

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of spiritual care program on quality of life and resilience of patients with heart failure

Protocol summary

Study aim

Improving and improving the quality of life and resilience of patients with heart failure

Design

In this study, 84 patients will be randomly divided into two groups of control and test by 6-block method. The study is not blind and does not apply.

Settings and conduct

The researcher will go to the heart failure clinic or the heart failure ward of Rajaei Heart Center and after the patient's consent to the patient, consciously and in writing, will hold his / her virtual sessions and follow for a month to do the above. They will be

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Heart failure of 40%, based on patient records approved by a cardiologist. Age group 18 to 65 years Muslim - The patient is satisfied to participate in the research. Has complete satisfaction with the referral and follow-up by telephone by the researcher. The patient has sufficient literacy Exclusion criteria: At each stage of the study, the patient did not want to continue participating in the study.

Intervention groups

.Spiritual care program (educational booklet and two CDs) for the experimental group, which includes two one-and-a-half hour sessions by group discussion and lecture in groups of 5 at the CCUG ward of Shahid Heart Hospital Rajai will be executed. Which was virtually altered due to Quidd's disease. The content of a number of CDs is Mozart's music that the patient will listen to before going to bed. Will listen to it for 15 minutes, the control group will receive only routine care

Main outcome variables

Quality of life and resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201014049021N1**

Registration date: **2020-11-01, 1399/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Farideh Movahedimoghadam

Name of organization / entity

مرکز آموزشی تحقیقاتی درمانی قلب و عروق شهید رجایی

Country

Iran (Islamic Republic of)

Phone

+98 21 23921

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care program on quality of life and resilience of patients with heart failure

Public title

The effect of spiritual care program on quality of life and resilience of patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Heart failure based on clinical signs and echocardiography showing a jump fraction of less than 40%, based on a patient's file approved by a cardiologist. Age group 18 to 65 years Being a Muslim Awareness of time and place Ability to communicate verbally No hearing, vision or cognitive impairment The patient is satisfied to participate in the study Have complete satisfaction with the referral and follow-up by telephone by the researcher Adequate literacy

Exclusion criteria:

- At each stage of the study, the patient did not want to continue participating in the study. Absence from attending spiritual care program training sessions Critical and emergency situations such as the need for hospitalization, surgery, death of the patient or the occurrence of any other accident Lack of access by telephone (several times a week) with the patient during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Block size 6

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

EVA therapy and space construction

Secondary Ids

empty

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

Ethics Committee of Rajaei Heart Center

Street address

Rajaei Heart Center, Next to Mallet Park, Valiasr

Street

City

Tehran

Province

Tehran

Postal code

195614331

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.RHC.REC.1399.042

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

Quality of Life

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Resilience

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

Quality of life

Timepoint

Before intervention and after one month follow-up

Method of measurement

Iranian Ring Quality Questionnaire designed by Dr. Naderi Heart Failure Fellowship

2**Description**

Resilience

Timepoint

Before intervention and after one month follow-up

Method of measurement

Connor Davidson Questionnaire

Secondary outcomes

empty

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

Intervention group Will receive Spiritual care program (educational booklet and two CDs) , which includes two one-and-a-half hour sessions by group discussion and lecture in groups of 5 at the CCUG training site of Shahid

Rajaei Heart Hospital will be implemented. The cause of corona disease will be virtual. The content of the educational booklet is based on the four main axes of spiritual care. These four main include: the importance of communicating with God, the importance communicating of with oneself, the importance of communicating with others, and the importance of communicating with nature because most mental health problems are caused by having unhealthy relationships and will be followed for a month to intervene. The content of the two CDs is the sound of nature and the music of Mozart, which the patient will listen to for a month. The intervention group will complete a questionnaire of quality of life, resilience and spirituality before the intervention and after completing a one-month follow-up.

Category

Other

2

Description

Control group: will receive only routine nursing care. and will complete a questionnaire of quality of life, resilience and spirituality before the intervention and after completing a one-month follow-up.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei Heart Center

Full name of responsible person

Fidan Shabani

Street address

Rajai Heart Center, Valiasr Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Fax

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Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal by the person herself

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Fidan shabani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the data and the method of work are published in the article

When the data will become available and for how long

Three months after the results are published

To whom data/document is available

All applicants

Under which criteria data/document could be used

Use in scientific research is allowed

From where data/document is obtainable

Frideh.movahedimoghadam@gmail.com

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

by Email

Comments