

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effectiveness of emotion regulation therapy on decentering, difficulty in emotion regulation and symptoms people with social anxiety disorder comorbid with generalized anxiety disorder

Protocol summary

Study aim

Investigating the effect of emotion regulation treatment on symptoms of social anxiety disorder comorbid with generalized anxiety disorder

Design

The clinical trial has an intervention group, a control group, and a blind strain, which were randomly assigned to the control and intervention groups

Settings and conduct

The statistical population of the study includes all patients with SAD comorbid with GAD who refer to psychotherapy clinics in Shiraz. These patients are selected if they are volunteers and considering the entry and exit criteria. 30 people from the mentioned community were selected by available sampling method and were randomly divided into two control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion: Diagnosis of comorbid SAD with GAD based on structured clinical interview for DSM-5
Exclusion: Suffering from severe clinical disorders such as psychosis, personality disorders and substance abuse disorder or other axis I and II disorders as the main diagnosis, simultaneous participation in other psychotherapy sessions, receiving drug therapy and three sessions of absence during treatment.

Intervention groups

Intervention group: The group of patients who are treated with emotion regulation therapy.
Control group: the group of patients who do not receive any intervention

Main outcome variables

Symptoms of social anxiety disorder comorbid with generalized anxiety disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056812N1**

Registration date: **2023-05-04, 1402/02/14**

Registration timing: **prospective**

Last update: **2023-05-04, 1402/02/14**

Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

Name

Soodeh Shadkam

Name of organization / entity

Bu-Ali Sina University

Country

Iran (Islamic Republic of)

Phone

+98 81 3829 2310

Email address

sshadkam5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of emotion regulation therapy on decentering, difficulty in emotion regulation and symptoms people with social anxiety disorder comorbid with generalized anxiety disorder

Public title
The effectiveness of emotion regulation therapy on symptoms people with social anxiety disorder comorbid with generalized anxiety disorder

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of SAD comorbid with GAD
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, a simple random method will be used, in this way, the names of the volunteers will be placed in an envelope, and the names of 15 people will be randomly drawn, and these will be the intervention group, and the rest will be the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
None of the sampled people will know about randomization and the process of allocation to groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Bu-Ali Sina University

Street address

Bu-Ali Sina university of Hamadan, Chaharbagh
Shahid Mostafa Ahmadi Roshan, Hamadan

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Approval date
2022-12-13, 1401/09/22
Ethics committee reference number
IR.BASU.REC.1401.044

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder comorbid with General Anxiety Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Symptoms of social anxiety disorder

Timepoint

Pre-test, post-test

Method of measurement

Social interaction anxiety scale

2

Description

Symptom of general anxiety disorder

Timepoint

Pre-test, post-test

Method of measurement

General anxiety disorder scale-7

Secondary outcomes

1

Description

Anxiety general distress

Timepoint

Pre-test, post-test

Method of measurement

Mind and anxiety symptom questionnaire (short form)

2

Description

Anxiety arousal

Timepoint

Pre test, post test

Method of measurement

Mind and anxiety symptom questionnaire (short form)

3

Description

Worry

Timepoint

Pre test, post test

Method of measurement

Penn state worry questionnaire

4

Description

Negative repetitive thinking

Timepoint

Pre test, post test

Method of measurement

Perseverative thinking questionnaire

5

Description

Decentering

Timepoint

Pre test, post test

Method of measurement

Experiences questionnaire

6

Description

Difficulty in emotion regulation

Timepoint

Pre test, post test

Method of measurement

Difficulties in emotion regulation scale

Intervention groups

1

Description

Intervention group: They receive 8 sessions of emotional regulation group therapy, each session of 90 minutes and on a weekly basis.

Category

Behavior

2

Description

Control group: without therapy

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Omid Reza Sahami professional clinic

Full name of responsible person

Soodeh Shadkam

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2 Abivardi St, Chamran Blvd, Shiraz

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bu_Ali Sina University

Full name of responsible person

Abbas Aflatuni

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Bu-Ali Sina University, Faculty of Economics, ministry of science

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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

Bu_Ali Sina University

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**

Bu-Ali Sina University of Hamadan

Full name of responsible person

Soodeh shadkam

Position
Ph.D student

Latest degree
Master

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only data related to the final result is accessible

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Psychologist and psychiatrist researchers and experts

Under which criteria data/document could be used

The use of documents is allowed only for further research

From where data/document is obtainable

Soodeh Shadkam , Email: sshadkam5@gmail.com

What processes are involved for a request to access data/document

Send an email to the researcher

Comments