

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of intervention based on illness perception on death anxiety and coping in patients with heart failure

Protocol summary

Study aim

Determining The effect of intervention based on illness perception on death anxiety and coping in patients with heart failure in zanjan educational hospitals

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 120 patients, randomized using random minimization method

Settings and conduct

This study was performed in the CCU and heart wards of Ayatollah Mousavi Hospital in Zanjan. If there were inclusion criteria and after obtaining written consent from the subjects , individuals were randomly divided into two groups of intervention and control. Patients were blind to the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definitive diagnosis of heart failure by a cardiologist; Having an EF (ejection fraction) equal to or less than 40% on echocardiography; Having a stable status in terms of hemodynamics and clinical conditions; Having satisfaction with the study; Being at least 35 years old; Must be alert and aware of time and place; Having the ability to complete a questionnaire and Participating in meetings physically and clinically; Not to be under others study.Exclusion criteria:History of death of loved ones in recent months ; Have a known mental illness and be treated with drugs that affect the psyche.

Intervention groups

In the intervention group, an intervention based on correcting the illness perception was performed during 3 sessions of 30 minutes individually based on each patient's response to the summarized questionnaire of illness perception. In the control group, no intervention was performed by the researcher and patients received only routine hospital care.

Main outcome variables

illness perception; death anxiety; coping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201020049083N1**

Registration date: **2020-12-02, 1399/09/12**

Registration timing: **retrospective**

Last update: **2020-12-02, 1399/09/12**

Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Negin Babaeivahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3341 2451

Email address

nbabaivahed69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-27, 1398/12/08

Expected recruitment end date

2020-05-28, 1399/03/08

Actual recruitment start date

2020-06-05, 1399/03/16

Actual recruitment end date

2020-09-20, 1399/06/30

Trial completion date

2020-09-20, 1399/06/30

Scientific title

The effect of intervention based on illness perception on death anxiety and coping in patients with heart failure

Public title

The effect of intervention based on illness perception on death anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of heart failure by a cardiologist
Having an EF (ejection fraction) equal to or less than 40% on echocardiography
Having a stable condition in terms of hemodynamics and clinical conditions
Having Satisfaction with participation in the study
To have at least 35 years old
The patient must be alert and aware of time and place.
Having the ability to complete the questionnaire and participate in sessions physically and clinically
Having ability to understand Persian language to complete the questionnaire
Not to be under others study

Exclusion criteria:

Have a known mental illness and take medication that affects the psyche.
history of death of loved ones in recent months

Age

From **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 120 patients are selected using the available sampling method and then the patients are assigned to the intervention (training) and control groups using the random sampling method. Age and gender variables are grouping variables in this allocation method. In this way, the first person is selected through a random method (coin toss) and the next people who enter the study are selected based on a table of random numbers, respectively, and considering the allocation protocol of the minimization method, treatment is assigned to them.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because patients are unaware of the educational intervention process, they are blind to the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Science, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-02-08, 1398/11/19

Ethics committee reference number

IR.ZUMS.REC.1398.456

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Illness perception

Timepoint

Before intervention, After 3 sessions of intervention

Method of measurement

Brief of illness Perception Questionnaire (BIPQ)

Secondary outcomes

1

Description

Death anxiety

Timepoint

Before the intervention, after 3 sessions of intervention

Method of measurement

Templer Death Anxiety Questionnaire

2

Description

Coping

Timepoint

Before the intervention, after 3 sessions of intervention

Method of measurement

A brief questionnaire of coping

Intervention groups

1

Description

Intervention group: An intervention based on correcting the perception of the disease was performed individually and during face-to-face interviews based on each patient's response to the Summary Perception of the Disease Questionnaire (BIPQ) during 3 30-minute sessions during hospitalization. Correction of disease perception in these 3 sessions was based on the Leventhal self-regulatory model, which provides knowledge of the disease based on 5 components including description of the nature of the disease, related symptoms and causes, disease outcomes, disease course, and control / treatment. The educational booklet compiled by the researcher was presented to the patients at the end of the third session.

Category

Prevention

2

Description

Control group: No intervention was performed in this group and patients received only routine hospital care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Negin Babaeivahed

Street address

Gavazang Road, Ayatollah Mousavi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shogli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mahin Roohani

Position

M.S of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Zanjan University of Medical Sciences, shahrak karmandan, Zanjan

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Roohani@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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