Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the Effectiveness of Cognitive-Behavioral Therapy (CBT) on Perceived Stress, Intolerance of Uncertainty, and Mental Rumination in University Students with Social Anxiety Disorder

Protocol summary

Study aim
The aim of this study is to examine the effectiveness of cognitive behavioral therapy on perceived stress, intolerance of ambiguity, and rumination among students with social anxiety.

Design
This study is a quasi-experimental pre-test–post-test design with a control group. Thirty students with high social anxiety scores from Islamic Azad University, Sari Branch were selected through purposive sampling and randomly assigned to an experimental group (15) and a control group (15).

Settings and conduct
This study is conducted among students of Islamic Azad University, Sari Branch. After screening for social anxiety, 30 individuals with higher scores are selected and randomly assigned to an experimental group and a control group. The experimental group receives cognitive behavioral therapy, while the control group receives no intervention. Blinding was not performed in this study.

Participants/Inclusion and exclusion criteria
Undergraduate and graduate students of Islamic Azad University, Sari Branch, who obtain high scores on the social anxiety screening questionnaire, are willing to participate in the study, provide informed consent, and are not receiving any similar psychological treatment during the study period. Exclusion criteria: Presence of severe psychiatric disorders, or receiving concurrent psychological treatments that may influence the study outcomes.

Intervention groups
Participants in this group receive cognitive behavioral therapy. The intervention is conducted in a group format over 8 weekly sessions and includes training in cognitive and behavioral skills. Control group: Participants in this group do not receive any psychological intervention during the study period.

Main outcome variables
Perceived stress; intolerance of ambiguity; rumination in students with social anxiety.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250421065429N1**
Registration date: **2026-06-24, 1405/04/03**
Registration timing: **prospective**

Last update: **2026-06-24, 1405/04/03**
Update count: **0**

Registration date
2026-06-24, 1405/04/03

Registrant information
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fatemeh kamalinia
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-07-11, 1405/04/20
Expected recruitment end date
2026-09-11, 1405/06/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effectiveness of Cognitive-Behavioral Therapy (CBT) on Perceived Stress, Intolerance of Uncertainty, and Mental Rumination in University Students with Social Anxiety Disorder

Public title
The Effect of Group Cognitive-Behavioral Counseling on Reducing Stress, Increasing Uncertainty Tolerance, and Reducing Negative Repetitive Thoughts in University Students with Social Anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Students aged 20-40 years from Islamic Azad University, Sari Branch Score ≥ 19 on the Social Phobia Inventory (SPIN) Having at least a high school diploma (ability to read and write) Providing written informed consent to participate in the study
Exclusion criteria:
Comorbid acute psychiatric disorders (e.g., major depressive disorder, bipolar disorder, psychotic disorder, or substance use disorder) Concurrent receipt of any other psychological treatment History of seizures, epilepsy, or neurological diseases
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After screening students using the Social Anxiety Questionnaire among undergraduate and graduate students of Islamic Azad University, Sari Branch (11,274 students) between 2025/04/20 and 2025/06/09, 30 students who obtained the highest scores in social anxiety and met the inclusion criteria were selected. These participants were then assigned to two groups, an experimental group (15 participants) and a control group (15 participants), using a simple randomization method with the help of statistical software. The unit of randomization was the individual participant. To reduce selection bias, the selected participants were first coded and then allocated to the two groups according to a randomly generated sequence.
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
دانشگاه آزاد اسلامی واحد آیت اله آملی
Street address
Islamic Azad University, Ayatollah Amoli Branch, Daneshgah Street, Amol–Babol Road, before Komdereh Village, Amol, Iran.
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4661616917
Approval date
2026-06-22, 1405/04/01
Ethics committee reference number
IR.IAU.AMOL.REC.1404.053

Health conditions studied

1

Description of health condition studied
Social Anxiety (Social Phobia) in University Students
ICD-10 code
P05.08
ICD-10 code description
Newborn light for gestational age, 2000-2499 grams

Primary outcomes

1

Description
Perceived Stress Score
Timepoint
Pre-test (Baseline): Measurement of perceived stress score using the Perceived Stress Scale (PSS-14), one week before the start of the intervention (first treatment session) Post-test (Immediately after intervention): Measurement of perceived stress score using the Perceived Stress Scale (PSS-14), immediately after the completion of the last treatment session (twelfth session) Follow-up (2 months): Measurement of perceived stress score using the Perceived Stress Scale (PSS-14), 2 months after the completion of the last treatment session
Method of measurement
The Perceived Stress Scale with 14 items (PSS-14). This

questionnaire is completed by participants as a self-report measure. Each item is scored on a 5-point Likert scale (ranging from 0 = never to 4 = always). The total score ranges from 0 to 56.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group Cognitive-Behavioral Therapy based on the standard and specific protocol for Social Anxiety Disorder (Social Phobia), consisting of 12 sessions of 90 minutes each, delivered in a group format (each group consisting of 8 to 12 participants). Sessions are held weekly for 12 consecutive weeks.Content of treatment sessions includes: Sessions 1 to 3 (Introduction and Psychoeducation): Familiarization of members with each other, establishing therapeutic alliance, teaching the cognitive-behavioral model of social anxiety, identifying and recording negative automatic thoughts in social situations Sessions 4 to 6 (Cognitive Restructuring): Teaching the identification of cognitive errors (such as catastrophizing, overgeneralization, mind reading), challenging maladaptive beliefs related to negative evaluation by others, replacing negative thoughts with balanced and realistic thoughts Sessions 7 to 10 (Social Skills Training and Exposure): Teaching effective communication skills (initiating and maintaining conversation, assertiveness, active listening), gradual in-session exposure to feared social situations (such as public speaking, talking to strangers, expressing opinions in groups), and practicing deep breathing and progressive muscle relaxation to manage physiological symptoms of anxiety Sessions 11 to 12 (Consolidation and Relapse Prevention): Review of learned skills, planning for independent exposure in natural environments, identifying signs of relapse risk, and developing strategies to prevent symptom recurrenceNumber of sessions: 12 sessionsDuration of each session: 90 minutesFrequency: One session per weekTotal intervention duration: 12 weeksMethod of delivery: Group-based (8 to 12 participants per group) and in-person

Category

Behavior

2

Description

Control group: The control group is placed on a waiting list and receives no psychological or pharmacological intervention during the study period. Participants in this group are assessed at the same time points as the intervention group (pre-test, post-test, and follow-up). After the completion of the treatment period for the intervention group and the post-test and follow-up assessments, the same cognitive-behavioral therapy program will be offered free of charge to the control group members if they wish.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Sari Branch

Full name of responsible person
Maryam Foolad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
1

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

Maryam Foolad

Position

Master

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Lack of participant consent

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable