

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effect of Self- monitoring Program on Outcomes of Patients with Heart Failure

#### Protocol summary

##### Summary

Objective: Determining the effect of the self- monitoring program implementation on outcomes of patients with heart failure (2) Design: Parallel Single blind clinical Controlled trial (3) Setting and conduct: Selecting 54 patients with heart failure referring to heart failure clinic of Tehran Heart Center affiliated to Tehran university of medical sciences and assigning them to two groups of intervention and comparison by simple random allocation method. (4) Participants including major eligibility criteria: Inclusion Criteria: age older than 18 years old, diagnosis of HF, availability to telephone; ability of reading and writing in Farsi language, having a working weighing scale at home; without diagnosed defect of hearing and sight; stable hemodynamic status; not smoking and drinking alcohol and addiction to substance; living with family or caregiver. Exclusion Criteria: Diagnosis of psychiatric and cognitive conditions; unavailability of patients during call follow-up stage; Filling- in self- monitoring charts for less than 60 percent; cardiac surgery, awaiting or receiving heart transplant or left ventricular assistive device. (5) Intervention: Education on living well with heart failure based on booklet prepared by Australian Heart Foundation and using weight and shortness of breath self- monitoring charts for three months after referring during one- hour educational session by researcher nurse at heart failure clinic of Tehran Heart Center, and 5-15 minute- call-follow up during 1, 3 and 7 days after referring and every week for 3 months (6) Main outcome measures (variables): self-care, Heart Failure Knowledge, quality of life, and hospital admission before and 3 months after initiation of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017021032476N1**

Registration date: **2017-04-07, 1396/01/18**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-07, 1396/01/18

##### Registrant information

###### Name

Mahin Nomali

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6692 7171

###### Email address

m-nomali@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2017-06-11, 1396/03/21

##### Expected recruitment end date

2017-11-12, 1396/08/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Self- monitoring Program on Outcomes of Patients with Heart Failure

##### Public title

Effect of Self- monitoring Program on Outcomes of Heart Failure

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion Criteria: age older than 18 years old, diagnosis of HF, availability to telephone; ability of reading and writing in Farsi language, having a working weighing scale at home; without diagnosed defect of hearing and sight; stable hemodynamic status; not smoking and drinking alcohol and addiction to substance; living with family or caregiver. Exclusion Criteria: Diagnosis of psychiatric and cognitive conditions; unavailability of patients during call follow- up stage; Filling- in self-monitoring charts for less than 60 percent; cardiac surgery, awaiting or receiving heart transplant or left ventricular assistive device.

## Age

From **18 years** old to **95 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **46**

## 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

Ethics committee of Tehran University of Medical Sciences

##### Street address

Keshavarz Blvd, Qods street, Research deputy of Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2017-02-05, 1395/11/17

#### Ethics committee reference number

IR.TUMS.FNM.REC.1395.1653

## 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

#### Timepoint

Before beginning of the study and 2 months later at the end of the study

#### Method of measurement

Measurement of self-care by Self-Care Heart Failure Index (SCHFI)

## Secondary outcomes

### 1

#### Description

Quality of life; and hospital readmission

#### Timepoint

Before initiation of the study and 2 months later at the end of the study

#### Method of measurement

Measurement of quality of life by Minnesota Living With Heart Failure Questionnaire (MLHFQ) ; and hospital readmission by asking patients about the number, place, treatment, chief complaints and cause of admissions during call follow- up stage

## Intervention groups

### 1

#### Description

Intervention group: Education on living well with heart failure based on booklet prepared by Australian Heart Foundation and using weight and shortness of breath self- monitoring charts for two months after discharge during a 120- minute educational session by researcher nurse at heart failure clinic of Tehran Heart Center, and 5-15 minute- call-follow up during 1, 3 and 7 days after discharge and every week for 2 months

#### Category

Behavior

### 2

#### Description

Control group: they receive no intervention.

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Tehran Heart Center

**Full name of responsible person**

North Kargar Street, Tehran, Iran

**Street address**

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masud Yunesian

**Street address**

Keshavarz Blvd., Qods street, Research deputy of Tehran university of medical sciences

**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, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahin Nomali

**Position**

MS.c student of Critical Care Nursing

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Dr. Maasumeh Zakeri Moghadam

**Position**

Ph.D of Nursing

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## Person responsible for updating data

### Contact

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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*