

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### 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  
Fahmideh Ave

**City**

Hamadan

**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

**Other areas of specialty/work****Street address**

Ekbatan Clinic, Taleghani Ave.

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Gholam Hossein Falahinia

**Position**

MSc in Nursing

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**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

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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*