

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Design, implementation, and evaluation of mobile application based on integrated behavior change model for primary prevention of atherosclerotic coronary artery disease risk factors.

Protocol summary

Study aim

Design, production and effectiveness of educational-supportive mobile application for atherosclerotic disease risk factors primary prevention based on integrated behavior change model

Design

Clinical trial for control group with parallel and single-blind groups, Randomized using random blocks method, Third phase on 430 people, website <https://www.sealedenvelope.com> was used for randomization

Settings and conduct

Residents of 10 health centers of Tehran are selected by cluster sampling method and with a risk score 2.5-15% are referred to Tehran Heart Center Hospital by cardiologist then groups, content and application are determined using quadrupled random blocks and systematic educational design. Application on people's mobile is installed. Reminder SMS and 3 consultation calls will be done after one month and during 6 months sequentially. At the beginning and 6 months later, in both groups, researcher-made questionnaire is completed based on integrated behavior change model and cardiac risk factors structures. One-sided blinding is done for data analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: to have two or more risk factors, A risk score of 2.5-15% of cardiovascular disease risk assessment, Age 18 to 75. Exclusion criteria: Presence of cardiovascular diseases, Other chronic diseases and mental diseases and physical disabilities

Intervention groups

Intervention group will receive an educational-supportive package as mobile application, SMS reminder and counseling calls as three calls during 6 months for CVD risk factors control besides routine care based behavior model and control group will receive routine care at first

and 6 months after intervention

Main outcome variables

Awareness, motive and behavior, Mobile application using satisfaction, BMI, Adherence to a healthy diet, Physical activity, Blood pressure, Blood sugar, Triglyceride, Total cholesterol, LDL, HDL, Stress control, Smoking.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200321046826N1**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

afsaneh aein

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Design, implementation, and evaluation of mobile application based on integrated behavior change model for primary prevention of atherosclerotic coronary artery disease risk factors.

Public title
Evaluation of the effectiveness of education with a mobile application on the prevention of atherosclerotic coronary artery diseases risk factors

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Have two or more risk factors for coronary artery atherosclerosis include an unhealthy diet, physical inactivity, high blood pressure, high blood fats, high blood sugar, obesity, smoking. Obtain a risk score of 2.5-15% based on cardiovascular disease risk assessment. 75 - 18 years old Have a desire to participate in the study Have a smartphone or tablet Have the ability to work with mobile applications Intention to stay at the place of study for the next one year
Exclusion criteria:
 History of cardiovascular diseases Physical disability Existence of other chronic diseases Mental Disease

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **430**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization method will be used in this study to randomize the samples. Blocking is used to balance the number of samples assigned to each of the study groups. This feature helps researchers in cases where the need for intermediate analysis during the sampling process in this method, the number of people assigned to each group is almost equal. In this method, blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as controls. The main goal of this method is to balance the number of participants in each group. The size of all blocks is equal and we will have

108 blocks of 4 in this two-group experiment (including 2 participants in the intervention group and 2 participants in the control group). Random allocation sequence and list of blocks will be obtained by the statistical consultant with the help of software. The website <https://www.sealedenvelope.com> is a useful site for generating random sequences for block randomization. This site is designed in such a way that there is no limit to the number of groups for random allocation. The 4-volume block method is used to create a random allocation sequence. According to the total number of samples required for the study, which is 430 patients (215 patients in the intervention group (A) and 215 patients in the control group (B), 108 quadruple blocks including two groups A and B were randomly selected through design software. It can be like (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Based on the sample size, 430 envelopes (215 envelopes containing paper containing A) and (215 envelopes containing paper Contains B) Based on the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for randomly assigning participants, after each participant enters, according to the 108 quadruple blocks prepared in the first stage. Each patient will be randomly assigned to group A (intervention) or B (control group) and the sampling process will be performed consecutively until the end of sampling. For example, according to the block (ABAB), after obtaining the informed consent of each person after entering the study, he/she enters the intervention, control, intervention, and control groups, respectively. The rain block will continue. Then, to hide the random allocation, non-transparent envelopes with random sequences (Sequentially numbered, sealed opaque envelopes) will be used. It will be written and placed in envelopes in order. The production of the allocation sequence and the preparation of the envelopes based on it will be done by a person not involved in the research. It is noteworthy that in the process of performing random allocation, the specialist has created a random sequence statistic, the cardiologist will examine the participants in terms of inclusion and exclusion criteria and will include them in the study and the researcher allocate participants' intervention and control group. Then, in order to hide the random allocation, non-transparent envelopes with random sequence (Sequentially numbered, sealed opaque envelopes) will be used. It will be written and placed in envelopes in order. The production of the allocation sequence and the preparation of the envelopes based on it will be done by a person not involved in the research. It is noteworthy that in the process of performing random allocation, the specialist has created a random sequence statistic, the cardiologist will examine the participants in terms of inclusion and exclusion criteria and will include them in the study and the researcher will send the participants to the group. Will allocate intervention and control measures.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind controlled trial that includes

the control group (not receiving the intervention) and the first intervention group (receiving training with mobile software). In this way, the outcome can be measured objectively. Due to the nature of the study and the fact that the researcher performs the educational intervention and also the participants are aware of the type of training they receive (routine clinic training or mobile training program) it is not possible to blind the participants and the researcher. In this intervention, to prevent possible bias in the results of the study, all samples will be screened by a cardiologist who is not aware of how the samples are placed in the intervention and control groups. The score-2 will be determined at the beginning of the study and individuals with a risk score of 2.5 to 15% will be included in the study. Also, in this study, the data analyzer is blinded and will not be aware of how individuals are assigned to groups and the method used for training. Then, to hide the random allocation, non-transparent envelopes with random sequences (Sequentially numbered, sealed opaque envelopes) will be used. It will be written and placed in envelopes in order. The production of the allocation sequence and the preparation of the envelopes based on it will be done by a person not involved in the research. It is noteworthy that in the process of performing random allocation, the specialist has created a random sequence statistic, the cardiologist will examine the participants in terms of inclusion and exclusion criteria and will include them in the study and the researcher allocate participants' intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics System in Biological Research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran. Website Statistics

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Tehran

Province

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Postal code

۱۳۹۶۱۴۵۳۵

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.932

Health conditions studied

1

Description of health condition studied

Atherosclerotic coronary artery disease

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease

Primary outcomes

1

Description

Knowledge score about risk factors for coronary artery atherosclerotic disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made questionnaire on knowledge of risk factors for atherosclerotic coronary heart disease

2

Description

Risk perception score on risk factors for atherosclerotic coronary heart disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made risk perception questionnaire about risk factors for atherosclerotic coronary heart disease

3

Description

Attitude score on risk factors for atherosclerotic coronary artery disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made attitude questionnaire about risk factors for atherosclerotic coronary heart disease

4

Description

Perceived self-efficacy score on risk factors for atherosclerotic coronary heart disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made perceived self-efficacy questionnaire on risk factors for coronary atherosclerotic disease

5

Description

Perceived social support score on risk factors for coronary artery atherosclerotic disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made social support questionnaire on the risk factors for coronary atherosclerotic disease

6

Description

Score of preventive behavior on risk factors for atherosclerotic coronary artery disease

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Researcher-made preventive behavior questionnaire on risk factors for atherosclerotic coronary heart disease

7

Description

Satisfaction with the use of mobile application

Timepoint

Six months after the intervention

Method of measurement

User Experience Questionnaire(UEQ) - Persian Version

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Mercury sphygmomanometers

2

Description

Triglyceride

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Spectrophotometry

3

Description

Low density lipoprotein (LDL)

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Spectrophotometry

4

Description

High Density Lipoprotein (HDL)

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Spectrophotometry

5

Description

Cholesterol

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Spectrophotometry

6

Description

Fasting blood sugar

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Spectrophotometry

7

Description

Body Mass Index (BMI)

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Calibrated weights, meters to measure height

8

Description

Weight

Timepoint

Before the intervention and six months after the intervention

Method of measurement

Digital scales

9

Description

healthy eating habits

Timepoint

Before the intervention and six months after the intervention

Method of measurement

National Survey Questionnaire on non-communicable diseases risk factors-WHO STEPS Instrument

10

Description

physical activity

Timepoint

Before the intervention and six months after the intervention

Method of measurement

International Physical Activity Questionnaire - Short Form (IPAQ)

11

Description

smoking

Timepoint

Before the intervention and six months after the intervention

Method of measurement

National Survey Questionnaire on non-communicable diseases risk factors-WHO STEPS Instrument

12

Description

Mental health

Timepoint

Before the intervention and six months after the intervention

Method of measurement

European Society of Cardiology (ESC) psychosocial screening instrument

Intervention groups

1

Description

Intervention group: The intervention includes three phases: pre-test, content education, and post-test. Pre-tests in both intervention and control groups are sent to their mobile phones as an online questionnaire. During a meeting, the members of the intervention group are introduced to the objectives of the study, and the expectations of the study team are raised from them. The application is installed on their mobile phones and how to work with it will be explained in the first face-to-face visit to Tehran Heart Center Hospital. The educational content in the intervention group will be activated immediately after completing the pre-test form. For 6 months at any time and place have access to educational content based on the needs assessment and recommendations of classes AI, IIA, IB guidelines of primary prevention of heart disease. From the first month, weekly behavioral reminder messages will be sent. One month later, 3 months later, and 5 months later, telephone counseling and follow-up will be provided. At the end of 6 months, access to educational content will be automatically disabled. And the link to receive the post-test by the researcher is sent immediately, 6 months after the educational intervention to both intervention and control groups.

Category

Prevention

2

Description

Control group: will receive the usual treatment. Common office treatments include clinical and laboratory evaluation, answering the patient's questions, prescribing the previous drug or changing the medication, and explaining how to use it according to the patient's condition and the specialist physician and education in the office.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Dr.Ali Vasheghani Farahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Primary Prevention of Cardiovascular Diseases Research Center, Tehran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Aein

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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