

# 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

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**

Associate professor

**Latest degree**

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**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**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**