

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of Supportive- Educative interventions on Self-Care behaviors & readmission rates of patients with heart failure

#### Protocol summary

##### Summary

Background Nowadays Chronic heart failure is a major health and social problem. Due to the chronic nature of the disease, self-care behaviors can has a major impact on managing of this chronic condition. Therefore To improve self-care behaviors and prevent potential self-care deficits, education and support can be important issues in nursing care in this population. Objectives The aim of this trial was to evaluate the effect of a supportive educational intervention on CHF self-care behaviors and readmission rates of patients referred to Shahid Madani Medical Training & Research Hospital(Tabriz, Iran, 2011) for 3 months after discharge. Methods We conducted a prospective, randomized trial of an education and support intervention on self-care behaviors and three-month readmission for patients hospitalized with Hf. A total of 80 patients were randomly assigned to either supportive educational or to usual care. Data were collected using the, SCHFI and CHFPLNI tools. The data were analyzed using SPSS- 11.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107041464N4**

Registration date: **2012-06-05, 1391/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-06-05, 1391/03/16

##### Registrant information

###### Name

Vahid Zamanzadeh

###### Name of organization / entity

University of Tabriz Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

zamanzadeh@tbzmed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Tabriz University of Medical Sciences

###### Expected recruitment start date

2011-07-11, 1390/04/20

###### Expected recruitment end date

2011-08-11, 1390/05/20

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of Supportive- Educative interventions on Self-Care behaviors & readmission rates of patients with heart failure

###### Public title

The effect of education on Self-Care behaviors & readmission of patients with heart failure

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion Criteria : 18 years or older patients who were hospitalized because of congestive heart failure; to have echocardiography form (EF lesser than 40%); talking in Turkish or Persian; consciousness at reception; accessibility after release by phone call; agreement with training at release time and self care pursuit; not to accompany at another study. Exclusion Criteria : death of

patients; disagreement with continuance of pursuit; long time journey after release from hospital up to 6 months; to have acute and progressive disease other than congestive heart failure and distinguished mental disorder.

#### **Age**

From **18 years** old to **85 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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**

Ethical Committee of Tabriz University of medical sciences

##### **Street address**

Emam Ave

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2010-08-20, 1389/05/29

#### **Ethics committee reference number**

9088

## **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**

self-care behavior

#### **Timepoint**

each month until three month

#### **Method of measurement**

based on self-care behaviour index tools

### **2**

#### **Description**

Readmission

#### **Timepoint**

Each month until three month

#### **Method of measurement**

Rate of admission to the hospital with worsen of heart failur

## **Secondary outcomes**

### **1**

#### **Description**

visit of physician

#### **Timepoint**

each month until three month

#### **Method of measurement**

rate of referal to the physician fore worsen of heart failur

### **2**

#### **Description**

Costs of treatment

#### **Timepoint**

Each month until three month

#### **Method of measurement**

Rate of costs for readmissions and visit of physician

## **Intervention groups**

### **1**

#### **Description**

The present study was included a two-part intervention. The first part of the intervention was included patient education in the intervention group. Patients in the intervention group were educated by nurses who worked in cardiac wards. Education had been personalized for each patient. After determining the learning needs of patients about heart failure and according to the previous information, the educational level and cognitive level of patients, researcher done the training. Training performed with the goal of improving self-care behavior such as receiving proper medical regimes, fluid and sodium restriction, Improving physical activity, control symptoms and signs of worsening the heart failure to prevent worsening of the disease in the patients with heart failure. Patients and their families were educated for an hour. Training was contain information about heart

failure definition, signs and symptoms of the disease, information about the diet, Information about medications, information about the activities and appropriate sports. The booklet was given to patients or their families at the time of discharge. The second part of the intervention, was include telephone follow-up of patients after discharge from the hospital. This support was to strengthen the basic education and providing strategies for improvement of patients self-care behaviors. In the first stage of the follow-up phone call was conducted after two days of hospital discharge to confirm the patient information and for establishment of the next time of phone contacts. Then, every two weeks for three months, the phone calls were conducted in order to support patients in the intervention group. At the end of each month during the period of study phone calls were conducted with patients, in both study groups, in order to obtain information about self-care behaviors, the cost of care, readmission rates and refer to physician.

**Category**

Rehabilitation

**2****Description**

Patients in the control group received All cares and treatments provided by Hospital and physician during the intervention.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Madani Teaching Hospital

**Full name of responsible person**

Fatemeh Jamshidi

**Street address**

Golbad street , Shahid Madane Hospital

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Tabriz University of Medical Sciences

**Street address**

Golbad Ave. Shahid Madani Heart Research Center

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Vahid zamanzadeh

**Position**

PhD /Associate Professor

**Other areas of specialty/work****Street address**

Nursing and Midwifery Scool

**City**

Tabriz

**Postal code**

51745-347

**Phone**

+98 41 1381 9129

**Fax**

+98 41 1479 6969

**Email**

zamanzadeh@tbzmed.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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**Phone**

+98 41 1381 9129

**Fax**

+98 41 1479 6969

**Email**

zamazadeh@tbzmed.ac.ir

**Web page address**

+98 41 1479 6969

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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Dr. Vahid Zamanzadeh

**Position**

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**Other areas of specialty/work****Street address**

Nursing and Midwifery School

**City**

Tabriz

**Postal code**

51745347

**Phone****Fax****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*