

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Design, Implementation and Evaluation of Lifestyle Modification Packages Based on Family Medicine Approach to Controlling Metabolic Syndrome Components

Protocol summary

Study aim

develop, implement, and evaluate the impact of lifestyle education package in order to control metabolic syndrome components

Design

The intervention group received educational package consists of a three months' scheduled schedule (First month: face- to- face and pamphlets education program .Second month: 14 educational message ,Third month: Educational film). The control group received usual care by a physician in each visit, and fasting blood glucose will be assessed at baseline and after 3month.

Settings and conduct

from two health centers

Participants/Inclusion and exclusion criteria

72 women and men aged over 18 years with MetS

Intervention groups

enrolled through randomized sampling to either intervention group who take usual care plus a 3-month lifestyle modification intervention or control group.

Main outcome variables

Anthropometric indices, blood pressure, lipid profiles, and fasting blood glucose will be assessed at baseline and after 3 month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200212046470N1**

Registration date: **2020-02-23, 1398/12/04**

Registration timing: **retrospective**

Last update: **2020-02-23, 1398/12/04**

Update count: **0**

Registration date

2020-02-23, 1398/12/04

Registrant information

Name

Shahed Samat

Name of organization / entity

Faculty of Medical Sciences, University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9686

Email address

sdrmed1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of Lifestyle Modification Packages Based on Family Medicine Approach to Controlling Metabolic Syndrome Components

Public title

Assessing the effectiveness of Educational Package for Controlling Metabolic Syndrome Components

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

minimum age of 18 years old The inclusion criteria were as follows: existence of $\geq 3/5$ elements for metabolic syndrome including: central obesity (men: ≥ 94 cm, women: ≥ 80 cm waist circumference); hypertension (systolic ≥ 130 mmHg, diastolic ≥ 85 mmHg and/or anti-hypertensive treatment); diabetes (fasting blood sugar (FBS) ≥ 100 mg/dL and/or anti-diabetic treatment); elevated triglycerides (TG) (≥ 150 mg/dL); low high-density lipoprotein (HDL) (men: < 40 mg/dL, women: < 50 mg/dL) and/or cholesterol-lowering treatment

Exclusion criteria:

level of education less than fifth grade hepatic diseases, hematologic diseases, renal failure (GFR < 30), Secondary causes of dyslipidemia, such as hypothyroidism and taking oral contraceptives, severe psychological illness, physical disability, known Cancer and treated type 1 diabetes, Alzheimer's and dementia Active TB disease, HIV

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee on Ethics in Biomedical Research

Street address

pursina

City

Tehran

Province

Tehran

Postal code

1411846877

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3071

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anthropometric indices, blood pressure, lipid profiles, and fasting blood glucose

Timepoint

before intervention and after 3 month of intervention.

Method of measurement

clinical Anthropometric measurement- Laboratory measurement- Clinical mercury manometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received educational package consists of a three months' scheduled schedule (First month: face- to- face and pamphlets education program .Second month: 14 educational message ,Third month: Educational film)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

health center Shah Abadi

Full name of responsible person

shahed samat

Street address

Shahid Rajaii Third Street,, No. 13, FLOOR. 2

City

Lahijan

Province

Guilan

Postal code

4415763391

Phone

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Email

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2

Recruitment center

Name of recruitment center

health center Imam Sadiq

Full name of responsible person

shahed samat

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

shahed samat

Street address

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Province

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

shahed samat

Position

family medicine

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

negar omidi

Position

Assistant Professor of Cardiology

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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+98 21 8802 9686

Email

negar.omidi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

shahed samat

Position

family medicine

Latest degree

Medical doctor

Other areas of specialty/work

Family Health

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For Prevention Studies with permission of Supervisor

From where data/document is obtainable

sdrmed1@yahoo.com

What processes are involved for a request to access data/document

An email send to the Trial Scientific responsible Dr. Negar Omid And receive them within a month

Comments