Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 steem 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 whith 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)

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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

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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-steem 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

wieght/(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

(Stroke volume / 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

questinnaire

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

questinnaire

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

questinnaire

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 questinnaire

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

questinnaire

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

questinnaire

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

questinnaire

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
questinnaire

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 questinnaire

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 Cl
Full name of responsible person
Hossein Sheibani
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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
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Erfan Kazemi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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 wil 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 starte 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