

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Effect of Education Based on Learning Needs to Patient and Family Member on Self-Care Behaviors and Frequency of Rehospitalization in Patients with Heart Failure

Protocol summary

Summary

Background and purpose: Inappropriate self-care behaviors in heart failure patients lead to Rehospitalization. One of the most effective strategies in controlling Rehospitalization and promoting self-care behaviors in these patients is to train self-care behaviors. Therefore, the aim of this study was to determine the effect of education based learning needs to patients and family on self-care behaviors and frequency of Rehospitalization in patients with heart failure. Methods: This study is a single blinded randomized clinical trial that was conducted on 75 patients with heart failure. Samples were divided into one test group and two control groups. In test group, training was done based on learning needs using CHFPLNI and with the presence of family member. In control group (1), training was done without learning needs assessment and with the presence of family member and in control group (2), training was conducted without learning needs assessment and without the presence of family member. SCHFI questionnaire was used to assess a self-care behaviors which was completed at the beginning and at the end of the 90 days after the discharge of the samples, and Rehospitalization frequency was calculated at the end of 30, 60 and 90 days after discharge. Data analysis was done using Statistical tests .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020320940N1**

Registration date: **2015-08-11, 1394/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-11, 1394/05/20

Registrant information

Name

Seyedeh Fatemeh Gheiasi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Zanjan University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2015-03-30, 1394/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Education Based on Learning Needs to Patient and Family Member on Self-Care Behaviors and Frequency of Rehospitalization in Patients with Heart Failure

Public title

The Effect of Education to Patient and Family on Self

Care and Rehospitalization

Purpose
Prevention

Inclusion/Exclusion criteria
Patients' inclusion criteria: Diagnosis of heart failure confirmed by a cardiologist contained in the file; left ventricular ejection fraction of 35% or less based on the results of echocardiography; at least being once hospitalized due to heart failure in the last year; being admitted to the heart department; being native; accessing to the phone; as well as having a family member over the age of 18 as an attendant; having normal IQ; accessing to daily weighing scales at home
Family member's inclusion criteria: Having a role in patient care; having a causal or relative relationship with the patient
Patients' exclusion criteria: Terms of acute illness; long traveling during the study; relocation of residence; employment in the medical team; participating in another training program in conjunction with the study; suffering from mental and memory disorders and chronic and debilitating diseases such as renal failure; severe respiratory diseases recorded in their medical records
Family members' exclusion criteria: Employment in the treatment team; being dissatisfied with continuing participation in the study

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Zanjan University of Medical Sciences

Street address

University of Medical Sciences, Azadi Sq, Zanjan, Iran

City

Zanjan
Postal code
۱۳۱۹۱۴۵۱۵۶

Approval date
2014-05-31, 1393/03/10

Ethics committee reference number
A-11-117-2

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

IX

ICD-10 code description

Diseases of The Circulatory System

Primary outcomes

1

Description

Self Care

Timepoint

First and 3 Month after Intervention

Method of measurement

Questionnaire

2

Description

Rehospitalization

Timepoint

30, 60 and 90 Days After Intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Family Contribution in Self Care

Timepoint

3 Months After Intervention

Method of measurement

Questionnaire

2

Description

Assessment of Observed Changes of Self Care Behaviors

Timepoint

3 Months After Intervention

Method of measurement

Questionnaire and Observation

Intervention groups

1

Description

In group 1, training is done based on the learning needs of patients with a family member, and learning needs of patients are extracted with the CHFPLNI questionnaire. The training program consisting of diet and medication, fluid and salt restriction, weight control and is performed in three 20-15 minute sessions with 15-minute rest period, during hospitalization and face-to-face in three groups

Category

N/A

2

Description

In Group 2, training is done based on a preset training booklet without needs assessment and with the presence of a family member. The training program consisting of diet and medication, fluid and salt restriction, weight control and is performed in three 20-15 minute sessions with 15-minute rest period, during hospitalization and face-to-face in three groups

Category

N/A

3

Description

in group 3, training is done based on a preset pamphlet without needs assessment and without the presence of a family member. The training program consisting of diet and medication, fluid and salt restriction, weight control and is performed in three 20-15 minute sessions with 15-minute rest period, during hospitalization and face-to-face in three groups

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital, Zanjan

Full name of responsible person

Sayede Fatemeh Gheiasi, Ms Critical Care Nursing Student

Street address

Gavazang Road, Zanjan, Iran

City

Zanjan

2

Recruitment center

Name of recruitment center

Hazrat Valiasr Hospital

Full name of responsible person

Sayede Fatemeh Gheiasi, Ms Critical Care Nursing Student

Street address

Valiasr Sq, Zanjan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohamad Masood Vakili

Street address

Vice Chancellor for Research of Zanjan University of Medical Sciences, Azadi Sq, Zanjan, Iran

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Zanjan

Grant name

00

Grant code / Reference number

00

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

Yes

Title of funding source

Vice Chancellor for Research of Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Saiede Fatemeh Gheiasi

Position

Ms Critical Care Nursing Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty