

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of educational-counseling program based smoking cessation on success and self - efficacy of smoking cessation in acute coronary syndrome patients

Protocol summary

Summary

Effect of educational-counseling program based smoking cessation on success and self -efficacy of smoking cessation in acute coronary syndrome patients. Objective: Determination the effect of educational-counseling program based smoking cessation on success and self -efficacy of smoking cessation in acute coronary syndrome patients. Design: This is a pretest-posttest randomized one blind clinical trial study with two groups. The non-probabilistic sampling method and available for inpatients with diagnosis of acute coronary syndrome in Ghaem and Imam Reza hospitals, Mashhad. All of patients have the inclusion criteria. Patients allocated to intervention and control groups. This means that considered for every week of the first block (a block-week intervention and a control block week). First hospital and the intervention and control blocks has been selected with drawing. Sample size calculated 52 patients based on pilot study. Setting and conduct: In the intervention group, educational-consultation program and advice to quit smoking given in the control group .Inclusion criteria consist of definitive diagnosis of ACS (acute coronary syndrome) by a specialist, would like to participate in the study, have history of smoking at least six months before admission, having at least read and write ability,lack of mental disorders,lack of drug addictions,having conversations Call. Exclusion criteria consist of Unwillingness to continue to participate in educational- counseling sessions. Intervention: Two educational-counselling quit smoking sessions has been run each group (3 patients in group) for 45-60 minutes. Main outcome measures: Effect of educational-counseling program based smoking cessation on success and self - efficacy of smoking cessation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015033021566N1**

Registration date: **2016-02-27, 1394/12/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-27, 1394/12/08

Registrant information

Name

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Name of organization / entity

Mashhad Univrsity of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational-counseling program based smoking cessation on success and self - efficacy of smoking cessation in acute coronary syndrome patients

Public title

counseling of smoking cessation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. The definitive diagnosis of ACS (acute coronary syndrome) is by a specialist. 2. is willing to participate in the study. 3. have a history of smoking at least six months before admission. 4. have at least read and write. 5. be able to communicate and is fluent in Farsi. 6. mental disorder is not known because it requires the active cooperation of group counseling individuals. 7. Drug addiction is not. 8. make phone calls possible. Exclusion criteria: lack of desire to continue to cooperate and participate in training sessions - consulting group

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

cross way of doctors-Ebn Sina street-university of nursing and midwife

City

mashhad

Postal code**Approval date**

2014-11-02, 1393/08/11

Ethics committee reference number

research/930440/1/213

Health conditions studied**1****Description of health condition studied**

cardiac disease

ICD-10 code

I51.9

ICD-10 code description

I51.9

Primary outcomes**1****Description**

success of smoking cessation

Timepoint

before intervention to 3 months after intervention

Method of measurement

success of smoking cessation questionnaire

2**Description**

self-efficacy of smoking cessation

Timepoint

before intervention to 3 months after intervention

Method of measurement

smoking abstinence self-efficacy questionnaire(SASEQ)

Secondary outcomes**1****Description**

Nicotine dependence

Timepoint

Every two weeks to 3 months2 weeks

Method of measurement

Fagerstrum questionnaire

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

Intervention group: Intervention consist of 2 educational - counseling quit smoking sessions for 60-45 minute. First session: This session has been held at the heart department of both the hospital. The researchers introduced themselves to patients and the individual members introduced themselves. As well as the expectations of their meetings and the meetings of the

researcher explained. The meeting is preparedness and intervention. The purpose of the meeting or the incentive to quit smoking. In this session researcher provides the necessary training about the dangers of smoking, the effects of smoking on the cardiovascular system, the importance of quitting smoking, the consequences and the effects of continued smoking. Researcher used video and slides, lecture, question and answer. Then, to start the procedure, researcher asked the question from members and asked them to think the problems encountered in quitting smoking. Researcher wrote Difficulties in quitting smoking expressed by members on the board and discussed about them. The task of the researcher, guide and encourage people to participate in the group and is accelerating. In addition, researchers using listening skills, empathy, understanding feelings, companionship, attention and other techniques aimed at establishing a therapeutic relationship with patients. At this meeting, the researcher tries to enable patients to know problems and share them with each other and their counterparts are the problems and experiences .After the meeting thinking about your problems and ask them at the next meeting. Second meeting: In this session researcher asked all members to identify problems related to smoking cessation based on their stated priorities. Based on the member’s consensus discussed about the most common problems. Researcher used of counseling techniques such as Socratic dialogue and insight at this stage and prior stage depending on the situation. At the end of the meeting, the overall conclusion of the solutions provided by the participants and to answer possible questions and ambiguities phone number will be placed at the disposal of clients. The maintenance phase is the phase of the three-month follow-up done. In the meantime, follow through 6 calls for up to 3 months in a row is done every two weeks. Phone calls made by a colleague. Self-efficacy and successfully questionnaire completed during a call. So the information gathered, classified and then will be compared and analyzed. Control group: In the control group were given routine care, including advice to quit smoking.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Mozhgan GHeyasi

Street address

Ebn-E-Sina street-Emam-Rza squer-Emam-Rza Hospital

City

Mashhad

2

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

GHasem Rahmanian

Street address

SHariati square- Ahmad abad street-Qaem hospital

City

mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

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Daneshgah street- Building Qureshi-Vice Chancellor for research of Mashhad University of Medical Sciences

City

mashhad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Zeinab Kazemzadeh

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Master of science of nursing education-medical-surgical

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty