

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of a care plan based on Pender's Health Promotion Model on adherence to the treatment regimen in patients with coronary Artery Disease

Protocol summary

Study aim

Effect of a Care Plan Based on the Pender Health Promotion Model on Adherence to the Treatment Regimen in Patients with Coronary Artery Disease

Design

A clinical trial with a control group in which the data will be collected in two stages before and after the intervention for the control and control group simultaneously. 64 samples were randomly assigned into two groups of 32 subjects.

Settings and conduct

This study will be carried out at the Charman Heart Center of Isfahan.

Participants/Inclusion and exclusion criteria

The company participated in a training program on compliance with treatment regimen during the study Affected by coronary artery disease with confirmation of a doctor's diagnosis Passed at least 6 months of diagnosis family's willingness to participate in the program The company participated in a training program on compliance with treatment regimen during the study

Intervention groups

In the test group, the Pandor Health Promotion-Based Health Care Program is grouped in 4 consecutive sessions each week. The duration of each session is 45 to 60 minutes. For the control group after the completion of the study, two discussion sessions are held on the importance of the diet, diet and exercise regime, and after the program is implemented, training books will be given about the importance of the treatment regime

Main outcome variables

visits to these hospitals the cost of treatment the complications of the disease

General information

Reason for update

Acronym

CAD

IRCT registration information

IRCT registration number: **IRCT20180227038886N1**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Forough Faroughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3252 5978

Email address

f.faroughi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-08, 1397/02/18

Expected recruitment end date

2018-09-09, 1397/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a care plan based on Pender's Health Promotion Model on adherence to the treatment regimen in patients with coronary Artery Disease

Public title

Effects of Pender's Health Promotion Model on adherence to the treatment regimen

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are alert and able to communicate. Affected by coronary artery disease with confirmation of a doctor's diagnosis Passed at least 6 months of diagnosis family's willingness to participate in the program family's willingness to participate in the program

Exclusion criteria:

The company participated in a training program on compliance with treatment regimen during the study

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by simple and continuous sampling. The samples will be assigned randomly into two groups of test and control according to the conditions of entry into the study. In this way, a card with number one and a card with number two in the envelope are placed in the package and they are asked to select a card. The people who choose the first-card number are in the control group in the group and those who take the number two card. Participants are unaware of being in the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

After determine of samples with inclusion criteria, samples allocated to the experimental and control groups. so, all of the samples enter to the study, but they don't know about the groups of this study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Dormitory of Isfahan University of Medical Sciences. Hazar Jarib Street. Shiraz gate

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

IR.MUI.REC.1396.3.916

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

IX Diseases of the circulatory system

2

Description of health condition studied

Ischemic myocardium

ICD-10 code

I25.2

ICD-10 code description

IX Diseases of the circulatory system

3

Description of health condition studied

Unstable unguine

ICD-10 code

I20.0

ICD-10 code description

IX Diseases of the circulatory system

Primary outcomes

1

Description

Percentage of people who have treatment adherence

Timepoint

Before the intervention begins. One month after the intervention and three months after the intervention

Method of measurement

Treatment Regimen Adherence Questionnaire

2

Description

Percentage of people who have drug adherence

Timepoint

Before the intervention and one month and three months after the end of the intervention

Method of measurement

morisky Medication Adherence Questionnaire

3

Description

Percentage of people who have nutrition adherence

Timepoint

Before the intervention begins. One month after the intervention and three months after the intervention

Method of measurement

nutrition Adherence Questionnaire

4

Description

Percentage of people who have exercise adherence

Timepoint

Before the intervention begins. One month after the intervention and three months after the intervention

Method of measurement

exercise Adherence Questionnaire

Secondary outcomes

1

Description

Score Adherence to the treatment regime

Timepoint

Pre-intervention and one month and three months after the end of the intervention

Method of measurement

treatment Adherence Questionnaire

2

Description

Score Adherence to the medication regime

Timepoint

Pre-intervention and one month and three months after the end of the intervention

Method of measurement

medication Adherence Questionnaire

3

Description

Score Adherence to the nutrition regime

Timepoint

Pre-intervention and one month and three months after the end of the intervention

Method of measurement

nutrition Adherence Questionnaire

4

Description

Score Adherence to the Exercise regime

Timepoint

Pre-intervention and one month and three months after the end of the intervention

Method of measurement

Exercise Adherence Questionnaire

Intervention groups

1

Description

"Intervention group:" In the test group, the Pandor Health Promotion-Based Health Care Program is grouped in 4 consecutive sessions each week. The duration of each session is 45 to 60 minutes. During the sessions, lecture, question and answer, and group discussion are used.

Category

Prevention

2

Description

Control group: In this group, there is no intervention during the study. But at the end of the intervention in the intervention group, the training group will also be given to the group in the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Heart Center

Full name of responsible person

Forough Faroughi

Street address

Chamran Hospital, Salman Farsi Street, Bozorgmehr street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 17 3252 5978

Email

f.faroughi@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayegh haghjoo javanmard

Street address

Isfahan university of medical Sciences.Hazar jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**Type of organization providing the funding**

Academic

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

Esfahan University of Medical Sciences

Full name of responsible person

Forough Faroughi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences.Hazarjerib street

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Phone

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Email

f.faroughi@nm.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

forough faroughi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Esfahan University of Medical Sciences

Full name of responsible person

Forough Faroughi

Position

masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

It will be discussed in a clinical study and report how the

study will be conducted

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers of academic institutions

Under which criteria data/document could be used

If reference is given to the study

From where data/document is obtainable

f.faroughi3504@gmail.com 09117003504

What processes are involved for a request to access data/document

Expression of the request by email and checking access to it and sending it

Comments

Observe referral laws