Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effectiveness of Emotion Regulation Therapy on reducing the severity of symptoms and certain emotional and cognitive components in individuals with Social Anxiety Disorder.

Protocol summary

Study aim

Determining The effectiveness of Emotion Regulation Therapy on reducing the severity of symptoms and certain emotional and cognitive components in individuals with Social Anxiety Disorder.

Design

This randomized, single-blind, parallel-group trial will include 23 patients in the intervention group and 23 in the control/waitlist group, with allocation determined using Excel's RAND function.

Settings and conduct

The Emotion Regulation Therapy (ERT) protocol developed by Mennin will be individually administered in 16 sessions to patients with Social Anxiety Disorder at Dr. Beheshti Psychiatric Hospital in Zanjan. Assessments will be conducted by an independent evaluator blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of Social Anxiety Disorder via SCID-I/II; LSAS score ≥55; age 18–60; high school diploma or higher and signed informed consent.
Exclusion Criteria: Substance/alcohol use in the past 3 months; prior ERT for SAD; current psychiatric medication use or diagnosis of depressive, bipolar, psychotic spectrum, autism spectrum, or personality disorders per SCID-I/II.

Intervention groups

The intervention group will receive Mennin's Emotion Regulation Therapy (ERT) with assessments at three phases, while the control group will undergo the same assessments without treatment. After the study, the control group will be offered ERT.

Main outcome variables

Severity of Social Anxiety Disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250715066505N1**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **prospective**

Last update: **2025-09-01, 1404/06/10**
Update count: **0**

Registration date

2025-09-01, 1404/06/10

Registrant information

Name

Reyhaneh Miralikhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of Emotion Regulation Therapy on reducing the severity of symptoms and certain emotional and cognitive components in individuals with Social Anxiety Disorder.

Public title
The effectiveness of Emotion Regulation Therapy on reducing the severity of symptoms and certain emotional and cognitive components in individuals with Social Anxiety Disorder.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Presence of symptoms consistent with Social Anxiety Disorder as determined by the Structured Clinical Interview for DSM-IV Axis I and II Disorders (SCID-I and SCID-II), and a minimum score of 55 on the Liebowitz Social Anxiety Scale (LSAS) Possession of a high school diploma or higher level of formal education Age range between 18 and 60 years Willingness of participants to take part in the study as indicated by the provisions of the written informed consent

Exclusion criteria:
Diagnosis of depressive disorders, bipolar disorder, psychotic spectrum disorders, autism spectrum disorders, or personality disorders Previous participation in formal emotion regulation clinical trials for Social Anxiety Disorder (SAD) Current psychiatric medication use Substance or alcohol use within the past three months

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be performed using Microsoft Excel. To do this, in the first column, 20 number “1” entries and 20 number “2” entries (representing the experimental and control groups, respectively) will be entered. Then, in the second column, 40 random numbers will be generated using the RAND function. The data will be sorted based on the values in the random number column (either in ascending or descending order). Through this sorting, the sequence of 1s and 2s will also be rearranged randomly. According to the new order of 1s and 2s, the participants will be assigned to the two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the implementation of this study, blinding will be done in such a way that the therapist and the evaluator are two different people, the therapist is the student, and the evaluator will be a clinical psychology graduate who will not know about the people of both groups in the process of evaluating the occurrence of consequences and reduction of symptoms before and after treatment and also during the follow-up period.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
1st Floor, Building No. 1, Zanjan University of Medical Sciences and Health Services, Beginning of Jomhouri Eslami Street, Azadi Square

City
Zanjan

Province
Zanjan

Postal code
4515613191

Approval date
2025-05-26, 1404/03/05

Ethics committee reference number
IR.ZUMS.REC.1404.070

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
Severity of Social Anxiety Disorder symptoms

Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention

Method of measurement
Liebowitz Social Anxiety Scale

Secondary outcomes

1

Description
Negative Mood Regulation Expectancies
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Negative Mood Regulation Expectancies Questionnaire (NMRE)

2

Description
Emotion dysregulation
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Difficulties In Emotion Regulation Scale (DERS)

3

Description
Post Event Processing
Timepoint
Before the start of the intervention, after the end of the intervention, 3 months after the end of the intervention
Method of measurement
Post Event Processing Questionnaire (PEPQ)

Intervention groups

1

Description
Intervention group: Intervention group: This group will consist of 23 patients diagnosed with Social Anxiety Disorder who will receive Mennin's Emotion Regulation Therapy (ERT) protocol twice weekly for a total of 16 sessions, each lasting 60–90 minutes. Assessments will be conducted at baseline, post-treatment, and three months after treatment completion. ERT is a third-wave, emotion-focused cognitive-behavioral therapy with a structured, stage-based format aimed at enhancing emotional awareness, developing regulation skills, and employing newly learned contextual strategies.
Category
Treatment - Other

2

Description
Control group: This group will include 23 patients with Social Anxiety Disorder who will receive no intervention during the study period and will be placed on a waitlist. After the study concludes, they will be offered Mennin's Emotion Regulation Therapy (ERT) protocol, delivered twice weekly for 16 sessions of 60–90 minutes each.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Beheshti Psychiatric Hospital
Full name of responsible person
Seyede Elnaz Mousavi
Street address
Dr. Beheshti Psychiatric Hospital, Ark Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mehrdad Hamidi
Street address
1st Floor, Building No. 1, Zanjan University of Medical Sciences and Health Services, Beginning of Jomhouri Eslami Street, Azadi Square
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zanjan University of Medical Sciences
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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Seyede Elnaz Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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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