

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Designing, implementation and evaluation of an educational intervention based on Health Belief Model on behaviors and risk factors affecting cardiovascular diseases in people over 30 years old with a ten-year risk score of 10-30% of cardiovascular diseases

Protocol summary

Study aim

Determining the effect of intervention based on health belief model on behaviors, risk factors and ten-year risk score related to cardiovascular diseases

Design

The clinical trial includes two intervention and control groups, with parallel groups, one blind, randomized on 120 patients. Simple randomization method of lottery type is used.

Settings and conduct

Before and after the intervention, the ten-year risk of cardiovascular disease in people is determined, and demographic questionnaires and constructs of health belief patterns and preventive behaviors are also completed. The place of the intervention is Dorcheh City Health Center and the trainings are face-to-face and group. The study is blinded and the target group does not know whether they are assigned to the control or intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 30 years old, no history of smoking, annual risk score of 10-30%, covered by Dorcheh health centers, completing the consent form, not participating in related trainings in the past.
Exclusion criteria: not completing the questionnaire, not participating in the training sessions and not responding to the researcher's call

Intervention groups

The educational program includes 10 sessions with educational content based on the source of the Ministry of Health (IRAPEN). The educational content is adjusted according to the constructs of the health belief model based on the preventive behaviors of diet, medication and physical activity and the results of the pre-test. The trainings are done in groups using a combination of lecture, question and answer, brainstorming and

discussion. The control group also receives the usual care of health centers.

Main outcome variables

Outcomes include improvement of dietary, medication and physical activity behaviors and reduction of risk factors and ten-year risk score of cardiovascular diseases.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047870N2**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Elham Ebrahimi dorcheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3375 5127

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2025-03-05, 1403/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementation and evaluation of an educational intervention based on Health Belief Model on behaviors and risk factors affecting cardiovascular diseases in people over 30 years old with a ten-year risk score of 10-30% of cardiovascular diseases

Public title

Investigating the effect of educational intervention on behaviors and risk factors affecting cardiovascular diseases

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

People over 30 years old
People with no history of smoking and alcohol consumption
People with a ten-year risk score of 10-30% of cardiovascular diseases

Exclusion criteria:

People who are very old and it is difficult to get information from them
People who have previously participated in training courses related to the present intervention

AgeFrom **30 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

120 people who are eligible and available to enter the study covered by Dorcheh 1 and Dorcheh 2 health centers (60 people from each center) by simple random sampling method of lottery type by taking names from the box as the target group of the study are selected and according to the homogeneity of the demographics and regional information of Dorcheh 1 and Dorcheh 2 health centers, using a simple random sampling method of lottery type by taking the names of the centers from inside the sealed envelope, 60 people from one center will be assigned to the intervention group and 60 people from the other center will be assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participants, who are the target group of the study, will not know whether they are assigned to the intervention or control group until after receiving secondary information from the individuals and completing the study. The information of each member of the intervention and control group will be kept confidential with the researcher.

Placebo

Not used

Assignment

Parallel

Other design features

The educational intervention of the present study is based on the health belief model in order to change behaviors and risk factors affecting cardiovascular diseases. And the main goal of the current intervention is to change the ten-year risk of cardiovascular diseases in high-risk people.

Secondary Ids

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib St., Esfahan

City

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Province

Isfahan

Postal code

81746-73461

Approval date

2023-12-16, 1402/09/25

Ethics committee reference number

IR.MUI.DHMT.REC.1402.046

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

The patients examined in this study include people with a ten-year risk score of 10-30% of cardiovascular diseases. The risk factors that are measured to determine the ten-year risk of cardiovascular diseases include body mass index, waist circumference, blood pressure, fasting blood sugar, and blood fat (total cholesterol).

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Diet, medication and physical activity behaviors

Timepoint

Diet, medication and physical activity behaviors are determined before the intervention and two and six months after the intervention.

Method of measurement

The scores of diet, medication and physical activity behaviors are determined using a questionnaire.

Secondary outcomes

1

Description

Ten-year risk score of cardiovascular diseases

Timepoint

The ten-year risk score of cardiovascular diseases is measured before the intervention and six months after the intervention.

Method of measurement

The ten-year risk score of cardiovascular diseases is determined based on the risk factors of body mass index, waist circumference, blood pressure, fasting blood sugar, blood fat (total cholesterol). These items are measured using a scale, tape measure, manometer, and blood test, respectively. After entering the information of the risk factors of people in the Sib electronic system, the system determines the ten-year risk score of cardiovascular diseases for each person.

Intervention groups

1

Description

Intervention group: The training program includes 10 sessions and each session lasts 90 minutes for the intervention group. The educational content is presented based on an authentic source from the Ministry of Health under the title of the collection of basic interventions of non-communicable diseases in the primary health care system of Iran and under the title of Irapen book. The content of this book is mainly related to the risk factors of cardiovascular diseases and the necessary training regarding the preventive behaviors of these diseases, including physical activity, diet and medication. In fact, the educational content of the study is determined and adjusted according to the structures of the health belief model based on the mentioned preventive behaviors as well as the results of the pre-test. Trainings are conducted in groups using a combination of lecture, question and answer, brainstorming and group discussion methods in each training session. During the educational classes, media such as pamphlets

(distributed among all those present in the class for studying at home), books, posters, videos and educational photos are used to increase learning.

Category

Behavior

2

Description

Control group: The control group will receive only the routine care of health centers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dorcheh Comprehensive Health Center

Full name of responsible person

Elham ebrahimi dorcheh

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Basij St., Dorcheh city, Esfahan city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

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Research and Technology Department, Building number 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib St., Esfahan

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research@mui.ac.ir

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham ebrahimi dorcheh

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

Start access after printing the results

To whom data/document is available

All people working in academic, scientific and industrial sectors are able to receive data

Under which criteria data/document could be used

1- Using information to conduct scientific and research studies 2- Not changing information and observing ethical standards

From where data/document is obtainable

1- Conductors and authors of the research plan 2- Research assistant of the university and the relevant

educational institution (Esfahan University of Medical Sciences). Communication channels of the research plan administrators: 1- Mrs. Elham Ebrahimi, Address: Alley 98, Nabavi Manesh St, Atashgah Street, Esfahan, Contact number: 09133764592, Email address: elhamebrahimi1344@gmail.com. 2- Dear Dr. Hossein Shahnazi, Address: Department of Health Education, Faculty of Health, Esfahan University of Medical Sciences, Hazar Jarib Street, Esfahan, contact number: 09133360148, email address: h_shahnazi@yahoo.com.

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

After contacting the project managers and checking the applicant's scientific and moral qualifications, the information will be provided to the person in the shortest possible time.

Comments