# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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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## 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*