

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)

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+98 21 6692 7171

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Maasumeh Zakeri Moghadam

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Ph.D of Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

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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