

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

investigate the effect of coping skills training on depression and adherence to treatment in patients with heart failure referred to Shahid Rajaei hospital

Protocol summary

Study aim

Determining the effect of coping skills training on depression and adherence to treatment in patients with heart failure.

Design

This randomized clinical trial study will be conducted with two control and intervention groups, with parallel groups, and single-blind strain on 72 patients with heart failure. A table of random numbers will be used for randomization.

Settings and conduct

This study will be conducted on 72 patients referred to Shahid Rajaei Hospital. In the intervention group, coping skills training will be taught. The control group will not receive any training. After the completion of the intervention, the depression and adherence to the treatment of the patients will be measured. Patients, caregivers, clinical outcome assessors, and data analysts will be blind to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include a definite diagnosis of Heart failure, not participating in the same training courses simultaneously, informed consent to participate in the study, and no cognitive-behavioral disease. Exclusion criteria is including having a history of similar training programs.

Intervention groups

In addition to routine hospital care, in the intervention group, coping skills will teach in 12 (20-minute) sessions over the phone. Routine hospital care will be conducted for the control group and no other training will be given.

Main outcome variables

Depression and adherence to the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221017056217N1**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Sepideh Taghavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2116

Email address

sepideh1349@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigate the effect of coping skills training on

depression and adherence to treatment in patients with heart failure referred to Shahid Rajaei hospital

Public title

The effect of coping skills training on depression and adherence to treatment of heart patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of Heart failure Not participating in the other training courses at the same time Informed consent to participate in the study No cognitive-behavioral disease

Exclusion criteria:

History of having a similar training program

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly selected based on the included criteria and allocated into two intervention and control groups of 35 people using a lottery. After selecting each patient, the patient's name will be written in a sealed envelope, and someone other than the researcher will be asked to choose whether to be assigned to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, randomization will be done by the researcher, and the other people, including clinical caregivers, outcome evaluators, and data analysts are blind to the allocation of samples to control and intervention groups. Thus, after the intervention by the researcher, the questionnaires will be completed by the assistant of the researcher who is blind to the type of sample group. The data also will be analyzed by a person who is blind to the type of sample group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Heart and Vascular Training, Research, and Treatment Center.

Street address

Shahid Rajaei Cardiovascular Training, Research, and Treatment Center - Next to Mellat Park- Wali Asr St - Tehran - Iran

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.RHC.REC.1400.119

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

2

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression score in Back questionnaire

Timepoint

Before and immediately after the end of the intervention

Method of measurement

Back Depression questionnaire

Secondary outcomes

1

Description

Adherence to treatment score In the Modanloo adherence to treatment questionnaire

Timepoint

Before and immediately after the end of the intervention

Method of measurement

Modanloo adherence to treatment questionnaire

Intervention groups**1****Description**

Intervention group: Coping skills training will include relaxation methods, mental imagery, an adaptation mechanism, a problem-solving method, and anger control in the form of telephone conversations and mutual interaction. This intervention will be taught in 12 sessions of 20 minutes during one month.

Category

Treatment - Other

2**Description**

Control group: Will not receive any intervention.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajae Cardiovascular Training, Research and Medical Center

Full name of responsible person

Sepideh Taghavi

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Rajae hospital, next to the Mellat Park, Vali Asr Street, Tehran, Iran

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sepideh1349@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rajae Cardiovascular Medical and Research Center

Full name of responsible person

Saeid Hosseini

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hosseini@rhc.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rajae Cardiovascular Medical and Research Center

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**

Iran University of Medical Sciences

Full name of responsible person

Sepideh Taghavi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

sepideh Taghavi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Sepideh Taghavi

Position

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Latest degree

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Other areas of specialty/work

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