

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**recruiting**

##### 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

**Street address**

5 kilometers to Tonekabon City - Vali Abad

**City**

TONEKABON

**Province**

Mazandaran

**Postal code**

4684161167

**Phone**

+98 11 5427 1105

**Email**

mobina.sadeghifarr@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

KHADIJEH HATAMIPOUR

**Street address**

5 kilometers to Tonekabon City - Vali Abad

**City**

tonekabon

**Province**

Mazandaran

**Postal code**

4684161167

**Phone**

+98 11 5427 1105

**Email**

mobina.sadeghifarr@gmail.com

**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

**Street address**

5 kilometers to Tonekabon City - Vali Abad

**City**

TONEKABON

**Province**

Mazandaran

**Postal code**

4684161167

**Phone**

+98 11 5427 1105

**Email**

kh\_hatamipour@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

MOBINA SADEGHIFAR

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Unit 12 ,floor 4, damoun 1 complex, bahmani alley,  
Razi ave

**City**

Tonekabon

**Province**

Mazandaran

**Postal code**

4681966869

**Phone**

+98 11 5422 7267

**Fax**

**Email**

mobina.sadeghifarr@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

MOBINA SADEGHIFARR

**Position**

Student

**Latest degree**

Master

**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**

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**