

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of Home care Program on Re-hospitalization in Advanced Heart Failure

Protocol summary

Study aim

Determining the effect of home care program on readmission rate of patients with advanced heart failure

Design

The present study was a clinical trial. 80 patients with heart failure were randomly divided into experimental (n = 40) and control (n = 40) groups. The block randomization was used to randomly assign to the control or experience group.

Settings and conduct

Rajaie Cardiovascular Medical and Research Center

Participants/Inclusion and exclusion criteria

1) Patients diagnosed with advanced heart failure who are hospitalized in one of the wards of Shahid Rajaee Hospital, have LVEF < 30%, according to the NYHA classification, have class III-IV symptoms of heart failure
2) Have a history of admission more than 1 time within the past 6 months
3) aged 18 or over.
4) Satisfaction to participate in the study.
5) live in Tehran
6) Have not had cardiogenic shock in the last 4 weeks
7) do not need dialysis
8) do not have severe cognitive impairment and severe chronic disease

Intervention groups

For the experimental group, the home care program was implemented for 6 months. The nurses participating in the study, visited the patients' homes once every two weeks and telephone follow-up was done every 3 days. In the control group, all steps and measurements were the same except for the home care program.

Main outcome variables

number of hospitalization, number of hospital days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190205042636N2**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Fidan Shabani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4424 8029

Email address

fidannahal@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Effect of Home care Program on Re-hospitalization in Advanced Heart Failure

Public title

Effect of Home care Program on Re-hospitalization in Advanced Heart Failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with advanced heart failure who are hospitalized in one of the wards of Shahid Rajaee Hospital have LVEF < 30% according to the NYHA classification, have class III-IV symptoms of heart failure Have a history of admission more than 1 time within the past 6 months aged 18 or over. Satisfaction to participate in the study live in Tehran

Exclusion criteria:

cardiogenic shock in the last 4 weeks need dialysis severe cognitive impairment and severe chronic disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization was used to randomly assign to the control or experience group. Patients who met the inclusion criteria were randomly assigned to the experimental or control group based on a quadruple block.

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

Medical Ethics Committee of Rajaei Cardiovascular Medical and Research Center

Street address

Rajaie Cardiovascular Medical and Research Center, next to Mellat Park, Vali Asr St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2017-08-26, 1396/06/04

Ethics committee reference number

RHC.AC.IR.REC.1396.36

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

number of hospitalization

Timepoint

30, 90 and 180 days before and after the home care program

Method of measurement

Registration form for the hospitalization of a patient with heart failure in a hospital

2

Description

number of hospital days

Timepoint

30, 90 and 180 days before and after the home care program

Method of measurement

Registration form for the hospital days of a patient with heart failure in a hospital

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the experience group, the home care program was implemented for 6 months. The nurses involved in the study visited patients' homes every two weeks to monitor patients, and telephone follow-ups were performed every three days.

Category

Prevention

2

Description

Control group: In the control group, all steps and measurements were the same except for the home care

program. So that the home care program was not implemented for the control group, but the number of times and the number of hospital days were recorded 30, 90 and 180 days before and after the program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Fidan Shabani

Street address

Rajaie Cardiovascular Medical and Research Center, next to Mellat Park, Vali Asr St., Tehran,Iran

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Email

fidannahal@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Majid Maleki

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rajaie Cardiovascular Medical and Research Center

Proportion provided by this source

30

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Fidan Shabani

Position

supervisor-nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Fidan Shabani

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available