

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of health-related lifestyle self-management intervention on quality of life in patients with ischemic heart disease

#### Protocol summary

##### Summary

Purpose: The effect of health-related lifestyle self-management intervention on quality of life in patients with ischemic heart disease in Farshchian Hospital in 2015. design study: a randomized, single-center, two-group, experimental before-after study. inclusion criteria: Patients with a diagnosis of ischemic heart disease is admitted in the Heart Farshchian Hospital in Hamedan; patient have at least one risk factors including hyperlipidemia, hypertension, obesity, limited physical activity and inappropriate diet; patient does not have other specific diseases (renal, respiratory, endocrine and orthopedic) with physician approval; The patient does not have mobility problems. Exclusion criteria: patient have major concomitant diseases, such as stroke and cancer that are influence in recovering. Sample size: 92. intervention study: health-related lifestyle self-management program (HELM). intervention time: 8 weeks. the primary outcome or consequences of the study: quality of life in heart patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011222712N3**  
Registration date: **2016-12-13, 1395/09/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-13, 1395/09/23

##### Registrant information

##### Name

Maryam Rajabi

##### Name of organization / entity

School of Nursing and Midwifery, Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38388464

##### Email address

m.rajabi@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Tecnology of Hamedan University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-05-21, 1395/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of health-related lifestyle self-management intervention on quality of life in patients with ischemic heart disease

##### Public title

The effect of self-management on quality of life in cardiac patients

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with a diagnosis of ischemic heart disease is admitted in the Heart Farshchian Hospital in Hamedan; Patient have at least one risk factors including hyperlipidemia, hypertension, obesity, limited physical activity and inappropriate diet; Patient

does not have other specific diseases (renal, respiratory, endocrine and orthopedic) with physician approval; The patient does not have mobility problems. Exclusion criteria: patient have major concomitant diseases, such as stroke and cancer that are influence in recovering.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **92**

**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**

Hamedan University of Medical Sciences Ethics Committee

**Street address**

Hamedan University of Medical Sciences,After Research square, Hamedan

**City**

Hamedan

**Postal code****Approval date**

2015-12-05, 1394/09/14

**Ethics committee reference number**

IR.UMSHA.REC.1394.400

**Health conditions studied****1****Description of health condition studied**

Ischemic heart disease

**ICD-10 code**

I20

**ICD-10 code description**

Angina pectoris

**Primary outcomes****1****Description**

Quality of life

**Timepoint**

Before the intervention and 8 weeks after the intervention

**Method of measurement**

Quality of life questionnaire MC new

**Secondary outcomes****1****Description**

Body mass index

**Timepoint**

Before the intervention and 8 weeks after the intervention

**Method of measurement**

Scale weight and meter

**2****Description**

Blood pressure

**Timepoint**

Before the intervention and 8 weeks after the intervention

**Method of measurement**

Mercurial pressure indicator

**3****Description**

Waist circumference

**Timepoint**

Before the intervention and 8 weeks after the intervention

**Method of measurement**

Handy meter

**Intervention groups****1****Description**

Intervention groups: Health-related lifestyle self-management intervention (HELM) use for 8 weeks. The main components include eight areas: goal setting, bibliotherapy, giving feedback to the patient about the risk factors associated with the disease according to tests and the physical condition of the patient, team building and communication with the physician, call (three supportive telephone), interview, the visual cue and a health diary for self monitoring.

**Category**

Lifestyle

## 2

### Description

The control group consists of patients who received the usual care patients.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Haert Farshchian Hospital

##### Full name of responsible person

Maryam Rajabi

##### Street address

Haert Farshchian Hospital, Above people park, After research square, Hamedan

##### City

Hamedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Tecnology of Hamedan University of Medical Scinces

##### Full name of responsible person

Docter Saeed Bashirian

##### Street address

Hamedan University of Medical Sciences, After Research square, Hamedan .

##### City

Hamedan

##### 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 and Tecnology of Hamedan University of Medical Scinces

##### 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Roya Amini

#### Position

MSc. of Nursing, Advisor

#### Other areas of specialty/work

#### Street address

Hamedan University of Medical Sciences, After Research square, Hamedan

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#### Phone

+98 918 315 0740

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aminiroy@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

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Roya Amini

#### Position

Master degree

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

School of Nursing and Midwifery, Hamedan University of Medical Sciences

#### Full name of responsible person

Maryam Rajabi

#### Position

Nursing Graduate Student

#### Other areas of specialty/work

#### Street address

Hamedan University of Medical Sciences, After Research square, Hamedan

#### City

Hamedan

#### Postal code

#### Phone

00

**Fax**

**Email**

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**Web page address**

## 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*