

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of education based on Pender's health promotion model versus control group on health promoting behaviors in patients undergoing coronary angioplasty: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of education based on Pender's health promotion model versus control group on health promoting behaviors in patients undergoing coronary angioplasty

Design

This is a randomized clinical trial, phase II, in which 96 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergoing coronary angioplasty 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 35 to 65 years, Undergoing coronary angioplasty, Literate, Exclusion criteria: Congenital heart disease, History of heart surgery, History of coronary angioplasty, Mental disorders

Intervention groups

Intervention group: Routine care after coronary angioplasty plus Pender Health Promotion-based training sessions include face-to-face training, question and answer, and video playback, 30 minutes each session three times at 5-day intervals Control group: Just routine care after coronary angioplasty plus

Main outcome variables

Primary outcome: Spiritual growth and individual self-actualization, responsibility about health, interpersonal relationships, stress management, the amount of physical activity, adherence to a healthy diet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N360**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **prospective**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education based on Pender's health promotion model versus control group on health promoting behaviors in patients undergoing coronary angioplasty: a randomized clinical trial

Public title

Effect of education based on Pender's health promotion model versus control group on health promoting behaviors in patients undergoing coronary angioplasty

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 35 to 65 years, Undergoing coronary angioplasty, Literate,

Exclusion criteria:

Congenital heart disease, History of heart surgery, History of coronary angioplasty, Mental disorders

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

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.

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,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-04-15, 1399/01/27

Ethics committee reference number

IR.UMSHA.REC.1399.051

Health conditions studied

1

Description of health condition studied

Coronary angioplasty

ICD-10 code

Z98.61

ICD-10 code description

Coronary angioplasty status

Primary outcomes

1

Description

Spiritual growth and individual self-actualization

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

2

Description

Responsibility about health

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

3

Description

Interpersonal relationships

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

4

Description

Stress management

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

5**Description**

The amount of physical activity

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

6**Description**

Adherence to a healthy diet

Timepoint

Before the intervention and 2 months later

Method of measurement

Using the standard questionnaire of health promotion behaviors

Secondary outcomes

empty

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

Intervention group: Routine care after coronary angioplasty plus Pender Health Promotion-based training sessions include face-to-face training, question and answer, and video playback, 30 minutes each session three times at 5-day intervals

Category

Treatment - Other

2**Description**

Control group: Just routine care after coronary angioplasty plus

Category

N/A

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

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Zinat Yunesi

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

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**Type of organization providing the funding**

Academic

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

Hamedan University of Medical Sciences

Full name of responsible person

Zinat Yunesi

Position

Student of Community Health Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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

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

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Full name of responsible person

Dr. Masoud Khodaveisi

Position

PhD in Nursing Training

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

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Full name of responsible person

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Position

Professor of Epidemiology

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Other areas of specialty/work

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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

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