

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of telephone based smoking cessation program and hospital smoking cessation program in smoking cessation in patients with coronary artery disease

Protocol summary

Study aim

evaluation of the efficacy of telephone based smoking cessation program in patients with coronary artery disease.

Design

This study will be conducted as a clinical trial study. Two hundred smokers with coronary artery disease admitted to Tehran Heart Center Hospital will be included in the study. Patients will be divided into intervention and control groups.

Settings and conduct

This study will be conducted as a randomized clinical trial. 200 smokers with coronary artery disease in Tehran Heart Center Hospital will be included in the study. Information about demographic variables and variables related to smoking cessation will be collected by questionnaire. Patients will be randomly divided into intervention and control groups. The intervention group will have a smoking cessation training session with telephone counseling. After 6 months of discharge, smoking cessation will be recorded.

Participants/Inclusion and exclusion criteria

Smokers with coronary artery disease who are admitted to Tehran Heart Center Hospital

Intervention groups

In the control group short-term hospital smoking cessation consisting of a one-hour training session on prevention of cardiac disease risk factors conducted in a group by a nurse and recommendation to use Nicotine Replacement Therapy (NRT). In the intervention group, in addition to all the measures performed in the control group, a long-term smoking cessation training program will be implemented which includes the following sections: After discharge, patients will receive five 10-minute telephone consultations (2 days, 1 week, 3 weeks, 3 months, and 5 months after discharge), which will be conducted by a trained nurse.

Main outcome variables

Number of cigarettes consumed per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190119042417N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Alireza Shamsi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2303 1357

Email address

ar.shamsi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of telephone based smoking cessation program and hospital smoking cessation program in smoking cessation in patients with coronary artery disease

Public title
The effect of telephone based smoking cessation program in patients with coronary artery disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Consume at least five cigarettes daily for at least one month before admission Suffering from coronary artery disease Attempted to quit smoking following coronary artery disease Patient consent for inclusion in the study
Exclusion criteria:
 Language problems that the patient is unable to complete the questionnaire Unstable clinical condition Patients with dementia (according to history) Patients with delirium (lack of awareness to time, place, or person at interview time) patient that cannot be reached by telephone for follow up

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals with inclusion criteria will be randomly assigned to one of two study groups after obtaining informed consent. Permuted Block Stratified Randomization with 2, 4, 6, and 8 random blocks with software of the same name (Block Stratified Randomization) will be used to generate the random list. To avoid selection bias, and to comply with allocation concealment the random list will be provided to the individual outside the sampling process.

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 Shahid Beheshti University of medical sciences

Street address

Shahid Beheshti university of medical sciences, Aarabi Ave, Yaman Ave, Chamran St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.SBMU.MSP.REC.1398. 673

Health conditions studied

1

Description of health condition studied

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

smoking cessation

Timepoint

at baseline and after 6 months

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

One hour training course on heart disease risk factors and the long-term smoking cessation training program will be implemented by telephone counseling, which includes the following sections: An interview session including diagnostic interview and motivational interview will be conducted by a psychiatric resident. In this interview, the patient's attitude toward smoking, the consequences of smoking in cardiac patients and the benefits of quitting smoking will be assessed. The

motivation to quit smoking will be assessed. Benefits of smoking cessation (In particular: five-year mortality reduction to half, reduction in surgical wound healing time, and reduction in pulmonary complications) And the risks of continued smoking (in particular: the increased likelihood of re-operation due to vessel congestion, the prolongation of hospital stay) will be explained to the patient. Afterwards the stages of smoking cessation and how to evaluate the patient after discharge will be explained. Patients will receive five 10-minute telephone consultations (2 days, 1 week, 3 weeks, 3 months and 5 months after discharge), which will be conducted by a trained nurse. In these consultations, the patient will be asked about whether or not to stop smoking. If the patient continues to smoke, the patient will be warned about the risk of heart disease and the dangers of continuing to smoke, and positive consequences of smoking cessation will be reminded if patient stops smoking.

Category

Treatment - Other

2

Description

Control group: One-hour training class on heart disease risk factors routinely taught to all hospitalized patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Majid Sadeghian

Street address

North kargar St, Tehran Heart Center Hospital

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<http://thc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Aarabi Ave, Yaman Ave, Chamran St, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Sadeghian

Position

psychiatry resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Shamsi
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

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Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The study protocol, informed consent form, participant data file, and study report will be shared.

When the data will become available and for how long

12 to 24 months after publication of study results.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in review studies and meta-analyses

From where data/document is obtainable

Majid sadeghian Tel: +989126008662
Email: sadeghian_5@yahoo.com

What processes are involved for a request to access data/document

The person in charge will respond to the request after receiving the email and review it within a maximum of one month.

Comments