

# 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**

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: 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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Ahmadabad Blvd

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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

**Street address**

Shahid Shahriari Square, Evin

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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

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**Person responsible for scientific inquiries**

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## 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

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**City**

Mashhad

**Province**

## 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