

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of self-management program on therapeutic adherence and quality of life in patient with ischemic heart disease

Protocol summary

Summary

Objectives, the purpose of this study is investigates The effect of self-management program on therapeutic adherence and quality of life in patient with ischemic heart disease. Design, the present research took place with two group and randomized clinical trial method in intensive care unit of Rajaei Cardiac Hospital. Subjects of study will be Patients with ischemic heart disease diagnosed by a physician. 60 eligible patients enroll in two groups. Setting and conduct, in this study, patients with convenience sampling method (available) will be selected randomly (draw) and will be enrolled the study in both intervention and control groups. Inclusion criteria: Confirmed ischemic heart disease by a physician, No previous enterprises self management training. Exclusion criteria: Being in acute phase of disease, wouldn't like to continue. Intervention, after completing informed consent, both control and experimental group will be completed pretest questionnaire of therapeutic adherence and quality of life. control group will be received regular cares but the intervention group in addition to receive the usual care, will participate in the workshop of self-management program, during the first week after discharging. This program contain a workshop, then it will be followed up by telephone once a week for 8 weeks. by the ending these eight-week, there is no defined intervention for the patients for next four weeks and finally, twelve weeks after the intervention, the questionnaire will be completed again by two control and experimental groups and differences will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504304443N19**

Registration date: **2015-09-01, 1394/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 2160

Email address

zakerimo@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management program on therapeutic adherence and quality of life in patient with ischemic heart disease

Public title

The effect of self-management program on ischemic heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:(ability to read and write; aged between 30 and 65 years; ischemic heart disease that diagnosed by physicians; traverse at least one year of diagnosis of ischemic heart disease; The absence of non cardiac chronic underlying disease that affects quality of life; No previous Enterprises self management training Exclusion criteria: The patient died during the study; The patient enters the acute phase; If the patient does not Enterprises in the telephone intervention)

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

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

In this study, patients with convenience sampling method (available) will be selected randomly (draw) and will be enrolled the study in both intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Office building of Tehran University of medical Sciences, Keshavarz St, Tehran.

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

94/250577/5

Health conditions studied

1

Description of health condition studied

Patient with ischemic heart disease

ICD-10 code

151.6

ICD-10 code description

125.0

Primary outcomes

1

Description

therapeutic adherence

Timepoint

before and 12 weeks after intervention

Method of measurement

therapeutic adherence questionnaire in patient with ischemic heart disease

2

Description

quality of life

Timepoint

before and 12 weeks after intervention

Method of measurement

mac new quality of life questionair

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In control group just will receive regular care at discharge include advice on medications and low salt and low-fat food, without any intervention.

Category

Other

2

Description

Intervention group : Beside receiving the usual care, the examination group will participate in self-management program which is hold with the partnership of 15 patients during sequential days, 4 hours each in the very first week after discharge. Workshops run by the researcher in the shape of educational lectures, discussions between patients and researchers, Exchange of experiences, correct the previous mistakes and finally answer the questions by researchers. The Workshop contains learning the nature of the disease, its complications, risk factors and methods of control, stress reduction techniques and methods to overcome the

problems by scenario of problems and comments, share information and experiences of patients with the help of researchers, the participants will practice problem solving. The intervention focuses on increasing acceptance of medication regimen, nutrition, weight loss if needed, reducing sodium intake, regular physical activity, (walking) and quit smoking. After that for next 8 weeks, it follows-up verbal encouragement, questions and answers, improving teaching and managing disease once a week for about 10 minutes, according to research done by the patient needs. Phone calls between 8 am to 8 pm on the specified date and time will be agreed by the researcher and the research units. After the eight-week intervention for the patients for next four weeks, except very necessary will be provided by Phone call.

Category

Lifestyle

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

Rajaei Cardiac Hospital

Full name of responsible person

Masoomah Zakeri Moghadam

Street address

Rajaei Cardiac Hospital, Niyayesh St, Valiasr St, Tehran

City

Tehran

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

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masoomah Zakerimoghadam

Street address

Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St, Tohid Square, Tehran

City

Tehran

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, Tehran 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**

Nursing- Midwifery Faculty of Tehran University of Medical Science

Full name of responsible person

Masoomah Zakerimoghadam

Position

lecturer

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

Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St, Tohid Square, Tehran

City

Tehran

Postal code**Phone**

+98 21 64359

Fax**Email**

zakerimo@sina.tums.ac.ir

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

Tehran University of Medicine

Full name of responsible person

Masoomah Zakeri Moghadam

Position

Lcturer

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

Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St, Tohid Square, Tehran

City

Tehran

Postal code**Phone**

+98 21 64359

Fax**Email**

zakerimo@sina.com

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

Nursing- Midwifery Faculty of Tehran University of Medical Science

Full name of responsible person

Masoumeh Zakerimoghadam

Position

lecturer

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

Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St, Tohid Square, Tehran

City

Tehran

Postal code**Phone**

+98 21 64359

Fax**Email**

mzakerimo@sina.tums.ac.ir

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