Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effectiveness of mindfulness-based stress reduction treatment on cognitive avoidance, social anxiety, and anxiety sensitivity of 6th grade female students with social anxiety

Protocol summary

Study aim
Studying the effectiveness of mindfulness-based stress reduction treatment on cognitive avoidance, social anxiety, and anxiety sensitivity of 6th grade female students with social anxiety

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software was used for randomization.

Settings and conduct
To select the sample, cluster random sampling method will be used. First, from the four education districts of Ahvaz city, two districts will be randomly selected, and then from each district, five sixth grade girls' schools and two sixth grade girls' schools will be selected. Finally, randomly from among the students who showed symptoms of social anxiety in the previous stage according to the social anxiety inventory questionnaire and in the clinical interview, 40 people will be selected by simple random selection and assigned to the experimental group and the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1 - No serious physical illness 2 - Social anxiety Exclusion criteria: Not participating in other psychotherapy sessions at least one month before the study

Intervention groups
After forming the groups, the subjects will be given questionnaires to measure the variables as a pre-test and they will be assured that the answers they give will remain confidential. People in the experimental group participated in a mindfulness-based stress reduction therapy training course for about a month in 8 90-minute sessions, two sessions per week. There was no intervention for the control group. After completing the training course, both the experimental and control groups were re-assessed with questionnaires to measure the variables as a post-test.

Main outcome variables
Cognitive avoidance, social anxiety, anxiety sensitivity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250829067041N1**
Registration date: **2025-08-31, 1404/06/09**
Registration timing: **prospective**

Last update: **2025-08-31, 1404/06/09**
Update count: **0**

Registration date
2025-08-31, 1404/06/09

Registrant information

Name
Fatemeh Ahleshakhe

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3333 3333

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-04, 1404/06/13

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effectiveness of mindfulness-based stress reduction treatment on cognitive avoidance, social anxiety, and anxiety sensitivity of 6th grade female students with social anxiety

Public title
Studying the effectiveness of mindfulness-based stress reduction treatment on cognitive avoidance, social anxiety, and anxiety sensitivity of 6th grade female students with social anxiety
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
No serious physical illness Having social anxiety disorder diagnosed by a clinical psychologist Female students aged 11 to 12 years
Exclusion criteria:
Attending other psychotherapy sessions at least one month before the study
Age
From **11 years** old to **12 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistical population of the present study consists of sixth grade female students who are studying in the academic year 2025-2026 and have social anxiety. To select a sample to diagnose social anxiety in students, a cluster random sampling method will be used. First, two districts will be randomly selected from four education districts, and then five sixth grade girls' schools from each district, and in the next stage, two sixth graders will be selected from each school. Then, after the students complete the social anxiety inventory, those whose scores on this questionnaire were one standard deviation above the mean and in a clinical interview conducted by a clinical psychologist based on the diagnostic and statistical criteria for mental disorders, fifth edition, will be selected as students with social anxiety. Finally, randomly selected students whose social anxiety score on the social anxiety inventory was one standard deviation above the mean in the previous stage, will also show symptoms of social anxiety in the clinical interview. 40 of them will be selected to participate in the research by simple random selection (drawing lots). Then, these people will be assigned to the experimental and control groups by simple random selection (20 people in the experimental group and 20 people 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 of Ahvaz Branch
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Approval date
2025-08-20, 1404/05/29
Ethics committee reference number
IR.IAU.AHVAZ.REC. 1404.355

Health conditions studied

1

Description of health condition studied
Social anxiety
ICD-10 code
F40.1
ICD-10 code description
Social phobias

Primary outcomes

1

Description
Social Anxiety Disorder: Social anxiety disorder is an extreme or unusual fear of situations in which one's behavior or performance may be scrutinized or evaluated by others. In other words, social anxiety is characterized by a significant, persistent, and irrational fear of being observed or negatively evaluated by others, which is accompanied by physical and psychological symptoms of anxiety. A person with social anxiety disorder avoids fearful situations or endures these situations with great stress. In the present study, it is the

score that the subject obtains from the Social Anxiety Inventory of Kanwar et al. (2000); standardized by Hassanvand Amuzadeh (2014).

Timepoint

In this design, subjects are measured before the independent variable is implemented (pre-test), then the experimental intervention or independent variables are applied. After that, subjects are measured again. The structure of the therapy sessions was developed based on the Kabat-Zinn method (2013) and is implemented in 8 90-minute sessions, two sessions per week for 1 month.

Method of measurement

The research tool will include the Social Anxiety Inventory of Kanver et al. (2000). Also, the research data analysis was performed using SPSS version 26 computer software. And the significance level in this study is considered to be P=0.5.

2

Description

Cognitive avoidance: Cognitive avoidance is a type of mental strategy based on which people change their thoughts. Each person makes hypotheses about themselves and their environment when dealing with a situation. These hypotheses are perfectionistic and biased criteria about social performance that can lead to the formation of physical and psychological symptoms. In other words, cognitive avoidance is one of the strategies that anxious people use to process information in anxiety-provoking environments and, through this, try to change their thoughts and mental images in order to free themselves from environmental concerns. In the present study, it is the score that the subject obtained from the cognitive avoidance questionnaire developed by Sexton and Dugas (2008), which was first translated in Iran by Basaknejad et al. (2010) and validated on a student population.

Timepoint

In this design, subjects are measured before the independent variable is implemented (pre-test), then the experimental intervention or independent variables are applied. After that, subjects are measured again. The structure of the therapy sessions was developed based on the Kabat-Zinn method (2013) and is implemented in 8 90-minute sessions, two sessions per week for 1 month.

Method of measurement

The research tool will include: Sexton and Dugas (2008) Cognitive Avoidance Questionnaire. Also, the research data analysis was done using SPSS version 26 computer software. And the significance level in this research is considered to be P=0.5.

3

Description

Anxiety sensitivity: Anxiety sensitivity is a cognitive component that indicates the fear of the appearance of anxiety symptoms. In other words, anxiety sensitivity causes the individual to believe that the signs and symptoms of anxiety are dangerous to the individual's health and can lead to bad results. On the other hand, in this anxiety, the individual fears that anxiety symptoms, such as increased heart rate and dizziness, will increase social, cognitive, and physical consequences in the individual and cause the individual harm. Anxiety sensitivity in this study refers to the score that the subject obtained on the Floyd et al. (2005) Anxiety Sensitivity Inventory.

Timepoint

In this design, subjects are measured before the independent variable is implemented (pre-test), then the experimental intervention or independent variables are applied. After that, subjects are measured again. The structure of the therapy sessions was developed based on the Kabat-Zinn method (2013) and is implemented in 8 90-minute sessions, two sessions per week for 1 month.

Method of measurement

The research tool will include: Floyd et al.'s Anxiety Sensitivity Index (2005). Also, the research data analysis was performed using SPSS version 26 computer software. The significance level in this study is considered to be P=0.5.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-Based Stress Reduction Therapy: In this method, with a psychological understanding, the mind-body medicine models of stress are integrated with findings related to how to cope with the challenges of modern life. Therefore, this program includes intensive mindfulness meditation training and participants are trained to apply what they have learned practically in relation to the problems of managing the challenges of daily life. In the present study, mindfulness-based stress reduction therapy sessions will be implemented based on the Kabat-Zinn protocol (2013) and will be implemented in an 8-week period with 90-minute sessions, one session per week for the experimental group. After forming the groups, the subjects will be given questionnaires to measure the variables as a pre-test and they will be assured that the answers they give will remain confidential. People in the experimental group participated in the training course for about a month, for the experimental group, the mindfulness-based stress reduction therapy intervention was considered in 8 90-minute sessions and two sessions per week. After completing the training period, the experimental group was re-assessed using questionnaires to measure variables as a post-test.

Category

Treatment - Other

2

Description
Control group: There will be no intervention for the control group. However, to prevent factors threatening the internal validity of the study, such as compensatory competition from the control group or demoralization, they will receive the intervention after data collection. After completing the training period, the control group will be re-assessed with questionnaires to measure the variables as a post-test.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Elementary schools

Full name of responsible person
Fatemeh Ahleshakheh

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No. 52, West Kashan Street, Saadi Alley, Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Pezhman Taghipour Birgani

Street address
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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
10

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
Fatemeh Ahleshakheh

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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No. 52, West Kashan Street, Saadi Alley, Golestan

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Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable