Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness training based on stress reduction on quality of life and mental well-being 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 life and mental well-being 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
Mental well-being, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250827067020N1**
Registration date: **2025-10-06, 1404/07/14**
Registration timing: **prospective**

Last update: **2025-10-06, 1404/07/14**
Update count: **0**

Registration date
2025-10-06, 1404/07/14

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
2025-10-07, 1404/07/15

Expected recruitment end date
2025-12-06, 1404/09/15

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 quality of life and mental well-being in students with generalized anxiety disorder

Public title
The effectiveness of mindfulness training based on stress reduction on quality of life and mental well-being

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
Ethtics Committee of Islamic Azad University-Tonekabon Branch

Street address
5 kilometers to Tonekabon City - Vali Abad, Tonekabon, Mazandaran, Iran

City
Tonekabon

Province
Mazandaran

Postal code
4684761167

Approval date
2025-07-22, 1404/04/31

Ethics committee reference number
IR.IAU.TON.REC.1404.123

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

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
Quality of life score

Timepoint
At the beginning and before the intervention begins and at the end after the intervention ends

Method of measurement
Short Form Quality of Life Questionnaire 36-question, SF-36

2

Description
Mental well-being score

Timepoint
At the beginning and before the intervention begins and at the end after the intervention ends

Method of measurement
Keyes and Magyarmo's Subjective Well-Being Questionnaire(sws)

Intervention groups

1

Description

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

2

Description

Control group: will not receive any intervention until the research project is fully completed.

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 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

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