Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of cognitive behavioral therapy on rumination and severity of panic attacks in people with panic disorder and comorbid depression.

Protocol summary

Study aim
Investigating the effectiveness of CBT treatment on panic attacks and rumination

Design
A controlled, parallel-group, unblinded, randomized, phase 2 clinical trial on 15 patients. A random number table was used for randomization.

Settings and conduct
Initially, the required approvals were obtained from the faculty, and the research protocol was reviewed and approved by the Ethics Committee of Islamic Azad University, Ayatollah Amoli Branch (Ethics Code: IR.IAU.AMOL.REC.1403.070). Subsequently, with permission from the Welfare Organization of Mazandaran Province, invitation letters were sent to its affiliated centers in the eastern and central regions of the province. Eight psychological centers agreed to cooperate. A licensed clinical psychologist conducted interviews with 145 clients diagnosed with Panic Disorder, among whom 67 were formally diagnosed with comorbid Major Depressive Disorder. From this pool, 30 individuals were selected using a random number table and randomly allocated into two groups of 15 (intervention and control) using sealed envelopes. No blinding was performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definite diagnosis of panic disorder along with co-occurring major depressive disorder based on DSM5-tr criteria, being a resident of Mazandaran, being a welfare referent. Exclusion criteria: diagnosis of another mental disorder

Intervention groups
The intervention group consists of patients with panic disorder and comorbid major depression who receive a 12-session cognitive behavioral therapy intervention. The comparison group consists of patients with panic disorder and comorbid major depression who remain on the waiting list.

Main outcome variables
Panic attacks - Rumination

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260726070373N1**
Registration date: **2026-08-02, 1405/05/11**
Registration timing: **prospective**

Last update: **2026-08-02, 1405/05/11**
Update count: **0**

Registration date
2026-08-02, 1405/05/11

Registrant information

Name
Sepideh Rahnama
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4321 7000
Email address
ps.sepi.rahi.79@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-05, 1405/05/14

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of cognitive behavioral therapy on rumination and severity of panic attacks in people with panic disorder and comorbid depression.

Public title
Effectiveness of cognitive behavioral therapy on rumination and panic attacks
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1. Definitive diagnosis of Panic Disorder by a qualified clinical psychologist, during a clinical interview (recorded in patients' files at the initial session) based on the DSM-5-TR diagnostic criteria 2. Definitive diagnosis of Major Depressive Disorder by a qualified clinical psychologist, during a clinical interview (recorded in patients' files at the initial session) based on the DSM-5-TR diagnostic criteria 3. Being a resident and a client of psychological centers in the eastern and central regions of Mazandaran province 4. Providing written informed consent to participate in the study 5. Not receiving concurrent treatment (psychiatric and psychotherapeutic)
Exclusion criteria:
Having severe psychological disorders (such as schizophrenia) that may interfere with the cognitive-behavioral therapy process Diagnosis of a mental disorder other than panic disorder and major depression
Age
From **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Following the initial diagnostic screening, a total of 67 patients diagnosed with Panic Disorder who also met the criteria for comorbid Major Depressive Disorder (MDD) were enrolled in the study. Among these, 30 individuals who met the final eligibility criteria were selected for inclusion in the trial. In this study, simple randomization with an individual-level unit of randomization was employed. Given the sample size (n=30) and the lack of necessity to balance the groups with respect to baseline covariates, no stratification based on age, gender, or treatment center was performed. The random allocation sequence for assigning participants to either the intervention or control group was generated using a random number table. To prevent bias in the allocation process, the generated random sequence was placed inside opaque, identical, tamper-proof, and sealed envelopes. These envelopes were prepared and numbered by an individual independent of the assessment and intervention processes. Following the initial evaluations conducted by the clinical psychologist, the envelope corresponding to each participant was opened in order of entry, and each individual was allocated to one of the two groups (intervention or control) based on the number contained within the envelope.
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
Research Ethics Committees of Islamic Azad University - Ayatollah Amoli Branch
Street address
Islamic Azad University, Ayatollah Amoli Branch, University Sub-road, Km 5 of the Old Amol-Babol Road, Amol, Mazandaran Province, Iran
City
Amol
Province
Mazandaran
Postal code
3358461514
Approval date
2024-06-10, 1403/03/21
Ethics committee reference number
IR.IAU.AMOL.REC.1403.070

Health conditions studied

1

Description of health condition studied
People with panic disorder have comorbid depression
ICD-10 code
F41.0
ICD-10 code description
Panic disorder [episodic paroxysmal anxiety] without agoraphobia

Primary outcomes

1

Description
Severity of panic attacks
Timepoint
Pre-test and post-test
Method of measurement
(Albany Panic and Phobia Questionnaire (APPQ))

Secondary outcomes

1

Description
rumination
Timepoint
Pre-test and post-test
Method of measurement
(Ruminative Response Scale (RRS))

Intervention groups

1

Description
Intervention group: The intervention group received 12 sessions of 90 minutes, one session per week, face-to-face and individually, with the protocol of Leahy and colleagues, cognitive-behavioral therapy training. This protocol has been translated and evaluated in Iran.
Category
Behavior

2

Description
Control group: The control group did not receive any intervention and remained on the waitlist. This group completed a pre-test and post-test at the beginning and end of the study, then after the study was completed, the same treatment was administered to them by a psychologist.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
8 Welfare Centers in the East and Center of Mazandaran Province
Full name of responsible person
Sepideh Rahnama
Street address
Islamic Azad University, Ayatollah Amoli Branch, University Sub-road, Km 5 of the Old Amol-Babol Road, Amol, Mazandaran Province, Iran
City
Amol
Province
Mazandaran
Postal code
3358461514
Phone
+98 11 4321 7061
Email
Sepideh.rahnama79@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sepideh Rahnama
Street address
-
City
Amol
Province
Mazandaran
Postal code
3358461514
Phone
+98 11 4321 7061
Email
Sepideh.rahnama79@gmail.com
Web page address
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
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
Gholamali Nikpoor
Position
Postdoctoral Researcher in Cognitive and Brain Sciences, Faculty Member, Rahe Danesh University of B

Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University, Ayatollah Amoli Branch, University Sub-road, Km 5 of the Old Amol-Babol Road, Amol, Mazandaran Province, Iran
City
Amol
Province
Mazandaran
Postal code
3358461514
Phone
+98 11 4321 7061
Email
Nikpoorg@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sepideh Rahnama
Position
M.A in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Islamic Azad University, Ayatollah Amoli Branch, University Sub-road, Km 5 of the Old Amol-Babol Road, Amol, Mazandaran Province, Iran
City
Amol
Province
Mazandaran
Postal code
3358461514
Phone
+98 11 4321 7061
Email
Sepideh.rahnama79@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sepideh Rahnama
Position
M.A in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Islamic Azad University, Ayatollah Amoli Branch, University Sub-road, Km 5 of the Old Amol-Babol Road, Amol, Mazandaran Province, Iran
City
Amol
Province
Mazandaran
Postal code
3358461514
Phone
+98 11 4321 7061
Email
Sepideh.rahnama79@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Pre-test and post-test data on dependent variables can be shared after de-identifying individuals.
When the data will become available and for how long
Since the beginning of the year 1406 AH
To whom data/document is available
University researchers with an official letter from their supervisor
Under which criteria data/document could be used
No further analysis is permitted.
From where data/document is obtainable
Corresponding author or supervisor
What processes are involved for a request to access data/document
A written request with the seal of the faculty's research vice chancellor is sufficient.
Comments