

# 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### 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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**Province**

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**Phone**

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**Email**

zinat.yunesi@gmail.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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**Email**

info.research@umsha.ac.ir

**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

**Street address**

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**

Hamedan University of Medical Sciences

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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