Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of cognitive behavioral therapy on anger control, distress tolerance, and negative automatic thoughts in widowed women with symptoms of social anxiety

Protocol summary

Study aim
Determining the effectiveness of cognitive behavioral therapy on anger control, distress tolerance, and negative self-defeating thoughts in single women with social anxiety symptoms

Design
A clinical trial with an intervention group and a control group, with parallel groups, unblinded, randomized, with pre-test and post-test, on 30 people, was used for randomization by lottery.

Settings and conduct
The experimental group will undergo cognitive behavioral therapy training; but the control group will not receive any intervention. Both the experimental group and the control group will be measured twice (pre-test-post-test) separately through social anxiety questionnaires, anger questionnaire, distress tolerance questionnaire, and negative spontaneous thoughts. The statistical population of this study will be all unaccompanied women covered by the Welfare Department. It will be implemented in Ahvaz city and will last for 12 sessions.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Not attending educational classes concurrent with this study's training sessions/Informed consent of the participant to participate in the research/Obtaining a low score on the anger control and distress tolerance questionnaire based on the cutoff score/Obtaining a high score on the negative automatic thoughts questionnaire according to the cutoff score/Absence of any specific physical or psychological illness affecting the treatment process Exclusion Criteria: Absence in more than 2 intervention sessions/Concurrent use of psychiatric medications with this treatment/ Participation in other psychological interventions/Development of a pervasive disorder

Intervention groups
The experimental group receives cognitive behavioral therapy intervention. The control group receives no intervention.

Main outcome variables
Anger control; Distress tolerance; Negative automatic thoughts

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250521065821N1**
Registration date: **2025-07-29, 1404/05/07**
Registration timing: **prospective**

Last update: **2025-07-29, 1404/05/07**
Update count: **0**

Registration date
2025-07-29, 1404/05/07

Registrant information

Name
Iran Davoudi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3320 0630

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-16, 1404/05/25

Expected recruitment end date

2025-10-17, 1404/07/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of cognitive behavioral therapy on anger control, distress tolerance, and negative automatic thoughts in widowed women with symptoms of social anxiety

Public title
The effect of cognitive behavioral therapy on anger control, distress tolerance, and negative automatic thoughts in single-parent women with symptoms of social anxiety

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Non-attendance in educational classes concurrent with the training sessions of this study Informed consent of the participant to participate in the research Obtaining a low score on the anger control and distress tolerance questionnaire based on the questionnaire's cutoff score. Obtaining a high score on the negative automatic thoughts questionnaire according to the questionnaire's cutoff score. Absence of any specific physical or psychological illness affecting the treatment process.

Exclusion criteria:
Absence in more than 2 intervention sessions. Concurrent use of psychiatric medications with this treatment. Not participating in other psychological interventions. Developing a pervasive disorder.

Age
No age limit

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
The selection will be done through a simple randomization method. According to this method, the names of each selected member will be written on paper as research samples, placed in a box for drawing, and then the pieces of paper will be drawn one by one. The first 15 individuals (1 to 15) will be part of the experimental group, and the next 15 individuals (16 to 30) whose names are drawn from the box will be members of the control group.

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
The Ethics Committee in Research of Islamic Azad University - Ahvaz Branch

Street address
South Kargar Boulevard؛ Farhang Shahr؛ Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

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

Ethics committee reference number
IR.IAU.AHVAZ.REC.1403.355

Health conditions studied

1

Description of health condition studied
Not applicable.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anger control

Timepoint
Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test.

Method of measurement
Spielberger Anger Questionnaire

2

Description
Distress tolerance

Timepoint
Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test.

Method of measurement
Simmons and Gahr Distress Tolerance Questionnaire

3

Description
Negative self-talk
Timepoint
Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test.
Method of measurement
Automatic Negative Thoughts Questionnaire (ATQ)

4

Description
Social anxiety
Timepoint
Measurements will be conducted at pre-test, post-test, and three-month follow-up after the post-test.
Method of measurement
Social Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1. First Session:The first session included psychoeducation, which consisted of:a) Teaching the basics of cognitive-behavioral therapy (CBT) and presenting the rationale for treatment.b) Educating about the fundamental principles of symptoms related to social anxiety disorder (SAD), introducing and discussing the cognitive-behavioral model of SAD.c) Encouraging patient engagement in therapy sessions and completing between-session assignments.d) Homework: Reviewing the cognitive-behavioral model worksheet for SAD. 2. Second Session:a) Reviewing the treatment model.b) Educating the patient about anxiety and the role of avoidance in maintaining social anxiety.c) Raising awareness about the importance of exposure and the nature of exposure situations.d) Creating a fear and avoidance hierarchy.e) Homework: Daily recording of anxiety-provoking social situations. 3. Third Session:a) Introducing the patient to negative automatic thoughts and maladaptive beliefs.b) Teaching the patient skills to identify and categorize negative automatic thoughts and challenge them.c) Homework: Completing the automatic thought challenging worksheet. 4-5. Fourth and Fifth Sessions:a) Developing a fear and avoidance hierarchy.b) Introducing the patient to the video feedback technique.c) Conducting video feedback exposure in the session: (The patient is asked to speak in front of a video camera about what they have learned in previous therapy sessions. The recorded video is then played back for the patient and those present during the exposure).d) Homework: (The patient is asked to stand in front of a mirror daily for a few minutes and talk about a topic or describe their own characteristics). 6-7. Sixth and Seventh Sessions:a) Preparing the patient for exposure in natural settings outside therapy sessions.b) Designing appropriate exposure situations for the patient based on the fear and avoidance hierarchy.c) Conducting exposure outside the therapy session.d) Providing feedback to the patient after exposure.e) Homework: The patient is asked to design and carry out several exposure situations and assess their anxiety levels before and after exposure. 8-9. Eighth and Ninth Sessions:a) Teaching assertiveness skills to the patient.b) Introducing the patient to assertiveness techniques and their different forms.c) Homework: The patient is asked to identify situations requiring assertiveness that they previously avoided and apply this skill. 10-11. Tenth and Eleventh Sessions:a) Relapse prevention.b) Identifying maintaining factors to prevent relapse in daily life.c) Preparing the patient to cope with temporary anxiety recurrence.d) Reviewing all therapy sessions, summarizing the patient's progress, and providing feedback. 12. Twelfth Session:Administering post-test questionnaires and thanking the participants.
Category
Behavior

2

Description
Control group: They receive no training.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
The General Department of Welfare of Khuzestan Province
Full name of responsible person
Mehran Karimian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Iran Davodi
Street address

South Kargar Boulevard؛ Farhang Shahr District؛ Golestan Highway

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Web page address
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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
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
Narges Yousefi Sheikh Robat

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Associate professor

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Person responsible for updating data

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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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

Only part of the data, such as information related to the primary outcome or similar, can be shared.

When the data will become available and for how long

Access period begins 6 months after publication of results.

To whom data/document is available

The data will only be accessible to researchers affiliated with academic or scientific institutions.

Under which criteria data/document could be used

Any type of analysis is permitted on the delivered data.

From where data/document is obtainable

Via email: nargesyousefi0203@gmail.com

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

The data will be sent after emailing narges yousefi Sheikh Robat and receiving approval from the research team members

Comments