Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A randomized clinical trial to evaluate the effectiveness of compassion-focused therapy on mindfulness skills and social self-efficacy in female students with social anxiety disorder

Protocol summary

Study aim

Assessment of the effectiveness of compassion-focused therapy on mindfulness skills and social self-efficacy in female students with social anxiety disorder

Design

A phase 2 randomized clinical trial with a pre-test,post-test,and follow-up design, including 30 female students diagnosed with social anxiety disorder who,after reviewing inclusion criteria,were randomly assigned using computer software to the experimental and control groups.

Settings and conduct

The study was conducted in a selected school from one district of Ahvaz,involving female students diagnosed with social anxiety disorder.Data were collected using questionnaires and field method.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Female secondary school students,aged 12–18,with high social anxiety and low mindfulness and social self-efficacy,with consent,not receiving other psychological treatments. Exclusion criteria:Other psychiatric disorders,receiving concurrent psychological treatments,lack of consen

Intervention groups

Intervention group:This group included female students diagnosed with social anxiety disorder who participated in 8 weekly compassion-focused therapy sessions.Each session lasted 90 minutes. Control group:This group did not receive any psychological intervention during the study period and only took part in the pre-test,post-test,and follow-up assessments.

Main outcome variables

Mindfulness skills (measured by FFMQ) and social self-efficacy (measured by the Sherer Self-Efficacy Scale).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250629066298N1**
Registration date: **2025-08-02, 1404/05/11**
Registration timing: **prospective**

Last update: **2025-08-02, 1404/05/11**
Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Fatemeh Tizvir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3372 2238

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-20, 1404/05/29

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A randomized clinical trial to evaluate the effectiveness of compassion-focused therapy on mindfulness skills and social self-efficacy in female students with social anxiety disorder

Public title
Studying the effect of compassion-based therapy on improving mindfulness and social confidence in female students with social anxiety

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female student enrolled in middle or high school Age between 12 to 18 years Low score in mindfulness and social self-efficacy Willingness to participate in the study (informed consent) Not currently receiving other psychological interventions High score in a social anxiety scale

Exclusion criteria:
Diagnosis of severe psychiatric disorders (e.g.,psychosis,bipolar disorder) Concurrent use of psychiatric medications affecting mood or anxiety Participation in other psychological interventions simultaneously Missing more than two interventions sessions Inability to understand intervention content or cooperate properly (based on researcher's judgment)

Age
From **12 years** old to **18 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting one educational district and one school from Ahvaz,30 female students who met the inclusion criteria and had been diagnosed with social anxiety disorder through counseling centers were recruited.Following screening,each participant was assigned a numerical code.Then,using a random number table,the participants were randomly allocated into two groups:intervention (n=15) and control (n=15).

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,Ahvaz Branch

Street address
Islamic Azad University of Ahvaz, Farhangshahr, Golestan Blvd., Ahvaz, Iran

City
Ahvaz

Province
Khouzestan

Postal code
۶۱۳۴۹۳۷۳۳۳

Approval date
2024-11-11, 1403/08/21

Ethics committee reference number
IR.IAU.AHVAZ.REC.1403.357

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
MindfulnessOutcome Description:The level of mindfulness in participants will be assessed using the Five Facet Mindfulness Questionnaire (FFMQ). This 39-item instrument evaluates the dimensions of observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience.

Timepoint
The pre-test was conducted one week before the beginning of the therapy sessions, the post-test was conducted immediately after the eighth session, and the follow-up was conducted one month after the end of the intervention.

Method of measurement
The mindfulness variable was measured using the Five Facet Mindfulness Questionnaire (FFMQ) at three stages (pre-test, post-test, and follow-up).

2

Description
Social Self-EfficacyOutcome Description:The level of social self-efficacy will be measured using the Social Self-Efficacy Questionnaire developed by Sherer and Maddux (1982), consisting of 17 items. This tool assesses an

individual’s ability to interact effectively in social situations and their confidence in social interactions.

Timepoint

The pre-test was conducted one week before the beginning of the therapy sessions, the post-test was conducted immediately after the eighth session, and the follow-up was conducted one month after the end of the intervention.

Method of measurement

The social self-efficacy variable was measured using the Sherer and Maddux Social Self-Efficacy Scale at three stages (pre-test, post-test, and follow-up)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consisted of 15 female students with social anxiety disorder who received compassion-focused therapy over 8 weekly sessions.

Category

Treatment - Other

2

Description

Control group: Consisted of 15 female students without receiving any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid mahshad shirazi School

Full name of responsible person
Fatemeh tizvir

Street address
Opposite Amir Kabir Hospital, North Amir Kabir Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Pejman Taghipour Birgani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University, Ahvaz Branch

Proportion provided by this source
1

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
Fatemeh tizvir

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Anonymized Data Sharing Plan for Qualified Researchers
When the data will become available and for how long
De-identified data will be available starting 6 months after study completion and will remain accessible for 3 years
To whom data/document is available
Qualified researchers who submit a formal request and obtain approval from the ethics committee will be allowed to access the de-identified data. Access will be granted solely for scientific and research purposes.
Under which criteria data/document could be used
The data may only be used for scientific and research purposes. Access requires a formal request, ethics committee approval, and a written commitment to maintain participant confidentiality. Commercial use of the data is not permitted.
From where data/document is obtainable
fati.tizvir75@gmail.com please send email.
What processes are involved for a request to access data/document
The applicant must submit a formal request via email to the Principal Investigator at fati.tizvi75@gmail.com. After identity verification and signing a confidentiality agreement (if required), the data will be provided within 7 to 15 working days.
Comments