Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 17 3326 0296

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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
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Shohada Hospital, Imam Khomeini South Street, Gonbad Kavus
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3

Recruitment center
Name of recruitment center
Payambarazam-Hospital
Full name of responsible person
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Beginning of Ince-Bron Road, Gonbad Kavus
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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
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Golestan University of Medical Sciences, Sari Road, Gorgan
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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
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Person responsible for scientific inquiries

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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