

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

Protocol summary

Study aim

Determining the Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

Design

Clinical trial with control group with parallel groups, without blindness, randomized

Settings and conduct

In this study, 120 patients with acute coronary syndrome admitted to the coronary Care Unit of Imam Hossein Hospital in Shahroud will be selected based on the criteria of the researcher and will be randomized in the intervention and control group. Nursing counseling will be conducted for the intervention group.

Participants/Inclusion and exclusion criteria

Entry criteria: The patient's presence on the third day in the hospital (the day the consultation process starts in the hospital), Earn less than 32 scores from Sullivan self-efficacy questionnaire (Self-efficacy Scherer), Patients with acute coronary syndrome (unstable angina, myocardial infarction) 35-70 years old, Ability to speak and understand Persian language Exit criteria: Unwillingness to continue cooperation in the study, Creating complications such as: cardiopulmonary arrest, resistant ventricular arrhythmia, cardiogenic shock following illness, death

Intervention groups

In the first stage, the patient will be trained face to face bout: the definition of acute coronary syndrome, the risk factors and symptoms of heart disease, the effect of disease on work and life and sexual relations and social activities, diet and drugs, and complications of non-compliance, in 20 minutes. In the next step, one week after the intervention, a telephone consultation will take place for 10 minutes and will be questioned about the treatment and use of medications, diet and self-care. In the final stage, three weeks after the first training, a 10-minute telephone consultation will be carried out on follow-up care at home and adherence to the medication.

Main outcome variables

Self-efficacy of patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100114003064N9**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

bagheri@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

empty

Scientific title

Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

Public title

Nursing counseling and self-efficacy of patients with acute coronary syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's presence on the third day in the hospital (the day the consultation process starts in the hospital)
 Earn less than 32 scores from Sullivan self-efficacy questionnaire (Self-efficacy Scherer) Patients with acute coronary syndrome (unstable angina, myocardial infarction) 35-70 years old Ability to speak and understand Persian language

Exclusion criteria:

Unwillingness to continue cooperation in the study
 Creating complications such as: cardiopulmonary arrest, resistant ventricular arrhythmia, cardiogenic shock following illness, death

AgeFrom **35 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be divided into two groups by block of 4: A (nursing counseling) and B (control group). The allocation will be done concealment. In this way, there will be 70 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)

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 Shahroud University of Medical Sciences

Street address

Haft-Tir square

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2018-05-30, 1397/03/09

Ethics committee reference number

ir.shmu.rec.1396.202

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**

Self-efficacy score in Sullivan self-efficacy questionnaire in people with scores of less than 32

Timepoint

Self-efficacy measurement as soon as the patient's condition improves before the intervention begins and one month after the intervention

Method of measurement

Sullivan self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the first stage, the patient will be trained face to face bout: the definition of acute coronary syndrome, the risk factors and symptoms of heart disease, the effect of disease on work and life and sexual relations and social activities, diet and drugs, and complications of non-compliance, in 20 minutes. In the next step, one week after the intervention, a telephone consultation will take place for 10 minutes and will be questioned about the treatment and use of medications,

diet and self-care. In the final stage, three weeks after the first training, a 10-minute telephone consultation will be carried out on follow-up care at home and adherence to the medication.

Category

Prevention

2**Description**

Control group: The control group will not receive intervention and will only receive routine care and care at the hospital and discharge time.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital

Full name of responsible person

Dr. Hoseein Bagheri

Street address

28-meter Touhidi, Imam Khomeini Street

City

Shahroud

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Phone

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bagheri@shmu.ac.ir

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

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Web page address

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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 Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Dr. Hossein Bagheri
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hafte-Tir Square
City

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