# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effectiveness of the cognitive-behavioral treatment-based model of Panic Attack Treatment in Comorbid Heart Diseases (PATCHD) on the risk factors of cardiovascular disease

## Protocol summary

**Study aim**
Determining the effectiveness of the intervention based on the cognitive-behavioral treatment model of panic attack in co-occurring heart diseases (PATCHD) on the risk factors of cardiovascular disease

**Design**
Randomized clinical trial with a waiting list control group, without blinding

**Settings and conduct**
The statistical population of this research is all the cardiovascular patients referred to Qaim Hospital (AS) in Mashhad who are diagnosed with panic disorder based on structured clinical interview based on DSM-5. People who have full symptoms of panic disorder and are willing to participate in the research are selected as samples. All participants will complete a written informed consent form.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: (1) having symptoms of panic disorder and cardiovascular diseases at the same time (2) being at least 18 years old (3) not undergoing psychiatric (drug) and psychological treatments at the same time, or completing previous psychological treatments until 6 months before entering the study (4) not suffering from severe mental disorders. Exclusion criteria: (1) patient's lack of consent to continue cooperation (2) commencing psychiatric or psychological treatment (3) absence of more than 2 sessions in treatment sessions

**Intervention groups**
Intervention and control group: 40 panic patients with cardiovascular disease. For the intervention group, 8 90-minute intervention sessions based on the cognitive-behavioral treatment model of panic attack in co-occurring heart diseases will be held once a week, and no intervention will be conducted for the control group.

**Main outcome variables**
Anxiety, depression, blood pressure, diabetes, blood lipid profile, inflammation

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220521054950N2**
Registration date: **2024-10-02, 1403/07/11**
Registration timing: **retrospective**

Last update: **2024-10-02, 1403/07/11**
Update count: **0**

**Registration date**
2024-10-02, 1403/07/11

**Registrant information**

**Name**
Mohsen Moohebati

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3801 2465

**Email address**
mouhebatim@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-08-22, 1403/06/01

**Expected recruitment end date**
2024-09-22, 1403/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effectiveness of the cognitive-behavioral treatment-based model of Panic Attack Treatment in Comorbid Heart Diseases (PATCHD) on the risk factors of cardiovascular disease

**Public title**
The effectiveness of cognitive-behavioral therapy on cardiovascular disease risk factors

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having symptoms of panic disorder and cardiovascular diseases at the same time being at least 18 years old Not undergoing psychiatric (drug) and psychological treatments at the same time, or completing previous psychological treatments up to 6 months before entering the study Not suffering from severe mental disorders

**Exclusion criteria:**

**Age**
From **18 years** old to **70 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**
Allocation Concealment Method: Using opaque, sealed envelopes with random sequences, where each generated random sequence is recorded on a card, and the cards are placed inside the envelopes in order. The envelopes are numbered in the same order on the outside to maintain the random sequence. Finally, the envelopes are sealed and placed in an orderly box. When the participant registration begins, based on the order of eligible participants entering the study, one of the envelopes is opened sequentially, revealing the assigned group for that participant. Randomization: Participants are divided into one of two intervention/control groups using PASS software in a 4-block method with the same allocation. Participants who enter the study choose an opaque, sealed envelope containing a random assignment to the intervention or control group. 20 people are included in the experimental group and 20 people in the control group.

**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**
Ahmedabad Blvd., Qaem Hospital

**City**
Khorasan Razavi

**Province**
Razavi Khorasan

**Postal code**
99199-91766

**Approval date**
2024-08-11, 1403/05/21

**Ethics committee reference number**
IR.MUMS.IRH.REC.1403.083

## 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

### 2

**Description of health condition studied**
cardiovascular disease

**ICD-10 code**
P29

**ICD-10 code description**
Cardiovascular disorders originating in the perinatal period

## Primary outcomes

### 1

**Description**
anxiety

**Timepoint**
One day before the intervention and one day after the intervention

**Method of measurement**
Beck's 21-question anxiety questionnaire

### 2

**Description**

depression

**Timepoint**

One day before the intervention and one day after the intervention

**Method of measurement**

Patient health questionnaire

**3**

**Description**

blood pressure

**Timepoint**

One day before the intervention and one day after the intervention

**Method of measurement**

Mercury sphygmomanometer

**4**

**Description**

diabetes

**Timepoint**

One day before the intervention and one day after the intervention

**Method of measurement**

Venous blood sample

**5**

**Description**

Blood lipid profile

**Timepoint**

One day before the intervention and one day after the intervention

**Method of measurement**

Venous blood sample

**6**

**Description**

inflammation

**Timepoint**

One day before the intervention and one day after the intervention

**Method of measurement**

Venous blood sample

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: 1-2 session: evaluation and case formulation; Education about heart disease, risk factors and anxiety. 3-4 session: improving coping skills; Reducing behavioral and situational avoidance. 5-6 session: Visceral exposures - starting a supervised exercise program; Mindfulness. 7-8 session: Cognitive Restructuring - Identifying Central Thoughts and Beliefs That Influence Panic Symptoms

**Category**

Treatment - Other

**2**

**Description**

Control group: This group is placed on the waiting list.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Qaem Hospital

**Full name of responsible person**

Mohsen Mohebati

**Street address**

Ahmadabad Blvd

**City**

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**Email**

mouhebatim@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street

**City**

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**Email**

TafaghodiM@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**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**
Mashhad University of Medical Sciences

**Full name of responsible person**
Mohsen Mohebati

**Position**
Associate Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Cardiology

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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