

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of self-esteem training on improving cardiovascular outcomes in patients with cardio vascular diseases.

#### Protocol summary

##### Study aim

The effect of self-esteem training on improving cardiovascular outcomes in patients with cardiovascular disease

##### Design

The study is a clinical trial without a control group with a one-year follow-up period which patients with cardiovascular disease are trained under the increasing self esteem training of mindfulness-based stress reduction protocol

##### Settings and conduct

Place of this project is Shahroud Imam Hossein hospital and Cardiovascular clinic of Shahroud University of Medical Sciences. Patients first complete the checklist, the SF-36 life quality questionnaire, the Rosenberg Self-esteem questionnaire, and the Connor- Davidson Stress Tolerance questionnaire. After completing the training, the patients have 4 follow-up periods with 3 months distance (3-6-9-12) that complete again the questionnaires and checklists.

##### Participants/Inclusion and exclusion criteria

Entry requirement: a person with coronary artery disease (coronary syndrome or heart failure or hypertension) is certified by a specialist doctor and has been with the disease for at least 6 months. Exit requirement: have cognition problem; have other acute disease.

##### Intervention groups

A psychologist expert does classic protocols of training to increase self-esteem and reduce stress. This protocol is administered as a two-and-a-half hour session per week for 8 weeks

##### Main outcome variables

BMI Frequency of arrhythmia (supra ventricular, ventricular, transient and stable) Blood pressure (systolic, diastolic, mean) Ejection fraction The frequency of recurrence of acute coronary syndrome (re-infarction, unstable angina) Dosage of medication Number of medicines consumed Continuance use of medication Stress Tolerance Number of readmission due to

cardiovascular disease The frequency of chest pain recurrence Functional Class Shortness of breath Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200112046101N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **prospective**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

##### Registration date

2020-02-11, 1398/11/22

##### Registrant information

##### Name

Erfan Kazemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3226 4711

##### Email address

kazemi.e@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of self-esteem training on improving cardiovascular outcomes in patients with cardio vascular diseases.

**Public title**  
The effect of self-esteem training on improving cardiovascular outcomes in patients with cardio vascular diseases

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
A person with coronary artery disease (coronary syndrome or heart failure or hypertension) is certified by a specialist doctor and has been with the disease for at least 6 months. The person consent to participate in the project  
**Exclusion criteria:**  
Have cognitive problems Have other acute disease

**Age**  
From **35 years** old to **75 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

##### Street address

Shahrud, 7 Tir Squar, Shahroud University of Medical Sciences

##### City

Shahrud  
**Province**  
Semnan  
**Postal code**  
3614773947

#### Approval date

2020-01-12, 1398/10/22

#### Ethics committee reference number

IR.SHMU.REC.1398.138

## Health conditions studied

### 1

#### Description of health condition studied

Hypertension

#### ICD-10 code

I10-I15

#### ICD-10 code description

فشار خون بالا (شریانی) (خوش خیم) (ضروری) (بدخیم) (اولیه) (سیستمیک)

### 2

#### Description of health condition studied

coronary disease

#### ICD-10 code

I25.1

#### ICD-10 code description

Coronary (artery):· atheroma· atherosclerosis· disease· sclerosis

### 3

#### Description of health condition studied

Heart failure

#### ICD-10 code

I24.8

#### ICD-10 code description

Coronary:· failure· insufficiency

## Primary outcomes

### 1

#### Description

Self-esteem mean person's inner feeling to himself

#### Timepoint

Before the start of training and during all 4 courses follow up

#### Method of measurement

Rosenberg Self-esteem Questionnaire

## Secondary outcomes

### 1

#### Description

body mass index

#### Timepoint

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months

after education  
**Method of measurement**  
weight/(length\*length)

## 2

### **Description**

Frequency of arrhythmia (supra ventricular, ventricular, transient and stable)

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

Electrocardiogram

## 3

### **Description**

Blood pressure (systolic, diastolic, mean)

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

sphygmomanometer

## 4

### **Description**

Ejection fraction

### **Timepoint**

Before intervention, 3 months after education, 12 months after education

### **Method of measurement**

$(\text{Stroke volume} / \text{end-diastolic volume of the heart}) * 100$

## 5

### **Description**

The frequency of recurrence of acute coronary syndrome (re-infarction, unstable angina)

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

Electrocardiogram

## 6

### **Description**

Dosage of medication

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## 7

### **Description**

Number of medicines consumed

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## 8

### **Description**

continuance use of medication

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## 9

### **Description**

Stress Tolerance

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

Connor-Davidson questionnaire

## 10

### **Description**

Number of readmissions due to cardiovascular disease (acute pulmonary edema, hypertension crisis)

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## 11

### **Description**

The number of chest pain recurrence

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## 12

### **Description**

Functional Class

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## **13**

### **Description**

Shortness of breath

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

questionnaire

## **14**

### **Description**

Quality of life

### **Timepoint**

Before intervention, 3 months after education, 6 months after education, 9 months after education, 12 months after education

### **Method of measurement**

sf-36 questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Patients will attend a two-and-a-half hour session per week for 2 months. During these sessions, patients will receive training of the mindfulness-based stress reduction protocol.

#### **Category**

Lifestyle

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

CCU and Post CCU wards of Imam Hossein Hospital and Shahroud University of Medical Sciences Heart CI

##### **Full name of responsible person**

Hossein Sheibani

##### **Street address**

7 Tir Square, Shahrud Medical University, Shahrud

##### **City**

Shahrud

##### **Province**

Semnan

##### **Postal code**

3614773947

##### **Phone**

+98 23 3234 2000

##### **Email**

e.kazemi@shmu.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

#### **Name of organization / entity**

Shahroud University of Medical Sciences

#### **Full name of responsible person**

Mohammad Hassan Emamian

#### **Street address**

Shahroud University of Medical Sciences, 7 Tir Square, Sharud

#### **City**

Shahrud

#### **Province**

Semnan

#### **Postal code**

3614773947

#### **Phone**

+98 23 3239 5054

#### **Email**

e.kazemi@shmu.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahroud 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**

Shahroud University of Medical Sciences

##### **Full name of responsible person**

Erfan Kazemi

##### **Position**

student

##### **Latest degree**

A Level or less

##### **Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

### Contact

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Shahroud University of Medical Sciences

**Full name of responsible person**

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student

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**Province**

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**Postal code**

3614773947

**Phone**

098 23 32395054

**Email**

e.kazemi@shmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Erfan Kazemi

**Position**

student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Shahroud University of Medical Sciences, 7 Tir Square, Shahrud

**City**

Shahrud

**Province**

Semnan

**Postal code**

36147-73947

**Phone**

+98 23 3239 5054

**Email**

e.kazemi@shmu.ac.ir

## 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

after completion of the study, data on participants (unnamed) and the results of their analysis and the statistical methods will be used in the study will be provided to other individuals along with the protocol.

**When the data will become available and for how long**

Access starts 1 month after the article was published

**To whom data/document is available**

Anyone can access the data

**Under which criteria data/document could be used**

People can use the data for therapeutic and research purposes

**From where data/document is obtainable**

e.kazemi@shmu.ac.ir Recipient: Erfan Kazemi Contact Phone Number of erfan kazemi: 00989155868605

**What processes are involved for a request to access data/document**

The researcher contact with the mentioned communication methods and then person receive information via email Less than a month.

**Comments**