

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation the effect of self-care education on adherence of the elders with heart failure to the treatment

Protocol summary

Study aim

Determining the effect of self-care education on adherence of the elders with heart failure to the treatment.

Design

The elders who scored 20-79 in the self-care assessment and 0-49 in the adherence questionnaire divided into two groups, Case and Control, using random allocation approach. The training package is presented to the Case group before dispensing from the hospital. Then, the training will be continued at home for 2 months by the training package. The control group receives routine training only at hospital. Two months post-training, both the Case and Control groups will fill out the adherence questionnaire at home, by the presence of researcher.

Settings and conduct

This study is started by the primary training of patients with heart failure and will be ended with the two-months home training package. During this time, the control group will only receive routine hospital training.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People over 60 years old 2. Heart failure , grade 1 & 2 3. Consent to participate in the research 4. Residents of Gonbad Kavus 5. No history of mental disorder Exclusion: 1. Unwillingness to participate in the study 2. Patient's death 3. Refractory diseases 4. Incomplete questionnaire

Intervention groups

A training package including: etiology and recurrence of the diseases, medicines, the route and dosage of medicine usage, medicine interactions and side effects, dietary restrictions, blood pressure control , weight control, smoking prohibition, the method of oxygen therapy, convenient positions, urinary catheter` s maintenance, Training the symptoms of heart diseases, importance of exercise and physical activity.

Main outcome variables

Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160930030058N2**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **prospective**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

Saeed Eimer

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3326 0296

Email address

saeed.eimer@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of self-care education on adherence of the elders with heart failure to the treatment

Public title

Effect of self-care education on adherence of the elders to treatment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

People over 60 years old Heart failure , grade 1& 2
Consent to participate in the research Residents of Gonbad Kavus No history of mental disorder

Exclusion criteria:

Unwillingness to participate in the study Patient's death
Refractory diseases Incomplete questionnaire

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation, Permuted block randomization and random sequencing methods, patients will be assigned to two Intervention and Control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Golestan University of Medical Sciences, Shast-Kola Road, Saari road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-07-01, 1397/04/10

Ethics committee reference number

IR.GOUMS.REC.1397.027

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

Adherence to treatment

Timepoint

Two months post-training

Method of measurement

Adherence of treatment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The elders who scored 20-79 in the self- care assessment and 0-49 in the adherence questionnaire divided into two groups, Case and Control, using random allocation approach. The training package is presented to the Case group before dispensing from the hospital. Then, the training will be continued at home for 2 months by the training package.

Category

N/A

2

Description

The control group receives routine training only at hospital.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital, Gonbad Kavus

Full name of responsible person

Saeed Eimer

Street address

POBox 151 Postcode 4979114635, Khatam Al-Anbia
Hospital, Al-Ghadir Square, Gonbad Kavus

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2

Recruitment center

Name of recruitment center

Gonbad Kavus Shohada Hospital

Full name of responsible person

Saeed Eimer

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Shohada Hospital, Imam Khomeini South Street,
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3

Recruitment center

Name of recruitment center

Payambarazam-Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Gholam Reza Mahmoodi-shan

Street address

Golestan University of Medical Sciences, Sari Road,
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mahmoodigh@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Golestan 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

Gholam Reza Mahmoodi-shan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Results of the study will be published as an article. The ethical principle will be respected during preparation of the article for publishing.

When the data will become available and for how long

Accessibility of the data can be started 6 months after publishing the results of the study as an article.

To whom data/document is available

Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The results could be used for scientific purposes with citing to the article published.

From where data/document is obtainable

_4918936316 TEL_01732451660 Fax_4421657, Golestan University of Medical Sciences, Sari Road, Gorgan, IRAN

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

Scholar valid documents and the title of study must be sent and the study must be about adherence of the elderly patients with heart failure.

Comments