Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

Purpose: The effect of health-related lifestyle self-management intervention on health promotion behaviors in patients with ischemic heart disease referred to Ekbatan Hospital in 2015. design study: a randomized, single-center, two-group semi-experimental before-after study. inclusion criteria: Patients with a diagnosis of ischemic heart disease is admitted in the Ekbatan 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: Compliance with health-promoting lifestyle in heart patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061422712N1**
Registration date: **2015-07-12, 1394/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-12, 1394/04/21

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Vice Chanceller for Research and Tecnology of Hamedan University of Medical Scinces

Expected recruitment start date

2015-06-26, 1394/04/05

Expected recruitment end date

2015-10-27, 1394/08/05

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 health promotion behaviors in patients with ischemic heart disease

Public title

The effect of self-management on health promotion in cardiac patients

Purpose

Supportive

Inclusion/Exclusion criteria

Iinclusion criteria: Patients with a diagnosis of ischemic heart disease is admitted in the Ekbatan 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, Pazhuhesh Crossroads, Hamedan

City
Hamedan

Postal code

Approval date
2015-05-23, 1394/03/02

Ethics committee reference number
IR.UMSHA.REC.1394.77

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
Health promoting behaviors

Timepoint
Before the intervention and at least 6 weeks after the intervention

Method of measurement
health promotion lifestyle questionnaire

Secondary outcomes

1

Description
Waist circumference

Timepoint
Before the intervention and at least 6 weeks after the intervention

Method of measurement
Handy meter

2

Description
blood pressure

Timepoint
Before the intervention and at least 6 weeks after the intervention

Method of measurement
mercurial pressure indicator

3

Description
body mass index

Timepoint
Before the intervention and at least 6 weeks after the intervention

Method of measurement
scale weight and meter

Intervention groups

1

Description
Intervention groups: health-related lifestyle, self-management intervention (HELM) use for at least six 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 telephone support), interview, the visual cue (fridge magnet) 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
Ekbatan Haspital
Full name of responsible person
Doctor Mohammad Mehdi Esmaeili
Street address
Ekbatan Haspital, Taleghani street, Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chanceller 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, Pazhuhesh crossroad, Hamedan .
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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 Chanceller 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
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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