Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of self-efficacy enhancement program on medication adherence among patients with acute coronary syndromes

Protocol summary

Study aim
Determining the effect of self-efficacy enhancement program on medication adherence among patients with acute coronary syndrome in the Cardiac Care Unit

Design
The study is a randomized controlled clinical trial with parallel groups.

Settings and conduct
In this study, 90 patients with acute coronary syndrome admitted to the coronary Care Unit of Imam Hossein Hospital in Shahroud will be selected based on inclusion criteria and will be randomly assigned into intervention and control groups. self-efficacy enhancement program will be conducted for the intervention group. Before and 40 days after the intervention, the SEAMS questionnaire will be completed for patients in both the test and the control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age ≥ 20; speak and understand Persian language; diagnosis of Acute coronary syndrome by a cardiologist. Non inclusion criteria: Treatment-resistant ventricular arrhythmia and cardiojenic shock following illness; having a history of cognitive impairment or known anxiety disorders based on patient's history and self-declaration and doctor's approval.

Intervention groups
Intervention group: The training intervention will be performed in face-to-face form during 40 minutes to determine the acute coronary syndrome, risk factors, symptoms of heart disease and medication. Control group: they receive usual care.

Main outcome variables
medication adherence among patients with acute coronary syndromes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180623040204N1**
Registration date: **2018-08-19, 1397/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-19, 1397/05/28**
Update count: **0**

Registration date
2018-08-19, 1397/05/28

Registrant information

Name
Maryam Mahdavian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3223 9249

Email address
maryam_mahdavian@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-12, 1397/05/21

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-efficacy enhancement program on medication adherence among patients with acute coronary syndromes

Public title
The effect of self-efficacy enhancement program on medication adherence
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 20 or over Ability to speak and understand Persian language diagnosis of Acute coronary syndrome by a cardiologist.
Exclusion criteria:
Treatment-resistant ventricular arrhythmia and cardiojenic shock following illness having a history of cognitive impairment or known anxiety disorders based on patient's history and self-declaration and doctor's approval
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups by block of size 4: group A (self-efficacy enhancement program) and group B (control group). The allocation will be done concealment. In this way, there will be 90 envelopes, each with A and B codes. The envelopes will be numbered. Individuals will be coded according to their entry into the study, and will be allocated an envelope for each patient to the group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the outcome assessor (who will complete the questionnaire) and the data analyser are not aware of how the patients are allocated to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Hafte-Tir square
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2018-07-02, 1397/04/11
Ethics committee reference number
IR.SHMU.REC.1397.066

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome
ICD-10 code
I25.9
ICD-10 code description
Chronic ischaemic heart disease, unspecified

Primary outcomes

1

Description
Medication adherence score in self-efficacy for Appropriate Medication Use Scale (SEAMS).
Timepoint
medication adherence measurement as soon as the patient's condition improves. It is done before the intervention and 40 days after the intervention
Method of measurement
Self-Efficacy for Appropriate Medication Use Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The questionnaire will be completed as soon as the condition is fixed.Then, educational intervention will be provided to the patient in addition to routine therapeutic care in relation to the definition of acute coronary syndrome, risk factors, signs of heart disease and drug regimen in face-to-face form within 40 minutes.10 days later, 3 telephone follow-ups will be held for 10 minutes every 10 days, asking about follow-up treatment and medication, and diet and self-care. Then, the last 10 days follow up, Then, 10 days after the last follow-up calls (After 40 days of discharging),Telephone coordination will be done for the presence of participants in the hospital and the

questionnaire will be completed again.

Category

Prevention

2

Description

Control group:The questionnaire will be completed as soon as the conditions are fixed. During this time, there will be no intervention for the participants of this group and will receive only routine and educational care at during hospitalization and and discharge time. After discharge, telephone follow up will not be done for participants, and after 40 days, while coordinating the phone to attend in the hospital, the questionnaire will be completed again.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Hoseein Ebrahimi

Street address

28th meter of Touhidi, Imam Khomeini Street

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3234 2000

Email

h_ebrahimi43@yahoo.com

Web page address

http://eh.shmu.ac.ir/home.html

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Hassan Emamian

Street address

Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

6314773955

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

Web page address

http://research.shmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Ebrahimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Hafte-Tir square

City

Shahroud

Province

Semnan

Postal code

6314773955

Phone

+98 23 3239 5054

Email

h_ebrahimi43@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Ebrahimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery
Street address
Hafte-Tir Square
City
Shahroud
Province
Semnan
Postal code
3617753917
Phone
+98 232332395054
Email
h_ebrahimi43@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hossein Ebrahimi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hafte-Tir Square
City
Shahroud
Province
Semnan
Postal code
36147753917
Phone
+98 23 3239 5054
Email
h_ebrahimi43@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available