Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of an educational intervention based on illness perception correction on control of some risk factors and incidence of acute coronary syndrome in patients with coronary artery disease

Protocol summary

Summary

The purpose of this study is to investigate the effect of an educational intervention based on illness perception correction on control of some risk factors and incidence of acute coronary syndrome in patients with coronary artery disease. This work is a clinical trial study with a control group, with patients undergoing angiography hospitalized in cardiology and post-angiography unit. One hundred patients, having inclusion criteria for the study, were randomly divided into two intervention and control groups (fifty patients for each group). Inclusion criteria: Being a candidate for angiography, not having a history of acute coronary syndrome, not having mental disease, not having cognitive disorder, not being a subject for another study. Exclusion criteria: Not being diagnosed with coronary artery disease by angiography and deterioration of the patient's medical condition before completing the intervention. Random allocation was determined based on odd and even weeks. After completing informed consent, demographic information and the status of some cardiovascular risk factors (systolic blood pressure, diastolic blood pressure, triglyceride, total cholesterol, fasting blood glucose, body mass index, smoking) and illness questionnaire-revised (IPQ-R) were completed before performing the angiography in the control and intervention groups. The control group just received routine care of the unit. In comparison, the intervention group received illness perception correcting intervention individually for three sessions. Then, the intervention group was followed up with telephone contact for three months after discharge. Six months after the clinical trial, the illness perception questionnaire-revised was completed and the status of some cardiovascular risk factors (systolic blood pressure, diastolic blood pressure, triglyceride, total cholesterol, fasting blood glucose, body mass index, smoking) and the incidence of acute coronary syndrome in both groups were assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010425842N1**
Registration date: **2016-04-01, 1395/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-01, 1395/01/13

Registrant information

Name

Zahra Zolfaghari Lakeh

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3315 6918

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Zanjan University of Medical Sciences

Expected recruitment start date

2015-03-08, 1393/12/17

Expected recruitment end date

2015-05-15, 1394/02/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of an educational intervention based on illness perception correction on control of some risk factors and incidence of acute coronary syndrome in patients with coronary artery disease

Public title
Illness perception correction in patients with coronary artery disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Being a candidate for angiography; Being older than 18 years; Not having a history of acute coronary syndrome; Not having any mental disease; Not having any cognitive disorder; Not being a subject for any other study; Possibility of making a phone contact with the patient Exclusion criteria: Not being diagnosed with coronary artery disease by angiography; Deterioration of the patient's medical condition before completing intervention; Discharge before completing the intervention; Reluctance to cooperate with the study
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi Sq, Zanjan, Iran
City
Zanjan
Postal code
Approval date
2015-02-10, 1393/11/21
Ethics committee reference number
ZUMS.REC.1393.212

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease

2

Description of health condition studied
Acute coronary syndrome
ICD-10 code
I24.9
ICD-10 code description
Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description
Illness perception
Timepoint
Before intervention, six months after intervention
Method of measurement
Illness Perception Questionnaire-Revised

2

Description
Fasting blood glucose
Timepoint
Before intervention, six months after intervention
Method of measurement
Enzymatic method

3

Description
Triglyceride
Timepoint
Before intervention, six months after intervention
Method of measurement
Enzymatic method

4

Description

Total cholesterol
Timepoint
Before intervention, six months after intervention
Method of measurement
Enzymatic method

5

Description
Systolic blood pressure
Timepoint
Before intervention, six months after intervention
Method of measurement
Aneroid sphygmomanometer

6

Description
Diastolic blood pressure
Timepoint
Before intervention, six months after intervention
Method of measurement
Aneroid sphygmomanometer

7

Description
Body mass index
Timepoint
Before intervention, six months after intervention
Method of measurement
weight (kg) / [height (m)]2, kg/m2

8

Description
Smoking
Timepoint
Before intervention, six months after intervention
Method of measurement
Questionnaire

9

Description
Incidence of acute coronary syndrome
Timepoint
Six months after intervention
Method of measurement
Patient's medical file and Diagnosis of the physician

10

Description
Length
Timepoint
Before intervention
Method of measurement
Measuring tape

11

Description
Weight
Timepoint
Before intervention, six months after intervention
Method of measurement
Scale

Secondary outcomes

empty

Intervention groups

1

Description
In control group no intervention was done.These patients just received routine care of the unit (routine nursing Care including carrying out doctors' orders, brief explanation on diet and medications at time of discharge)
Category
N/A

2

Description
In intervention group, an intervention on the basis of correcting the patient’s perception of the illness was carried out for three 30-40 minute sessions during hospitalization. The intervention was individually through the face-to-face conversation according to the response of each patient to the Illness Perception Questionnaire-Revised version. On discharge, the patients were supplied with an education booklet and CD. Then, the intervention group was followed up by telephone contacts for 20 to 30 minutes for three months after discharge. In this follow-up, the appropriate behaviors of the patients were encouraged, the benefits of adopting these behaviors were emphasized, and finally their questions were answered.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital, Zanjan
Full name of responsible person
Zahra Zolfaghari Lakeh
Street address
Gavazang Road, Zanjan, Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice Chancellor for Research of Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohamad Masood Vakili

Street address

Vice Chancellor for Research of Zanjan University of Medical Sciences, Azadi Sq, Zanjan, Iran

City

Zanjan

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 of Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mahin Roohani

Position

Master of Nursing

Other areas of specialty/work

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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