Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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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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

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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