Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of group cognitive behavioral therapy on anxiety treatment and social support in patients with panic disorder.

Protocol summary

Study aim
Determining the effectiveness of group cognitive behavioral therapy on anxiety sensitivity and perceived social support in patients with panic disorder

Design
Clinical trial of the effectiveness of the treatment group plus the control group, with a parallel group, does not have blinding. 30 people are selected through purposeful randomization and then they are placed into groups through simple randomization.

Settings and conduct
The study is conducted among people with panic disorder who refer to counseling and psychological services centers in Ahvaz. After screening and meeting the entry requirements, 30 people are selected through purposive sampling and randomly assigned to two experimental and control groups (15 people in each group). Interventions are implemented in 12 60-minute sessions, one session per week, for two months. The control group will not receive any intervention until the end of the study, and blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria included: diagnosis of generalized anxiety disorder based on DSM-5-TR criteria, having a minimum level of literacy to understand treatment materials and respond to research instruments, informed consent to participate in the study, and exclusion criteria included: having severe psychiatric disorders, cognitive disability, or mental retardation that prevents effective participation in sessions, and receiving other concurrent psychotherapy.

Intervention groups
The intervention group includes patients with panic disorder who will undergo a therapeutic intervention protocol during 12 60-minute sessions, one session per week, while the control group will not receive any intervention.

Main outcome variables
Anxiety sensitivity, perceived social support

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260801070482N1**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date
2026-08-29, 1405/06/07

Registrant information

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Masomeh Kamaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-15, 1405/05/24

Expected recruitment end date
2026-10-16, 1405/07/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effectiveness of group cognitive behavioral therapy on anxiety treatment and social support in patients with panic disorder.

Public title
Investigating the effectiveness of group cognitive behavioral therapy on anxiety sensitivity and perceived social support

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of panic disorder based on DSM-5-TR criteria by a psychiatrist or clinical psychologist Have a minimum level of reading and writing literacy to understand treatment materials and respond to research tools Willingness to participate in the research and signing the informed consent form

Exclusion criteria:
Starting another psychological treatment at the same time Having severe psychiatric disorders Cognitive disability or mental retardation that prevents effective participation in meetings

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
Random assignment of eligible individuals to the intervention and control groups will be simple random, using a random sequence generated by a random number table on the Randomization.com website. (To prepare a randomization list on the Randomization.com website, first enter the number of samples, the number of groups, and the type of randomization (such as block); then the website automatically generates a random list for assigning individuals to the research groups, which can be used in the sampling or subject allocation process.) This sequence is written in lowercase letters and kept in a sealed envelope. When each individual is selected, the envelope is opened and the individual is assigned to the counseling or control group according to the code.

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
Southern Kargar Boulevard, Culture City, Golestan Highway

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Khouzestan

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6134937333

Approval date
2026-07-21, 1405/04/30

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.446

Health conditions studied

1

Description of health condition studied
Panic disorder

ICD-10 code
F41.0

ICD-10 code description
Panic disorder [episodic paroxysmal anxiety] without agoraphobia

Primary outcomes

1

Description
Anxiety sensitivity

Timepoint
At the start of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement
Anxiety Sensitivity Scale (ASI) (2005)

2

Description
Perceived social support

Timepoint
At the start of the intervention, 2 weeks after the intervention, 8 weeks after the intervention, 2 months after the end of the intervention

Method of measurement
Zimet et al.'s Perceived Social Support Questionnaire (1988)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Session 1: The first session focused on establishing a therapeutic alliance by introducing the therapist and group members and explaining the fundamental group rules, including confidentiality, mutual respect, and active participation. The overall structure of the treatment program was then outlined, followed by an introduction to panic disorder, its clinical features, and common symptoms. The cognitive-behavioral model of panic disorder was presented, emphasizing the panic cycle consisting of bodily sensations, catastrophic misinterpretations, increased anxiety, intensification of physical symptoms, and the occurrence of panic attacks. In addition, the concept of anxiety sensitivity and its role in maintaining panic attacks were explained. At the end of the session, participants were asked to draw their own personal panic cycle and were assigned homework to monitor and record panic attacks, associated thoughts, emotions, and behaviors throughout the week.Session 2: The second session began with a review of the previous week's homework. Participants were then introduced to the concept of automatic thoughts and the cognitive distortions commonly associated with panic disorder. The concept of anxiety sensitivity and its relationship with catastrophic interpretations of bodily sensations was further explored, enabling participants to recognize automatic thoughts that occur during episodes of anxiety. Practical exercises focused on identifying and recording automatic thoughts, and participants were assigned homework to complete thought-record forms whenever they encountered anxiety-provoking situations during the week.Session 3: The third session was devoted to cognitive restructuring. Participants were taught how to evaluate evidence supporting and contradicting dysfunctional thoughts and were encouraged to examine irrational beliefs and catastrophic interpretations related to bodily sensations and panic attacks. Subsequently, techniques for replacing maladaptive thoughts with more rational and realistic alternatives were introduced. Participants practiced cognitive restructuring using an actual panic attack they had experienced. Daily cognitive restructuring exercises were assigned as homework to reinforce the newly acquired skills.Session 4: The primary objective of the fourth session was to reduce physiological arousal and enhance participants' sense of control over anxiety symptoms. Diaphragmatic breathing and progressive muscle relaxation techniques were introduced and practiced. The role of breathing patterns in maintaining or alleviating the panic cycle was also discussed. Participants engaged in guided breathing and relaxation exercises during the session and were instructed to practice these techniques daily at home.Session 5: The fifth session focused on interoceptive exposure as a key cognitive-behavioral intervention for panic disorder, with the aim of reducing fear of anxiety-related bodily sensations. Participants were introduced to the rationale for interoceptive exposure and completed exercises such as rapid breathing, spinning in a chair, and running in place to deliberately induce physical sensations similar to those experienced during panic attacks. Subjective anxiety levels were monitored using the Subjective Units of Distress Scale (SUDS). Participants were instructed to continue these interoceptive exposure exercises at home while recording their anxiety levels.Session 6: During the sixth session, participants identified their individual safety behaviors commonly used to prevent or reduce anxiety and examined how these behaviors contributed to the maintenance of panic disorder. Strategies for the gradual elimination of safety behaviors were introduced, and each participant selected one specific safety behavior to discontinue. As homework, participants were asked to document their experiences of eliminating the selected safety behavior and to report any resulting changes.Session 7: The seventh session focused on situational exposure. Participants first developed individualized fear hierarchies consisting of anxiety-provoking and avoided situations. The principles of gradual exposure were then explained, followed by the implementation of an initial exposure exercise within the therapeutic setting using a relatively low-anxiety situation. This exercise allowed participants to gain confidence through successful exposure experiences. Participants were subsequently instructed to continue gradual exposure in real-life situations as their weekly homework.Session 8: The eighth session aimed to improve participants' coping abilities by teaching a structured problem-solving approach. Participants learned the sequential steps of problem-solving, including problem identification, generation of alternative solutions, evaluation of possible outcomes, selection of the most appropriate solution, and implementation of the chosen strategy. Real-life problems presented by participants were addressed using this framework, and they were assigned homework to apply the problem-solving process to an actual stressful situation encountered during the following week.Session 9: The ninth session emphasized the importance of social support in managing anxiety. The therapeutic role of family members, friends, and supportive social networks was discussed, followed by training in effective interpersonal skills, including assertiveness, appropriate help-seeking, and active listening. Participants practiced requesting support through role-playing exercises and were instructed to apply these communication skills with at least one family member or friend during the week while documenting their experiences.Session 10: The tenth session focused on strengthening social relationships and reducing behavioral isolation. Participants identified barriers that limited their social interactions and discussed the beneficial effects of supportive relationships on anxiety reduction. Individualized plans for increasing social engagement were then developed, and participants created weekly activity schedules designed to enhance

social participation. Homework consisted of completing at least two planned social activities and recording their experiences and emotional responses.Session 11: The eleventh session was designed to consolidate and integrate the cognitive and behavioral skills acquired throughout the treatment program. Cognitive restructuring, interoceptive and situational exposure techniques, and interpersonal communication skills were comprehensively reviewed, and participants' therapeutic progress was evaluated. Participants then analyzed a real-life anxiety-provoking situation by simultaneously applying all previously learned cognitive and behavioral strategies. They were encouraged to continue integrating these skills into everyday anxiety-provoking situations as part of their homework.Session 12: The final session focused on reviewing the major therapeutic concepts and evaluating the progress achieved throughout the intervention. Potential risk factors for relapse were identified, and each participant developed a personalized relapse prevention plan. Emphasis was placed on the continued practice of cognitive and behavioral techniques, gradual exposure exercises, effective communication skills, maintenance of supportive interpersonal relationships, and ongoing self-monitoring of anxiety symptoms. Finally, participants designed individualized anxiety management plans intended to help maintain therapeutic gains and reduce the likelihood of relapse following completion of the treatment program.

Category

Treatment - Other

2

Description

Control group: They do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ideh Clinic

Full name of responsible person

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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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Web page address

https://ahvaz.iau.ir/fa

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

Masomeh Kamaei

Position

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
Study data, treatment protocol

When the data will become available and for how long
After publishing the articles

To whom data/document is available
All those interested in research in this field

Under which criteria data/document could be used
Any type of analysis on the submitted data is permitted and acceptable with attribution of the source

From where data/document is obtainable
Via Masomeh Kamaei at: m_kamaeiii@gmail.com

What processes are involved for a request to access data/document
Send an email to Masomeh Kamaei and after approval by the research team members, the data will be sent.

Comments