

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Effectiveness of Dietary and Physical Activities Counseling on Components of Metabolic Syndrome in School Age Children With Metabolic Syndrom

Protocol summary

Summary

Study objective :To rdetermine the effectiveness of dietary and Physical activities counseling on components of metabolic syndrome in school age children with metabolic syndrom. This study is a randomized clinical trial. Key inclusion and exclusion criteria: 1 - Diagnosis of metabolic syndrome defined according to the International Diabetes Federation and the doctor 2 - The minimum age is 12 years and maximum 6 years 3 - with the patient and the patient's caregivers Bymarbashd lives. 4 - Children and parents are willing to participate in the study. 5 - patients and families who have not previously participated in the training groups. 6 - no use of drugs affecting lipid metabolism, glucose and blood pressure 7 - at least not to participate in a training session. The study population consisted of school children aged 6 to 12 with metabolic syndrome and a sample size is 60. Study interventions included: nutrition education intervention on a group of 15 people, Physical activity education intervention on a group of 15 people, Physical activity and nutrition education intervention on a group of 15 people and a group of 15 people without any intervention. Intervention period is three months. Before and after the interventions waist circumference, blood pressure, triglycerides, high-density lipoprotein and glucose is measured and differences are evaluated

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110815318N1**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Roya Bagheri

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 322 7656

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Dietary and Physical Activities Counseling on Components of Metabolic Syndrome in School Age Children With Metabolic Syndrom

Public title

The effect of dietary and Physical activities counseling on children with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for intervention: 1 - Diagnosis of metabolic syndrome defined according to the International Diabetes Federation and the doctor 2 - The minimum age is 12 years and maximum 6 years 3 - with the patient and the patient's caregivers Bymarbashd lives. 4 - Children and parents are willing to participate in the study. 5 - patients and families who have not previously participated in the training groups. 6 - no use of drugs affecting lipid metabolism, glucose and blood pressure Exclusion criteria for intervention: 1 - at least not to participate in a training session.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Science,
Golestan Autobahn, Ahvaz

City

Ahvaz

Postal code

1579461357

Approval date

2013-10-05, 1392/07/13

Ethics committee reference number

ajums.REC.1392.141

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E88

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Abdominal obesity (waist Circumference)

Timepoint

Before intervention, Two months after intervention, four months after intervention

Method of measurement

waist Circumference According to cm by Using a height gauge

2

Description

Blood Pressure

Timepoint

Before intervention, Two months after intervention, four months after intervention

Method of measurement

According to Millimeters of mercury and by using Manometer

3

Description

Triglycerides

Timepoint

Before intervention, Two months after intervention, four months after intervention

Method of measurement

According to Mg per deciliter by Using blood samples

4

Description

High-density lipoprotein

Timepoint

Before intervention, Two months after intervention, four months after intervention

Method of measurement

According to Mg per deciliter by Using blood samples

5

Description

Fast Blood Sugar

Timepoint

Before intervention, Two months after intervention, four months after intervention

Method of measurement

According to Mg per deciliter by Using blood samples

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Children and their parents will be placed in a group based nutrition education program. The training consisted of four consecutive and An interval of one week and Time is 120 minutes. These sessions will be led by the researcher.

Category

Lifestyle

2

Description

Intervention group B: Children and their parents will be placed in a group based Physical activity education program. The training consisted of four consecutive and An interval of one week and Time is 120 minutes. These sessions will be led by the researcher.

Category

Lifestyle

3

Description

Intervention group c: Children and their parents will be placed in a group based on both physical activity and nutrition education program. Tutorial sessions for eight consecutive, Twice in a week and four weeks, time will be 120 minutes. These sessions will be led by the researcher.

Category

Lifestyle

4

Description

The control group: in this period will not be under any kind of formal training (no action)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialist Clinic of Golestan Hospital

Full name of responsible person

Roya Bagheri

Street address

Golestan Hospital, Golestan Street

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ashraf Alsadat Hakim

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ashraf Alsadat Hakim

Position

Bachelor of Nursing

Other areas of specialty/work

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Ashraf alsadat hakim

Position

Educator

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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

Data Dictionary

empty