

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Development and evaluation of educational intervention to promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease in secondary school students

Protocol summary

Summary

Almost all risk factors for cardiovascular heart disease shaped from childhood or adolescence period and or to be associated with this period. So any movement of preventive intervention should start in childhood or adolescence period. The purpose of this study is to development and evaluation of educational intervention to promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease in secondary school students. The study population is 13- 15 years old students in the seventh, eighth and ninth grade in the second school. This research is a semi- experimental study. Sample size is 330; 165 in intervention group and 165 in control group. Simple random sampling method will be used. The questionnaire included demographic characteristics and Social cognitive theory constructs and validity and reliability of the questionnaire will be achieved during the study. After pretest, subjects will be classified to two intervention and control groups. In the intervention group, educational interventions to improve lifestyle will be implemented. Finally data extracted from before, 3 and 6 months after intervention will be compared. Outcome of study is promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease in secondary school students.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112212460N9**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Roya Sadedgi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 327 5692

Email address

sadeghir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Educational vice chancellor of Tehran University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of educational intervention to promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease in secondary school students

Public title

Development and evaluation of educational intervention

to promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease in secondary school students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Lack of consent for participating in the study ;not having physical disability ;Students who are in the age group 13 to 15 years.Exclusion criteria:lack of desire to continue participate in the study ;Students at a management plan for each of nutritional behaviors, physical activity, smoking and other stress participated ; The dissatisfaction of the Parents of student.

Age

From **13 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **330**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

165 each group, 330 total

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Main building of Tehran University of Medical sciences

City

Tehran

Postal code

Approval date

2015-11-17, 1394/08/26

Ethics committee reference number

IR.TUMS.REC.1394.1184

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

429.2

ICD-10 code description

Cardiovascular disease, unspecified

Primary outcomes

1

Description

promote behaviors related to prevent behavioral risk factors for cardiovascular heart disease

Timepoint

Before , three and six months after the intervention

Method of measurement

Questionnaires related to nutritional behaviors, physical activity, smoking and stress management

Secondary outcomes

1

Description

social cognitive theory constructs

Timepoint

Before and six months after the intervention

Method of measurement

Questionnaire according to social cognitive theory constructs

Intervention groups

1

Description

In the intervention group, the following measures will be done:holding educational interventions in order to improve lifestyle. Type of intervention, intervention of the target groups, educational content, teaching methods, number and timing of training classes, will be determined according to the analysis of the results of the pretest .

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Girly and Boys Secondary Schools in Haji Abad City

Full name of responsible person

Street address

City

Haji Abad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Educational vice chancellor of Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Jalili

Street address

Main Building of Tehran University of Medical sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Educational vice chancellor of 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

Dr. Roya Sadeghi

Position

PhD of Health Education and Promotion/Academic staff

Other areas of specialty/work**Street address**

School of Public Health, Tehran University of Medical Sciences ,Poorsina Ave.

City

Tehran

Postal code

141556446

Phone

+98 21 4293 3210

Fax**Email**

sadeghir@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. Roya Sadeghi

Position

PhD of Health Education and Promotion/Academic staff

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Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

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Dr. Roya Sadeghi

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City

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Postal code

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Phone**Fax****Email****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

