

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effectiveness comparison of an interactive web-based intervention for lifestyle modification on metabolic syndrome

Protocol summary

Summary

This study is an interactive web-based randomized trial on 160 people with metabolic syndrome in Tehran. The aim of this parallel randomized controlled trial is comparison the effectiveness of an interactive web-based lifestyle intervention focusing on dietary and physical activity for reducing metabolic syndrome indicators. A website namely Healthy Heart Education (<http://www.Heartresearch.ir>) is designed in order to increase knowledge of visitors about cardiovascular diseases risk factors and attract the attention for metabolic syndrome. Participants enrolled to the study by registering on the website and completing information including: name, age, gender, weight, height, waist circumference, phone number, living home addresses. Participants who meet the study criteria contacted and invited for the study. Randomization carried out after baseline measurements. Participants randomly assigned to two arms. All participants received information on dietary intake and physical activity through the study website. The intervention group received additional resources via the study website including interactive Healthy Heart Profile and calorie restricted diet tailored to the participants. Participants in the intervention group receive username and password to use the Healthy Heart Profile program. The primary outcome is to detect differences in metabolic syndrome between the intervention and the control group. The secondary outcomes are comparing quality of life, physical activity and food intake among the study arms. The participants followed up for 6 months with data collection scheduled at baseline, 3 and 6 months. Anthropometric and clinical measures were (weight, waist circumference, BMI and blood pressure, Total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, Fasting blood glucose.

General information

Acronym

Red Ruby Study

IRCT registration information

IRCT registration number: **IRCT201111198132N1**
Registration date: **2013-05-27, 1392/03/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-27, 1392/03/06

Registrant information

Name

Leila Jahangiry

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 307 0128

Email address

jahangiry@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-09-10, 1391/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness comparison of an interactive web-

based intervention for lifestyle modification on metabolic syndrome

Public title

Interactive web-based intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Waist circumference, men and women equal or more than 90; Blood pressure equal or more than 130/85; Access to internet; having simple skills to work with the Internet; Informed consent Exclusion criteria: having history of cardiovascular diseases; diabetics; having cancer; patients with renal diseases; being peragnant; taking medication for high blood pressure; taking medication for dislipidemia.

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Tehran University Of Medical Sciences

Street address

Tehran university Of Medical sciences, Enqelab Avenue, Tehran

City

Tehran

Postal code

0098

Approval date

2011-11-16, 1390/08/25

Ethics committee reference number

15287

Health conditions studied

1

Description of health condition studied

Metabolic syndrome disorders

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

waist circumference

Timepoint

0, 3, 6 month

Method of measurement

cm

Secondary outcomes

1

Description

Nutrition and physical activity

Timepoint

3, 6 after baseline measurment

Method of measurement

questionnaire

Intervention groups

1

Description

Educational intervention be done through website on healthy nutrition and physical activity. intervention group can use of educational materials on the site and take self monitoring tools for cardiovascular risk assessment, time of the study take 6 month.

Category

Lifestyle

2

Description

Control receive educational materials by emails every 3 week.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart center, Tehran University of Medical

Sciences

Full name of responsible person

Dr.Mehdi Najafi

Street address

Tehran Heart Center,Nourth Kargar Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Esmaeil Shojae zade

Street address

Public Health Faculty, Tehran University of Medical Sciences, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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. Davoud Shojaezade

Position

PhD, Health education and Health Promotion

Other areas of specialty/work

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Person responsible for updating data

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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

