

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effect of palliative care education on self efficacy of elderly with Chronic Heart Failure

Protocol summary

Study aim

Determining the effect of palliative care education on self-efficacy of elderly patients with chronic heart failure

Design

This study is a randomized clinical trial with control group. First, 48 qualified patients will be selected using convenience sampling. Then Participants based on the self-efficacy scores will be classified into two intervention and control groups (24 patients in each group) by "Stratified Randomization" method. In this study, the phase of clinical trials is not applicable.

Settings and conduct

This randomized control trial study will be done in 5th Azar Medical and Educational Center. Because of the nature of interventions which is obvious for patient, the blindness is not possible

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 60 and 80 years old; the willingness to participate in the study; known case of grade 3 heart failure; not attending in education course with similar topics at the same time; lack of psychiatric disorder; lack of musculoskeletal diseases; lack of hearing impairment and lack of visual impairment. Exclusion criteria: cancel participating in the study; traveling or change the living place.

Intervention groups

For the intervention group, in addition to the usual care, the educational palliative care package, for 6 weeks, in groups of 6 to 8 people, once a week, one-hour training classes, will be implemented.

Main outcome variables

Self-efficacy

General information

Reason for update

Acronym

CHF: Chronic Heart Failure

IRCT registration information

IRCT registration number: **IRCT20160521027993N1**

Registration date: **2018-06-28, 1397/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-28, 1397/04/07**

Update count: **0**

Registration date

2018-06-28, 1397/04/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17134421660

Email address

tazikeh@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of palliative care education on self efficacy of elderly with Chronic Heart Failure

Public title

Palliative care and self efficacy in elderly with CHF

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 60 and 80 years old The willingness to participate in the study Known case of grade 3 heart failure according to medical records which approve by the cardiologist Not attending in education course with similar topics at the same time Lack of psychiatric disorder Lack of musculoskeletal diseases Lack of hearing impairment Lack of visual impairment

Exclusion criteria:
Cancel participating in the study Traveling or change the living place

Age
From **60 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be carried out in an accessible manner to 48 people. And the scores obtained from the questionnaire will be arranged from small to large, respectively. Then, according to the scores obtained, the classes of two or four or more with a pair number will be formed. Grades that are not included the paired groups, will be eliminated. Then a series to either ABABAB or BABABA, was meaked and select one of these series randomly and each person will be in the target group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The Blinding will be done by a single blind and will be performed before the determination of the intervention group and the control group. At first, participants (48) people fill in demographic information, clinical information, and Sullivan cardiac self-efficacy questionnaire and to fill up, in the next turn of the same questionnaire, they will be notified by telephone. After determining the intervention and control groups (patients (24) in each group), for palliative care educational classes, only will be notified into the intervention group and training classes without the knowledge of the control group, in an appropriate place at the clinic will run. After finish the training classes, immediately and one month after the follow up, the questionnaires will again be filled in for both groups (intervention and control), so that the intervention and control group does not have any meeting.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

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Gorgan

Province
Golestan

Postal code
4934174515

Approval date
2018-05-14, 1397/02/24

Ethics committee reference number
IR.GOUMS.REC.1397.002

Health conditions studied

1

Description of health condition studied
Chronic Heart Failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Self efficacy

Timepoint
Before intervention (pre-test) and immediate and one month after intervention (post test)

Method of measurement
Sullivan's cardiac self efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for participants in the intervention group the palliative care package, according to the WHO protocol, will be trained for 6 weeks, in groups of 6 to 8 people, once a week. The educational content included physical problems management and strategies for promoting physical activity, self-care (Diet, sleep pattern, proper use of drugs and no smoking) and psychological and spiritual care and social communication.

Category

Lifestyle

2**Description**

Control group: routine care without any intervention

Category

N/A

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

5th Azar Medical and Educational Center

Full name of responsible person

Nasser Saffar

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6th Azar, 5Azar Street, Gorgan

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

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Ameneh Tazikeh Lemeski

Position

Ms Student of Nursing Geriatric

Latest degree

Bachelor

Other areas of specialty/work

Others

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD will be shared.

When the data will become available and for how long

6 months after publication the data files will be available.

To whom data/document is available

The data will be shared for people working in academic institutions.

Under which criteria data/document could be used

Meta analyses on data is permitted.

From where data/document is obtainable

Please contact to person responsible for scientific inquiries.

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

The data will be available through email and researcher permission.

Comments

Please contact to both email address:
modanloo1@yahoo.com modanloo.mahnaz@goums.ac.ir