

# 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)

###### Phone

+98 24 3377 2513

###### Email address

karimiv88@zums.ac.ir

##### 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

### City

Zanjan

## 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

#### City

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

#### Street address

Zanjan School of Nursing and Midwifery School, Parvin Etesami Sq, Zanjan, Iran

#### City

Zanjan

#### Postal code

4515789589

#### Phone

+98 243377251314

#### Fax

+98 24 3377 0305

**Email**

fatemeh.gheiasi@gmail.com

**Web page address**

www.zums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mahin Rohani

**Position**

Master of Nursing

**Other areas of specialty/work**

**Street address**

Zanjan School of Nursing and Midwifery School,  
Parvin Etesami Sq, Zanjan, Iran

**City**

Zanjan

**Postal code**

4515789589

**Phone**

+98 98243377251314

**Fax**

+98 24 3377 0305

**Email**

mahroo2050@yahoo.com

**Web page address**

www.zums.ac.ir

## Person responsible for updating data

**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**

**Street address**

Zanjan School of Nursing and Midwifery School,  
Parvin Etesami Sq, Zanjan, Iran

**City**

Zanjan

**Postal code**

4515789589

**Phone**

+98 243377251314

**Fax**

+98 24 3377 0305

**Email**

fatemeh.gheiasi@gmail.com

**Web page address**

www.zums.ac.ir

## 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*