

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

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+98 21 4293 3210

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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

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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