Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of self-care education on the quality of life of patients with acute coronary syndrome

Protocol summary

Study aim
Improvement of self-care and quality of life in patients with acute coronary syndrome

Design
In this study, 70 eligible patients with acute coronary syndrome admitted to the Coronary Care Unit of Modarres Hospital of Saveh were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct
The present study will be conducted at Modarres Hospital of Saveh and on patients with acute coronary syndrome. Samples and data analyzers will not know how to place the samples in the intervention and control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of acute coronary syndrome; 20 to 60 years old; not having of previous history of hospitalization in the Coronary Care Unit; reading and writing skills; not having hearing and vision impairments
Exclusion criteria:candidate candidates for angiography or coronary artery bypass graft surgery; cardiac heart failure class 4; unwillingness of the patient's participant to do the study

Intervention groups
Intervention group: self-care education program perform for the intervention group during three sessions of 30 to 45 minutes with a one-day interval during one week.
Control group: control group samples do not receive any intervention

Main outcome variables
The quality of life of patients with acute coronary syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161223031522N6**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**
Update count: **0**

Registration date
2018-02-07, 1396/11/18

Registrant information

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Vahid Naseri Salahshour

Name of organization / entity
Arak University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-11, 1396/08/20

Expected recruitment end date
2018-02-09, 1396/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-care education on the quality of life of patients with acute coronary syndrome

Public title

The effect of self-care education on the quality of life of patients with acute coronary syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of acute coronary syndrome 20 to 60 years old Not having of previous history of hospitalization in the Coronary Care Unit Reading and writing skills Not having hearing and vision impairments

Exclusion criteria:

Stage 4 of cardiac failure Patients to candidates for angiography or coronary artery bypass graft surgery Unwillingness of patients to participant in the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into intervention and control groups using randomized block allocation method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a double-blind and clinical trial. Data and data analyzers will not be aware of the random allocation method in the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Committee of Saveh University of Medical Sciences

Street address

Shariati St, Madar Sq

City

Saveh

Province

Markazi

Postal code

3918698786

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.SAVEHUMS.REC1396.07

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Quality of life questionnaire score

Timepoint

Before intervention, immediately after intervention and two months after intervention

Method of measurement

(Short-form 36) SF-36 Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: self-care education program perform for the intervention group during three sessions of 30 to 45 minutes with a one-day interval during one week

Category

Lifestyle

2

Description

Control group: control group samples do not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Dr Hojjat Tamizi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Saveh University of Medical Sciences
Full name of responsible person
Hamidreza Baradaran
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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
Saveh 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.
When the data will become available and for how long
The beginning of the access period is 18 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions.
Under which criteria data/document could be used
In order to utilize scientific purposes and mention the source used.
From where data/document is obtainable
Neda Fayazi, MSc of Nursing, Faculty of Nursing and Midwifery, Saveh University of Medical Sciences, Saveh, Iran. E-mail address: nedafayazi10@yahoo.com
What processes are involved for a request to access data/document
After receiving the email from the requester, the information will be sent within 2 to 3 business days.
Comments