

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of an educational program on controlling the related risk factors of Metabolic Syndrome and oxidative Stress Markers: a clinical trial study

Protocol summary

Summary

This proposed clinical trial is aimed to evaluate whether nutritional interventions and physical activities enhance the life style and reduce the related risk factors to the Metabolic Syndrome (METS) and Oxidative Stress Markers. In this regard, 180 individuals with METS within the personnel of SHMU will be selected. To form the study group, our objectives will be discussed with the personnel; and then, the interested ones to participate will be required to give their consent and fill a form. The form is intended to collect specific data, including name, age, sex, weight, height, waist, medical history (i. e. Using antihypertensive and cholesterol lowering drugs, and history of diabetes), telephone number and work address. Then, the individuals with said disease will be selected by an initial evaluation. Using Simple Randomly method, the participants will be divided into two groups (i. e. control and intervention). All the participants will receive an educational brochure about the subjects of healthy diet, physical activity, and dietary antioxidants. The intervention group, in addition to this, will be asked to attend an educational class in which METS and its effects, and the ways of controlling it via following a healthy diet, increasing physical activities, and improving the life style will be discussed. Several tests, including HDL-C, LDL-C, Triglyceride, FBS, Total Antioxidant Capacity, Malondialdehyde, Catalase, Superoxide Dismutase Activity, CRP and Anthropometric Index (Weight, Waist, BMI, and BP) will be taken before and three months after starting the study.

General information

Acronym

Metabolic Syndrome

IRCT registration information

IRCT registration number: **IRCT2015041821813N1**

Registration date: **2015-06-08, 1394/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2015-06-08, 1394/03/18

Registrant information

Name
Maryam Abbasian
Name of organization / entity
Shahroud University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Shahroud University Of Medical Science

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational program on controlling the related risk factors of Metabolic Syndrome and oxidative

Stress Markers: a clinical trial study

Public title

The effect of educational program on controlling the related risk factors of Metabolic Syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The satisfaction from participation in the study, Metabolic syndrome was diagnosed using Adult Treatment Panel-III (ATP-III) guidelines when any three of the following were present: raised triglycerides \geq 150mg/dl, HDL-C $<$ 40mg/d in men and 50mg/dl in woman, blood pressure \geq 130 / 85 mm Hg, FBS \geq 100mg/dl. Abdominal obesity \geq 102 cm in men and \geq 88 cm in women). Exclusion criteria: Pregnancy and lactation

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University Of Medical Science

Street address

Shahroud- 7Tir SQ- Shahroud University Of Medical Science

City

Shahroud

Postal code

3624773955

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

940.02

Health conditions studied

1

Description of health condition studied

Patients with metabolic syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Zero -3 months after baseline measurements

Method of measurement

Enzymatic colorimetric method

2

Description

Oxidative Stress markers

Timepoint

Zero -3 months after baseline measurements

Method of measurement

Enzymatic colorimetric method

3

Description

HDL-C, Triglyceride

Timepoint

ero -3 months after baseline measurements

Method of measurement

Enzymatic colorimetric method

Secondary outcomes

1

Description

Waist

Timepoint

Zero -3 months after baseline measurements

Method of measurement

Centimeter

2

Description

Blood pressure

Timepoint

Zero -3 months after baseline measurements

Method of measurement

mmHg

Intervention groups

1

Description

The intervention group will participate in a 60 minute classes(three week: a session per week) learning how to approach with disease, its complications and ways to control disease especially dietary containing antioxidants, increases physical activity and improving the life style .The intervention period will take 3 months

Category

Lifestyle

2

Description

The control group will receive an educational brochure about how to approach with disease, its complications and ways to control disease especially dietary containing antioxidants, increases physical activity and improving the life style

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud University Of Medical Science

Full name of responsible person

Maryam Abbasian

Street address

Shahroud- 7Tir SQ- Shahroud University Of Medical Science

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Assistance Research Information Technology
Shahroud University Of Medical Science

Full name of responsible person

Mohammad Hassan Emamian

Street address

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Shahroud - 7Tir SQ Shahroud University Of Medical Science

Grant name

2

Grant code / Reference number

10506

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

Yes

Title of funding source

Assistance Research Information Technology Shahroud
University Of Medical Science

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

Shahroud University Of Medical Science

Full name of responsible person

Mehrei Delvarianzadeh

Position

Masters /Faculty Member

Other areas of specialty/work

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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