

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

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Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Haft-e-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

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28th meter of Touhidi, Imam Khomeini Street

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

Shahroud University of Medical Sciences

Full name of responsible person

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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

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

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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