

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of education and telephone follow-up after hospital discharge versus control group on self-care behaviors in patients with myocardial infarction: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of education and telephone follow-up after hospital discharge versus control group on self-care behaviors in patients with myocardial infarction

Design

This is a randomized clinical trial, phase II, in which 116 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with myocardial infarction referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 30 to 70 years, Myocardial infarction, Literate, The possibility of telephone call to the patients or their family Exclusion criteria: Other concurrent chronic diseases, Inability of self-care

Intervention groups

Intervention group: Routine cares and trainings after myocardial infarction plus one session face to face training along with pamphlets and educational CD, providing information about the signs and symptoms need for returning, following medication instructions, diet follow-up, allowable physical range, risk factors for re-myocardial infarction, and the effects of stress Control group: Just routine cares and trainings after myocardial infarction

Main outcome variables

Primary outcome: Assessing the self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N363**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **prospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

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

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education and telephone follow-up after hospital

discharge versus control group on self-care behaviors in patients with myocardial infarction: a randomized clinical trial	Hamadan University of Medical Sciences, Shahid Fahmideh Ave
Public title Effect of education and telephone follow-up after hospital discharge versus control group on self-care behaviors in patients with myocardial infarction	City Hamadan
Purpose Education/Guidance	Province Hamadan
Inclusion/Exclusion criteria Inclusion criteria: Age of 30 to 70 years, Myocardial infarction, Literate, The possibility of telephone call to the patients or their family Exclusion criteria: Other concurrent chronic diseases, Inability of self-care	Postal code 6517838695
Age From 30 years old to 70 years old	Approval date 2020-07-25, 1399/05/04
Gender Both	Ethics committee reference number IR.UMSHA.REC.1399.409
Phase N/A	Health conditions studied 1 Description of health condition studied Myocardial infarction ICD-10 code I21 ICD-10 code description ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
Groups that have been masked <i>No information</i>	Primary outcomes 1 Description Assessing the self-care behaviors Timepoint Before the intervention and weekly after the treatment for 8 weeks Method of measurement Using standard Miler self-care questionnaire
Sample size Target sample size: 116	Secondary outcomes empty
Randomization (investigator's opinion) Randomized	Intervention groups 1 Description Intervention group: Routine cares and training after myocardial infarction plus one session face to face training along with pamphlets and educational CD, providing information about the signs and symptoms need for returning, following medication instructions, diet follow-up, allowable physical range, risk factors for re-myocardial infarction, and the effects of stress Category Behavior
Randomization description The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.	2 Description Control group: Just routine cares and training after myocardial infarction Category
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 Hamadan University of Medical Sciences Street address Vice-chancellor for Research and Technology,	

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Mehran Salmani Ghabeshi

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1740

Email

gabeshi1347@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Person responsible for general inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Mehran Salmani Ghabeshi

Position

MSc in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

gabeshi1347@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Masood Khdaveisi

Position

Community Health Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

khodaveisimasoud@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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