

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of promoting healthy lifestyle program among individual at risk of cardiovascular diseases: An application of Health Behavior Model

#### Protocol summary

##### Summary

The main objectives of the project: Evaluation of the program designed with the health belief model on improving healthy lifestyle behaviors in people with suspected cardiovascular disease Objectives of the project: Determining and comparing the mean score of healthy lifestyle behaviors in the intervention and control group before and after the intervention, determining and comparing the mean of BMI in the intervention and control groups before and after the intervention, and determining and comparing the mean of activity time Physical characteristics of the intervention and control group before and after the intervention, determining and comparing the mean of blood pressure in the intervention and control groups before and after the intervention, determining and comparing the mean of blood glucose in the intervention and control groups before and after the intervention, determining and comparing the mean Tobacco use in intervention and test groups before and after intervention Design: The design of the study will be based on the health belief model. Implementation: Group intervention in five groups for five weeks continuously Entry requirements: Minimum reading and writing skills, non-severe depression, mental and physical disability. Conditions of Exit: Dissatisfaction with the continuation of the study by the person himself. Interventions: Including training on blood pressure, blood glucose and health promotion behaviors in the intervention group based on the results of the measurement of health belief model structures. Also, in order to enhance training and as a reminder dose, messages will be sent using mass communication applications. Ethical considerations: Provide the right information to the participants in the study on the goals, how to conduct the study, and the informed consent to participate in the study, the confidentiality of the information of the participants in all phases of the study, observance of the principle of usefulness, equity and independence in the participants in the study , Receiving

the approval of the University's Ethics Committee and receiving the Ethics Code, providing the intervention to the control group after the completion of the measurements related to the research (if the intervention was effective).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017101625431N3**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-08, 1396/08/17

##### Registrant information

##### Name

Elham Shakibazadeh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4293 3210

##### Email address

shakib@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research of School of Public Health, Tehran University of Medical Sciences

##### Expected recruitment start date

2017-11-21, 1396/08/30

##### Expected recruitment end date

2017-12-11, 1396/09/20  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**

Evaluation of promoting healthy lifestyle program among individual at risk of cardiovascular diseases: An application of Health Behavior Model

**Public title**

Evaluation of promoting healthy lifestyle program among individual at risk of cardiovascular diseases: An application of Health Behavior Model

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Major entry requirements: At least reading and writing literacy; Lack of severe depression; Mental and physical disability Major exclusion criteria: lack of consent to continue study by the person himself

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **170**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**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, School of Public Health, Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Enqelab St, Tehran, Iran

**City**

Tehran  
**Postal code**  
**Approval date**  
2017-10-07, 1396/07/15  
**Ethics committee reference number**  
IR.TUMS.SPH.REC.1396.3636

**Health conditions studied**

**1**

**Description of health condition studied**

Cardiovascular disease

**ICD-10 code**

I51.6

**ICD-10 code description**

Cardiovascular disease, unspecified

**Primary outcomes**

**1**

**Description**

Age

**Timepoint**

Before intervention

**Method of measurement**

Questionnaire

**2**

**Description**

Ex

**Timepoint**

Before intervention

**Method of measurement**

Questionnaire

**3**

**Description**

Education

**Timepoint**

Before intervention

**Method of measurement**

Questionnaire

**4**

**Description**

Income

**Timepoint**

Before intervention

**Method of measurement**

Questionnaire

**5**

**Description**

Marital status

**Timepoint**

Before intervention

**Method of measurement**

Questionnaire

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

Perceived sensitivity

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**2****Description**

Perceived severity

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**3****Description**

Perceived benefits

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**4****Description**

Perceived barriers

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**5****Description**

Guidance for practice

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**6****Description**

Self-sufficiency

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**7****Description**

Body mass index

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

BMI

**8****Description**

Smoking

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Questionnaire

**9****Description**

Blood pressure

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Blood Pressure Monitor

**10****Description**

Blood glucose

**Timepoint**

Before intervention, after intervention, three months after intervention

**Method of measurement**

Blood glucose meter

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

Intervention group: Group intervention in five groups for five weeks includes training on blood pressure, blood glucose and health promotion behaviors in the intervention group based on the results of measuring the health belief model.

**Category**

Lifestyle

**2****Description**

Control group: The control group did not intervene and only blood pressure and blood glucose were measured twice weekly.

**Category**

Lifestyle

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Health Center of Fatima

**Full name of responsible person**

Dr. Alireza Mohammadzade Fardfini

**Street address**

Plaque 131, Health Center of Fatima, Taslihat Square, Narmak, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, School of Public Health, Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraeiyan

**Street address**

Tehran University of Medical Sciences, Enqelab St, Tehran, Iran

**City**

Tehran

**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, School of Public Health, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Sohrab Babaei

**Position**

Student Master

**Other areas of specialty/work**

**Street address**

Tehran University of Medical Sciences, Enqelab St,

Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 7726 6553

**Fax**

**Email**

sbabaei@razi.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Eelham Shakibazadeh

**Position**

Phd

**Other areas of specialty/work**

**Street address**

Tehran University of Medical Sciences, Enqelab St, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21214293

**Fax**

**Email**

shakibazadeh@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sohrab Babaei

**Position**

Student Master

**Other areas of specialty/work**

**Street address**

Tehran University of Medical Sciences, Enqelab St, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 912 388 2387

**Fax**

**Email**

sbabaei@razi.tums.ac.ir

**Web page address**

## 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*