Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of a Mindfulness-Based Stress Reduction (MBSR) Program on Anxiety Sensitivity and Fear of Negative Evaluation in Non-Athlete Adolescent Girls with Symptoms of Social Anxiety Disorder

Protocol summary

Study aim

Determining the effectiveness of a mindfulness-based stress reduction program on anxiety sensitivity and fear of negative evaluation in non-athlete adolescent girls with symptoms of social anxiety disorder.

Design

A controlled randomized clinical trial with two parallel groups and single-blind design will be conducted on 40 adolescent girls with symptoms of social anxiety (20 intervention, 20 control). Randomization will be performed using variable blocks with allocation concealment in numbered envelopes, and stratification will be based on age and symptom severity.

Settings and conduct

This study will be conducted at Nikan Counseling Center in Ahvaz. Participants (40 adolescent girls) will be assigned to two groups after referral by psychologists: an intervention group (receiving 8 sessions of the Mindfulness-Based Stress Reduction program) and a control group (waiting list). Assessments and sessions will take place at the same center, adhering to ethical principles.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.Having a diagnosis of social anxiety disorder symptoms based on DSM-5 criteria and confirmed by a psychologist. 2. Female gender and age range of 13 to 18 years. 3. No participation in regular, organized sports programs in the past 6 months. 4. Having written informed consent from parents and the adolescent themselves to participate in the study. Exclusion Criteria: 1.Simultaneous participation in other treatment programs for social anxiety. 2.Missing more than 2 sessions during the intervention period.

Intervention groups

1.Intervention Group (Experimental): Receiving the Mindfulness-Based Stress Reduction (MBSR) program in 8 sessions of 90 minutes each (one session per week).

2.Control Group: Receiving no active intervention (waiting list).

Main outcome variables

Anxiety sensitivity and fear of negative evaluation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260715070197N2**
Registration date: **2026-08-28, 1405/06/06**
Registration timing: **prospective**

Last update: **2026-08-28, 1405/06/06**
Update count: **0**

Registration date

2026-08-28, 1405/06/06

Registrant information

Name

mojdeh pahlavani

Name of organization / entity

Country

Iran (Islamic Republic of)

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darya.j2018@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of a Mindfulness-Based Stress Reduction (MBSR) Program on Anxiety Sensitivity and Fear of Negative Evaluation in Non-Athlete Adolescent Girls with Symptoms of Social Anxiety Disorder

Public title

The Effectiveness of a Mindfulness-Based Stress Reduction Program on Anxiety Sensitivity and Fear of Negative Evaluation in Non-Athlete Adolescent Girls with Symptoms of Social Anxiety Disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of symptoms of social anxiety disorder based on DSM-5 criteria and confirmed by a clinical psychologist or psychiatrist. Female gender and age range of 13 to 18 years. No participation in regular, organized sports programs (non-athlete status) in the past 6 months. Written informed consent from parents or legal guardians, along with verbal assent from the adolescent to participate in the study.

Exclusion criteria:

Diagnosis of other acute or severe psychiatric disorders (e.g., schizophrenia, bipolar disorder, major depressive disorder with psychotic symptoms, or severe eating disorders). Simultaneous participation in other therapeutic programs or psychological interventions for social anxiety.

Age

From **13 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After initial assessment and confirmation of eligibility, participants will be randomly assigned to intervention and control groups using variable block randomization with a 1:1 allocation ratio. The unit of randomization is individual. To enhance group homogeneity, stratified randomization will be performed based on age and symptom severity. The randomization sequence will be generated using statistical software and concealed in opaque, numbered envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the nature of the intervention (group-based mindfulness training sessions), it is not possible to blind the participants and the therapist. Therefore, only the outcome assessor and the data analyst will be blinded to group allocation. The outcome assessor, who is responsible for data collection and administering the questionnaires at pre-test and post-test stages, will be unaware of the participants' group assignments and will work only with individual codes. Additionally, the data analyst will receive the data without knowledge of group allocation, and the decoding of groups will be performed only after the final analysis is completed. The principal investigator, therapist, and participants are aware of the group allocation, and this has been explained to the participants during the informed consent process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Islamic Azad University, Ahvaz Branch.

Street address

Islamic Azad University, Ahvaz Branch, 22 Bahman Boulevard, Ahvaz, Iran.

City

Ahvaz

Province

Khouzestan

Postal code

3733361349

Approval date

2026-08-23, 1405/06/01

Ethics committee reference number

IR.IAU.AHVAZ.REC.1405.461

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes

1

Description
Anxiety Sensitivity
Timepoint
Pre-test and Post-test
Method of measurement
The Anxiety Sensitivity Index (ASI) is a self-report questionnaire consisting of 16 items. It was developed by Reiss and Peterson in 1985. The questionnaire comprises three factors: fear of physical concerns (8 items), fear of cognitive dyscontrol (4 items), and fear of publicly observable anxiety symptoms (4 items).

2

Description
Fear of Negative Evaluation
Timepoint
Pre-test and Post-test
Method of measurement
This questionnaire, whose short form was developed by Leary in 1983, was designed to measure the fear of negative evaluation. The brief version (FNES-B) consists of 12 items, rated on a 5-point Likert scale. This instrument has demonstrated good validity and reliability.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention consists of a Mindfulness-Based Stress Reduction program delivered in 8 sessions of 90 minutes each (one session per week) in a group format. Session content includes training in progressive muscle relaxation, mindfulness of breathing, body scan, mindfulness of thoughts, and meditation exercises. The control group is placed on a waiting list and receives no intervention. Between-session assignments are provided to reinforce skill consolidation.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Nikan Counseling Center
Full name of responsible person
Rouhangiz Soltani
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اهواز، کیانپارس، بلوار ۹ غربی، مجتمع نوشین، مرکز مشاوره نیکان
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Sponsors / Funding sources

1

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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
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Zeynab Khatibi
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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
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available