to the time of the study Not receiving psychotherapy in the past 6 months up to the time of the study Refusal to participate in the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
کمیته اخلاق دانشگاه آزاد اسلامی واحد تنکابن
Street address
5 kilometers to Tonekabon City - Vali Abad, Tonekabon, Mazandaran, Iran
City
Tonekabon
Province
Mazandaran
Postal code
4684761167
Approval date
2026-03-17, 1404/12/26
Ethics committee reference number
IR.IAU.TON.REC.1405.004

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder
ICD-10 code
F41.1
ICD-10 code description

Primary outcomes

1

Description
Anxiety score on the Spitzer et al. Generalized Anxiety Disorder Questionnaire
Timepoint
Anxiety score was measured using the Spitzer et al. Generalized Anxiety Disorder Questionnaire at the beginning of the study and before the start of the mindfulness-based stress reduction intervention.
Method of measurement
Spitzer et al. General Anxiety Inventory

Secondary outcomes

1

Description
Sleep quality score
Timepoint
At the beginning and before the intervention begins and at the end after the intervention ends
Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
Anxiety score
Timepoint
At the beginning and before the intervention begins and at the end after the intervention ends
Method of measurement
Beck anxiety questionnaire

Intervention groups

1

Description
Intervention group: Mindfulness-based stress reduction is a group program developed by Jon Kabat-Zinn in the 1970s to treat patients struggling with life problems and

physical or mental illnesses. Mindfulness-based stress reduction is an 8-week training program that uses formal and informal mindfulness exercises. The standard order of each session will include a review of homework from the previous session, feedback on resolving existing questions and problems, teaching the intended content and techniques, meditation skills, discussing stress and coping methods, and assigning homework. The content presented during the 8 sessions will include the following: introduction to mindfulness training, training and doing exercises related to the state of mindfulness exercises, practicing paying attention to breathing, doing body scan exercises, doing sitting meditation, doing yoga movements, practicing mindful eating, practicing mindful walking meditation, and creating a personal mindfulness plan. Participants are asked to do mindfulness exercises for 45 minutes daily as homework. Number of treatment sessions: 8 sessions, 30 to 60 minutes, once a week, treatment is done individually.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Tonekabon Mazandaran Branch
Full name of responsible person
MOBINA SDEGHIFAR
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
KHADIJEH HATAMIPOUR
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Results, tables and treatment protocol

When the data will become available and for how long
6 months after results are published

To whom data/document is available
Applicants from qualified individuals (general practitioners, medical specialists, psychiatrists, psychologists)

Under which criteria data/document could be used
The use of the documentation of this trial will only be possible for academic and scientific researchers on a limited basis and with permission from the person responsible for this trial.

From where data/document is obtainable
Correspondence via email address mobina.sadeghifarr@gmail.com

What processes are involved for a request to access data/document
Any request for access to data or documentation from this study must be made by sending a formal written request to the principal investigator or supervisor. This request must include the applicant's details, the purpose of using the data, the type of data required, and how to ensure the confidentiality of the information. After receiving the request, the following will be reviewed: Verification of the applicant's scientific identity and organizational affiliation Evaluation of the research purpose and its alignment with the ethical principles of the study Final approval by the principal investigator and, if necessary, the university ethics committee If approved, the data will be provided to the applicant in an anonymized and limited to the requested items, in a scientifically usable format. Use of the data is permitted only with acknowledgement of the source and observance of the confidentiality of the participants' information.

Comments