

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of the implementation of family-centered empowerment model on the quality of life in patients with heart failure

#### Protocol summary

##### Summary

Objective: provide simple administrative solutions in order to create attitudes and behavior in order of importance of life style in patient with heart failure. Field of study: randomized, double-blind, placebo-uncontrolled, uni-center, one phase of clinical trial. A) Study population: Patients with heart failure, referred to Taleghani Hospital. Inclusion criteria: willingness to participate in the study; 18- 65 years old; without learning disorders such as Alzheimer disease; without attending similar training. Exclusion criteria: reluctance to continue to participate in the study; irregular participation in training classes; Death of a patient. Sample size: 70, with the possibility of sample loss. B) Intervention study: The effect of the implementation of family-centered empowerment model on the quality of life in patients with heart failure. C) The study period: from 21 May 2017 to 22 July 2017. D) The primary outcome: the creation of a positive attitude about the importance of family empowerment to improve the quality of care in heart failure patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902173850N2**

Registration date: **2017-06-03, 1396/03/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-03, 1396/03/13

##### Registrant information

###### Name

Sima Zohari

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 9648

##### Email address

sima\_zohari@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2017-05-21, 1396/02/31

##### Expected recruitment end date

2017-07-22, 1396/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the implementation of family-centered empowerment model on the quality of life in patients with heart failure

##### Public title

The effect of the implementation of family-centered empowerment model on the quality of life in patients with heart failure

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study; 18- 65 years old; without learning disorders such as Alzheimer disease; without attending similar training. Exclusion criteria: reluctance to continue to participate in

the study; irregular participation in training classes;  
Death of a patient.

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

The samples by blocking Randomization were randomly placed in two groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of SHahid Beheshti University of  
Medical Sciences

##### Street address

SBUMS, Arabi Ave, Yaman Ave, CHamran Highway,  
Tehran

##### City

Tehran

##### Postal code

#### Approval date

2017-03-07, 1395/12/17

#### Ethics committee reference number

IR.SBMU.PHNM.1395.650

## Health conditions studied

### 1

#### Description of health condition studied

Heart failure

#### ICD-10 code

150

#### ICD-10 code description

Heart failure

## Primary outcomes

### 1

#### Description

The quality of life in patient with heart failure

#### Timepoint

The questionnaire immediately after the intervention and a month and a half after it is completed by samples of two experimental and control groups

#### Method of measurement

The quality of life questionnaire of minnesota

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: training classes to improve quality of life for patients in the three domains of cognitive, performance and mental health during the 5 to 7 sessions of training runs and then the samples immediately after the intervention and again one month and a half then proceed to complete the questionnaires.

#### Category

Lifestyle

### 2

#### Description

Control group: samples of the control group not received intervention and after the intervention, as well as examples of intervention group samples have attempted to complete the questionnaire.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Sima Zahri Anboohi, Ph.D of Nursing

##### Street address

Taleghani hospital, Arabi Ave, Yaman Ave, CHamran Highway, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti  
University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Rezghi

**Street address**

Shahid Beheshti University of Medical Sciences, Arabi  
Ave, Yaman Ave, CHamran Highway, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Shahid Beheshti  
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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sima Zahri Anboohi, Ph.D of Nursing

**Position**

Assistant Professor

**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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**Other areas of specialty/work**

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**Web page address**

## 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*