Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness exercises on improving anxiety behaviors and social adjustment in students

Protocol summary

Study aim
Determining the effectiveness of artificial intelligence-based mindfulness exercises on improving anxiety behaviors and social adaptation in students

Design
This study is a randomized, double-blind, parallel-group clinical trial conducted on 30 female high school students in Baghmalek city (15 in each group). The sample allocation is done by simple random method using the RAND function in Excel software; first, each participant receives an identification code and is divided into two groups of 15 based on a random number.

Settings and conduct
This research will use a field experimental research method and an extensive pre-test and post-test design. The research will be conducted at the first secondary school in Izeh city. All participants, clinical caregivers, and evaluators who interpret the data, and all information will be kept confidential and participants will be given pseudonyms.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Be between at least 12 and at most 15 years old. Be students of the first secondary education level in Izeh County. Have informed consent to participate in the research. Exclusion Criteria Having a physical illness that causes a disruption in the treatment process. Consumption of psychiatric medications.

Intervention groups
Intervention group: Artificial intelligence-based mindfulness training intervention based on the Foroughi protocol (1403) is implemented in a group setting in 8 90-minute sessions, one session per week. Control group: Do not receive any intervention.

Main outcome variables
Anxious behaviors; social adjustment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260825070799N1**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **prospective**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date
2026-08-29, 1405/06/07

Registrant information

Name
Roqayeh Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 916 647 3901

Email address
parsakarimimpk@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-09-21, 1405/06/30

Expected recruitment end date
2026-10-07, 1405/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness exercises on improving anxiety behaviors and social adjustment in students

Public title
The effectiveness of mindfulness exercises on improving anxiety behaviors and social adaptation
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be between at least 12 and at most 15 years old. Be students of the first secondary education level in Izeh County. Have informed consent to participate in the research.
Exclusion criteria:
Having a physical illness that causes a disruption in the treatment process. Consumption of psychiatric medications.
Age
From **12 years** old to **15 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization method is used to assign participants to two experimental and control groups. The randomization unit in this study is female high school students in Baghmalek city who are eligible to enter the study. First, a complete list of volunteers who have been selected based on the study entry criteria is prepared. Then, each participant is assigned a unique numerical identification code. These codes are entered into the Random Number Generator software and a random number is generated for each individual. After generating these numbers, the participants are sorted in ascending order based on the value of the random number. Then, the individuals are assigned to two groups; sequentially, the first 15 people on the list are assigned to the experimental group and the next 15 people to the control group. With this method, the order of entry into the study and the researcher's knowledge of the participants will not play any role in determining the group. To ensure allocation concealment, the person responsible for entering data and performing the randomization process in the software will be independent of the intervention administrators and study evaluators and will not have access to information about the session implementation process or changes in the allocation of individuals. Participant identification codes will also be kept confidential and separate from their other personal information. Therefore, it will not be possible to predict the assigned group for each participant before the randomization process.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to control bias and improve the internal validity of the study, this study was designed with a double-blind protocol; in this way, the intervention implementers, outcome assessor, and data analyst will be kept unaware of the allocation of female students in the first high school of Baghmalek County to the experimental and control groups. In this process, the outcome assessor will collect data in all stages of pre-test, post-test, and follow-up, without knowing the assigned group of the participants, in order to prevent bias in the measurement; also, all raw data will be provided to the statistical analyst with anonymous codes (such as groups 1 and 2), and the true nature of the groups will not be revealed until the end of the data analysis process. All allocation steps will be carried out by an independent person from the research team, and the decoding of the allocation codes will be done only after the final completion of the statistical analyses.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Behbahan Islamic Azad University Ethics Committee
Street address
Shahid Bayani St., Amir Kabir Blvd.
City
Behbahan
Province
Khouzestan
Postal code
6361713198
Approval date
2026-07-21, 1405/04/30
Ethics committee reference number
IR.IAU.BEHBAHAN.REC.1405.193

Health conditions studied

1

Description of health condition studied
Anxiety and social problems of students
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxious behaviors
Timepoint
before performing the intervention and two weeks after completion of the intervention
Method of measurement
Ligerka and Stone's Anxiety Behavior Questionnaire (1993)

2

Description
Social adaptation
Timepoint
before performing the intervention and two weeks after completion of the intervention
Method of measurement
Sinha and Singh's Social Adaptation Scale (1993)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The AI-based mindfulness training intervention sessions will be based on the treatment protocol designed by Foroughi (1403). The intervention sessions will be conducted in 8 90-minute sessions (one session per week) in a group setting for the experimental group. AI-based mindfulness training is an approach that aims to reduce anxiety-related behaviors and promote social adaptation through intelligent monitoring and interactive exercises, helping students manage their emotions and interpersonal challenges by replacing reactive and automatic patterns with conscious and adaptive responses. This approach has main educational axes that lead to improved emotion regulation and improved communication skills; These axes include: familiarization with the smart system and conscious breathing practice appropriate to the level of anxiety, training in the body scan technique with dynamic feedback, identifying and naming emotions by drawing a weekly emotional pattern, training in conversation skills and conscious listening through interaction with the smart bot, cognitive restructuring and managing negative thoughts with the perspective of a neutral observer, cultivating self-kindness through personalized messages, implementing conscious stopping techniques in real stressful situations with smart reminders, and finally, consolidation, summarizing progress, and presenting a plan.
Category
Behavior

2

Description
Control group: hey do not receive any intervention or treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Girls' High School Teacher
Full name of responsible person
Roqayeh Hosseini
Street address
Sadra Alley, Next to the Municipality Motor Pool, Mohammad Rasool-Allah St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Behrang Mohammad Salehi
Street address
Daneshjo Square, Zagros Blvd.
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6391693627
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bsalehi@iau.ac.ir
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
Roqayeh Hosseini
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participant data is completely confidential and I do not intend to publish it.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be 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