

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Intervention Based on the Cognitive Behavioral Therapy Model of Panic Attack Treatment in Comorbid Heart Diseases (PATCHD) and Exploring Patients' Experience of Treatment: A Mixed-Method Approach

Protocol summary

Study aim

To determine the effect of intervention based on the PATCHD model on the symptoms of panic disorder in cardiovascular patients

Design

A randomized controlled trial will use the Excel software rand function for randomization.

Settings and conduct

The participants are randomly assigned to the experimental and control groups of the waiting list. The intervention is carried out in 8 sessions of 90 minutes as a group on the experimental group. Before and after the intervention, the experimental and control group patients will complete the waiting list of the panic disorder severity scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) have symptoms of panic disorder and cardiovascular disease, (2) be at least 18 years old, (3) not be undergoing simultaneous psychiatric treatment (pharmacological), and it is important that psychological therapies and previous psychological therapies must have been completed up to 6 months before the start of the treatment, (4) not be suffering from severe mental disorders (e.g. psychosis, bi-polar depression, dementia). Exclusion criteria: (1) patients' dissatisfaction with continued cooperation, (2) initiation of simultaneous psychiatric or psychological treatment, and (3) absence of more than two sessions in treatment sessions.

Intervention groups

Participants will be randomly assigned to one of two groups intervention group or waitlist control group. The randomization sequence will be generated by a statistical program random sequence in blocks of 3.

Main outcome variables

Panic Disorder Severity

General information

Reason for update

Acronym

PATCHD

IRCT registration information

IRCT registration number: **IRCT20220925056036N1**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **prospective**

Last update: **2022-11-14, 1401/08/23**

Update count: **0**

Registration date

2022-11-14, 1401/08/23

Registrant information

Name

Sajjad Bodaghi

Name of organization / entity

The University of Shahid Beheshti

Country

Iran (Islamic Republic of)

Phone

+98 51 3274 5902

Email address

s_bodaghi@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intervention Based on the Cognitive Behavioral Therapy Model of Panic Attack Treatment in Comorbid Heart Diseases (PATCHD) and Exploring Patients' Experience of Treatment: A Mixed-Method Approach

Public title

Intervention Based on the Cognitive Behavioral Therapy Model of Panic Attack Treatment in Comorbid Heart Diseases (PATCHD) and Exploring Patients' Experience of Treatment: A Mixed-Method Approach

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Have symptoms of panic disorder and cardiovascular disease Be at least 18 years old Not be undergoing simultaneous psychiatric treatment (pharmacological), and it is important that psychological therapies and previous psychological therapies must have been completed up to 6 months before the start of the treatment Not be suffering from severe mental disorders (e.g. psychosis, bi-polar depression, dementia)

Exclusion criteria:

Patients' dissatisfaction with continued cooperation Initiation of simultaneous psychiatric or psychological treatment Absence of more than two sessions in treatment sessions

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using Excel software. halve the number of participants and enter in tow columns 1 and 2. in the second column, we generate a random number using the Rand function option; then we sort the data by their values(ascending or descending). according to the order of numbers 1 and 2, the samples are randomly assigned to two groups.

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 Mashhad University of Medical Sciences

Street address

Ibn Sina Hospital, Horr Ameli Blvd.

City

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Razavi Khorasan

Postal code

9195983134

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.MUMS.REC.1401.244

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**

Severity of panic disorder

Timepoint

Before and after the intervention and after 3 months after the intervention

Method of measurement

Panic Disorder Severity Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention will be implemented based on the model of cognitive-behavioral treatment of panic attacks in concomitant heart diseases (PATCHD). This intervention will be implemented in 8 sessions as a

group. This model includes six components: (1) case formulation; (2) psychoeducation about heart disease and anxiety; (3) mindfulness-based stress reduction; (4) promoting coping skills and action plans for chest pain; (5) exposures to the opposite of avoidant behavior (situational and visceral, including a supervised physical exercise program), and (6) cognitive interventions designed to address the maladaptive and alarmist thought patterns that perpetuate panic and avoidance. The intervention will be implemented during 8 sessions of 90 minutes for 8 weeks.

Category

Behavior

2

Description

Control group: routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital Mashhad

Full name of responsible person

Sajjad Bodaghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Shahid Beheshti

Full name of responsible person

Seyedeh Mehri Hamidi

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Shahid Shahriari Square, Evin

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1983969411

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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

The University of Shahid Beheshti

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

The University of Shahid Beheshti

Full name of responsible person

Sajjad Bodaghi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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