

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigation of the effect of mental health education intervention on the resilience and psychosocial adjustment of patients with heart failure under the care of counseling centers and nursing home services

Protocol summary

Study aim

Determination of the effect of mental health education intervention on the level of resilience and social psychological adjustment of patients with heart failure under the care of counseling centers and nursing home services at Shahid Rajaei Heart Center in Tehran

Design

Clinical trials with a control and experimental group with a sample size of 24 and randomly divided into control and experimental groups

Settings and conduct

Patients referred to a home care unit at the Shahid Rajaei Heart Center in Tehran by a physician. Social resilience and adaptability questionnaire are complemented before intervention. the home care program is performed by the researcher within a month, so the researcher will provide mental health training at home, then every 3 days he will have a phone call to follow up. A total of 15 follow-up calls are made. The researcher attends the patient's home twice a week and provides training for 6 sessions (one hour per session).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of advanced heart failure by the treating physician, 18 years of age or older, resident of Tehran, hospitalization history of more than 1 time in the last 6 months and complete consent to participate in the study. Exclusion criteria: He has undergone heart surgery in the last 8 weeks, patients who in the last 4 weeks, they have had myocardial infarction, patients who have had cardiogenic shock in the last 4 weeks, and patients who have not been able to attend training courses due to complications or illness.

Intervention groups

In this study, in the intervention group, mental health education is given in the field of resilience and social psychological adjustment. In the control group, no intervention is performed.

Main outcome variables

In this study, patients' resilience and psychosocial adjustment are measured after mental health training.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046493N1**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

ramin avazpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3875 4661

Email address

r_avazpour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of mental health education intervention on the resilience and psychosocial adjustment of patients with heart failure under the care of counseling centers and nursing home services

Public title

Determination of the effect of mental health education on patients with heart failure under the care of counseling centers and home nursing services

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: definitive diagnosis of advanced heart failure by the treating physician, aged 18 years or older, resident of Tehran, hospitalization history more than 1 time in the last 6 months and full consent to participate in the study.

Exclusion criteria:

He has undergone heart surgery in the last 8 weeks, patients who have had a myocardial infarction in the last 4 weeks, patients who have had cardiogenic shock in the last 4 weeks, and patients who have not been able to attend training courses due to complications or illness. Be.

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is block randomization using www.randomization.com website

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

shiraz

Province

Fars

Postal code

7477177751

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.SUMS.REC.1398.917

Health conditions studied**1****Description of health condition studied**

Chronic heart failure

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

resilience

Timepoint

One week after mental health training

Method of measurement

Connor Davidson Resilience Questionnaire

2**Description**

Psychosocial adjustment

Timepoint

One week after mental health training

Method of measurement

Social Psychological Adaptation Questionnaire pais

Secondary outcomes**1****Description**

mental health

Timepoint

One week after the study

Method of measurement

Connor Davidson Resilience Questionnaire - Pais Social Psychological Adaptation Questionnaire

Intervention groups

1

Description

In the intervention group, the home care program is performed by the researcher within a month, so that during the first 6 hours after discharge, the researcher will provide mental health training at home, then every 3 days he will have a phone call to follow up. A total of 15 follow-up calls are made. The researcher attends the patient's home twice a week and provides training for 6 sessions (one hour per session).

Category

Lifestyle

2

Description

Control group: There are no interventions in the control group and only the questionnaires are filled before and after the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Heart Center in Tehran

Full name of responsible person

DR NASIM NADERI

Street address

Vali-e-Asr St. - Next to Mellat Park - Corner of Prayer of Shahid Rajaei Cardiovascular Training, Research and Treatment Center

City

TEHRAN

Province

Tehran

Postal code

1995614331

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Email

RAMINAVAZPOUR@YAHOO.COM

Web page address

http://rhc.ac.ir/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR YOUNES GHASEMI

Street address

Shiraz, Zand St., Opposite Palestine St., Central Building of Shiraz University of Medical Sciences

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SHIRAZ

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Postal code

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Phone

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Fax

Email

info@sums.ac.ir

Web page address

https://www.sums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

50

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

Shiraz University of Medical Sciences

Full name of responsible person

dr ladan zarshenas

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

Shiraz University of Medical Sciences

Full name of responsible person

dr ladan zarshenas

Position

Associate professor

Latest degree

Ph.D.