Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Mashhad

Province
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: routin care

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital Mashhad

Full name of responsible person
Sajjad Bodaghi

Street address
Ahmadabad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3840 0001

Email
b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Shahid Beheshti

Full name of responsible person
Seyedeh Mehri Hamidi

Street address
Shahid Shahriari Square, Evin

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 29901

Email
pr-office@sbu.ac.ir

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

Street address
Horr Ameli Blvd, Ebn'e Sina Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9148964467

Phone
+98 51 3274 5902

Email
s_bodaghi@sbu.ac.ir

Person responsible for scientific 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

Street address

Ebn'e Sina Hospital, Horr Ameli Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9195983134

Phone
+98 51 3274 5902

Email
s_bodaghi@sbu.ac.ir

Person responsible for updating data

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

Street address
Horr Ameli Blvd, Ebn'e Sina Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9195983134

Phone
+98 51 3274 5902

Email
s_bodaghi@sbu.ac.ir

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