

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of cooperative caregiver training versus individual training on the adherence to treatment in patients with heart failure: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of cooperative primary caregiver training versus individual training on the adherence to treatment in patients with heart failure

Design: a randomized clinical trial. **Setting and conduct:** The eligible patients with heart failure who will refer to Ekbatan Clinic during the study period will be enrolled into the trial. **Inclusion criteria:** (a) having heart failure class 2 or 3; (b) ability to read and write; (c) cooperation of one the patient's family member as the main caregiver. **Exclusion criteria:** (a) having congenital heart disease; (b) history of heart surgery; (c) living alone; (d) severe physical disability; (e) history of participating in similar training and rehabilitation class. **Intervention group:** Six one-hour training sessions during 2 weeks for patients and their caregivers. **Control group:** Six one-hour training sessions during 2 weeks only for patients. **Primary outcome:** Assessing the adherence to treatment 6 weeks after intervention using adherence to treatment questionnaire. **Secondary outcome:** Nothing. **Randomization:** Random assignment of the patients to the intervention and control groups using random number table. **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511209014N84**
Registration date: **2015-11-27, 1394/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2016-02-04, 1394/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cooperative caregiver training versus individual training on the adherence to treatment in patients with heart failure: a randomized clinical trial

Public title

Effect of cooperative caregiver training versus individual training on the adherence to treatment in patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (a) having heart failure class 2 or 3; (b) ability to read and write; (c) cooperation of one the patient's family member as the main caregiver. Exclusion criteria: (a) having congenital heart disease; (b) history of heart surgery; (c) living alone; (d) severe physical disability; (e) history of participating in similar training and rehabilitation class.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups using random number table. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-08-17, 1394/05/26

Ethics committee reference number

IR.UMSHA.REC.1394.250

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

Assessing the adherence to treatment

Timepoint

6 weeks after intervention

Method of measurement

using adherence to treatment questionnaire

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

Six one-hour training sessions during 2 weeks for patients and their caregivers

Category

Other

2

Description

Six one-hour training sessions during 2 weeks only for patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Clinic

Full name of responsible person

Zahra Ghanbari Azarm

Street address

Ekbatan Clinic, Taleghani Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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**

Ekbatan Clinic

Full name of responsible person

Zahra Ghanbari Azarm

Position

Nursing Student

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Associate Professor

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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