

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of nursing counseling on anxiety of patient with acute coronary syndrome

Protocol summary

Study aim

Determining the effect of nursing counseling on anxiety of patients with acute coronary syndrome

Design

Randomized controlled trial with a parallel group design of 70 patients

Settings and conduct

In this study, 70 patients with acute coronary syndrome admitted to the coronary Care Unit of Imam Hossein Hospital in Shahroud will be selected based on entry criteria and will be randomized in the intervention and control group. Nursing counseling will be conducted for the intervention group. Before and one month after intervention, the Spielberger Anxiety Questionnaire will be completed for patients in both the intervention and control groups. In present study, because patients are trained, there is no possibility of blinding participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with acute coronary syndrome having anxiety scores less than 32 with Spielberger questionnaire, Age range between 35-70 years.

Exclusion criteria: Patients with history of approved anxiety disorders

Intervention groups

Intervention group: Intervention group will receive an educational intervention in 3 phases. First phase of intervention will be conducted in the hospital, the second and third phase of intervention will conduct 1 and 3 weeks after first intervention. In every intervention phases a telephone based consultation will take place for 10 minutes and will be questioned about the treatment and use of medications, diet and self-care. Control group: Control group will receive routine nursing cares.

Main outcome variables

Patient anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100114003064N12**

Registration date: **2018-10-04, 1397/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-04, 1397/07/12**

Update count: **0**

Registration date

2018-10-04, 1397/07/12

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 anxiety of patient with acute coronary syndrome

Public title

Nursing counseling and anxiety of patient with acute coronary syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with acute coronary syndrome (unstable angina, myocardial infarction) Earn less than 32 scores from the Spielberger trait anxiety questionnaire 35-70 years old

Exclusion criteria:

Having a history of approved anxiety disorders

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected based on inclusion criteria and will be randomly assigned into two groups: A (nursing counseling) and B (control group). As patients gradually enter the study, and also because the number of allocators is equal to each group, a block of 4 will be used by SPSS software to create a random allocation sequence. The random allocation sequence will be concealed. 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 target 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

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2018-05-31, 1397/03/10

Ethics committee reference number

IR.SHMU.REC.1397.026

Health conditions studied**1****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**

Anxiety score in Spielberger questionnaire

Timepoint

Anxiety measurement as soon as the patient's condition improves before the intervention and one month after the intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

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

Intervention group: Intervention group will receive an educational intervention on 3 phases according to anxiety level. In the first stage, the patient will be trained according to Anxiety level in the hospital. In the next steps, 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 third phase, 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. The control group will receive routine care without any telephone consultations.

Category

Prevention

2**Description**

Control group: 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. Hossein Bagheri

Street address

28-meter 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

Dr. Mohammad-Hassan Emamian

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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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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

No decision has been taken at this time. 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