Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness-based cognitive behavioral therapy on sleep quality, emotional regulation, and Test anxiety in female high school students

Protocol summary

Study aim
Explaining the effectiveness of mindfulness-based cognitive-behavioral therapy on sleep quality, emotion regulation, and exam anxiety in female students

Design
The present study is an applied research in terms of purpose and a field research in terms of implementation. This study was conducted using an experimental method and a pretest-posttest design with a control group.

Settings and conduct
This study was conducted over two months and ten 90-minute sessions at the Comprehensive Health Clinic of the Vice Chancellor for Medical Sciences, Shiraz Azad University, without blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having informed consent and willingness to actively participate in all phases of the study, Not taking any specific psychiatric medication in the past six months, Achieving a quorum in the pre-test of sleep quality, emotion regulation, and test anxiety, in order to be eligible to receive the intervention. Inclusion criteria: Expressing unwillingness to continue cooperating with the researcher at any stage of the study, Having new chronic or acute physical illnesses that could potentially affect sleep quality, emotion regulation, or test anxiety levels, Onset of major family issues or crises, such as bereavement, parental divorce, or severe financial difficulties, that could significantly affect the subject's mental state or responses.

Intervention groups
After completing the pre-test, the experimental group underwent ten 90-minute sessions of mindfulness-based cognitive behavioral therapy for two months and then completed the post-test. After completing the pre-test, the control group did not receive any intervention or training for two months. After the end of the last training session of the experimental group, the control group completed the post-test.

Main outcome variables
Sleep Quality Emotional Regulation Test Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260516069420N1**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date
2026-06-13, 1405/03/23

Registrant information

Name
Hadis Bagherzadeh

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
2026-06-22, 1405/04/01

Expected recruitment end date
2026-08-22, 1405/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based cognitive behavioral therapy on sleep quality, emotional regulation, and Test anxiety in female high school students

Public title
effect of mindfulness-based cognitive behavioral therapy on sleep quality, emotional regulation, and Test anxiety
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent and willingness to actively participate in all stages of the research Not taking any specific psychiatric medications in the past six months Achieving a quorum on the pre-test of sleep quality, emotion regulation, and test anxiety in order to be eligible to receive the intervention
Exclusion criteria:
Expressing unwillingness to continue working with the researcher at any stage of the research Having new chronic or acute physical illnesses that could potentially affect sleep quality, emotion regulation, or test anxiety levels The occurrence of major family issues or crises, such as bereavement, parental divorce, or severe financial difficulties, which can significantly affect the subject's mental state or responses
Age
From **15 years** old to **18 years** old
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, based on the inclusion and exclusion criteria, 60 subjects will be selected using a cluster method, and after a pre-test with a 50% probability of failure, 30 subjects will be assigned to two groups of 18 people, the experimental and control groups, by simple random method and by drawing lots. Regarding the method of drawing lots, one name from each name that comes out of the bag of names will be placed in the experimental group and the next name will be placed in the control 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 Islamic Azad University, Shiraz Branch
Street address
Faculty of Dentistry, Alley 14, South Ghaani Street
City
Shiraz
Province
Fars
Postal code
۷۱۹۵۶۱۵۸۷۸
Approval date
2025-04-14, 1404/01/25
Ethics committee reference number
IR.IAU.SHIRAZ.REC.1404.021

Health conditions studied

1

Description of health condition studied
sleep quality
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Emotional regulation
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Test anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sleep quality
Timepoint
This variable is measured once before the start of the intervention and a second time, after the intervention period, by post-test.
Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description
Emotional Regulation
Timepoint
This variable is measured once before the start of the intervention and a second time, after the intervention period, by post-test.
Method of measurement
Gross and John's Emotional Regulation Questionnaire (2003)

3

Description
Test Anxiety
Timepoint
This variable is measured once before the start of the intervention and a second time, after the intervention period, by post-test.
Method of measurement
Dries Cole Test Anxiety Questionnaire (2007)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The experimental group underwent mindfulness-based cognitive behavioral therapy training for ten 90-minute sessions over a period of two months. In each session, the experimental group was given practical exercises and homework and activities for the following sessions were also reviewed (Sari et al., 2022). This treatment protocol is adapted from the Kabat-Zinn protocol (2000).
Category
Behavior

2

Description
Control group: The control group did not receive any intervention or training for two months after completing the pre-test. After the last training session of the experimental group, the control group was administered the post-test by distributing the same questionnaires as the pre-test.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Counseling and Psychological Services Center, Islamic Azad University, Shiraz Branch
Full name of responsible person
Dr. Fatemeh Ghanbari
Street address
Medical Vice-Chancellor's Building, Islamic Azad University Shiraz Branch, between Alley 2 and Alley 4, Daneshjo Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Bahram Amiri
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Islamic Azad University, Firoozabad, Islamic Azad University Boulevard
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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
Private
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
Hadis Bagherzadeh

Position
Master

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
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
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All information and data collected will be shared after being de-identified to aid in related studies and future research.

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

To whom data/document is available
Psychology professors, researchers, and students are allowed to submit requests to receive data and other documentation.

Under which criteria data/document could be used
The data will be used to develop future research results and meta-analyses.

From where data/document is obtainable
Applicants can contact the corresponding author by email to receive the data.

What processes are involved for a request to access data/document
Applicants will be able to receive the data within one month after submitting their request, along with research documentation demonstrating the necessity of the data

to achieve the research goals.

Comments