

# 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

##### Email address

elhamebrahimi1344@gmail.com

##### 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

**Age**From **30 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target 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**

Esfahan

**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

##### Street address

Basij St., Dorcheh city, Esfahan city

##### City

Esfahan

##### Province

Isfahan

##### Postal code

84316-36631

##### Phone

+98 31 3376 8797

##### Email

elhamebrahimi1344@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Gholamreza Asgari

##### Street address

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

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 8138

##### Fax

+98 31 3668 7898

##### Email

research@mui.ac.ir

##### Web page address

<https://research.mui.ac.ir/fa>

**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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**Person responsible for scientific inquiries**

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**Full name of responsible person**

Elham ebrahimi dorcheh

**Position**

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**Person responsible for updating data**

**Contact**

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**Full name of responsible person**

Elham ebrahimi dorcheh

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Health Promotion

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**Web page address**

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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**