

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

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

#### Protocol summary

##### Summary

Study objective :To determine the effectiveness of dietary and Physical activities counseling on components of metabolic syndrome in school age children with metabolic syndrome. 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

###### Email address

bagheri.r@ajums.ac.ir

##### 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 Syndrome

##### 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

##### Street address

Ahvaz Jundishapur University of Medical Sciences

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6135715794

##### Phone

+98 61 1373 8622

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hakim - a@ajums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Ashraf alsadat hakim

**Position**

Educator

**Other areas of specialty/work**

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**Name of organization / entity**

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Roya Bagheri

**Position**

Graduate Student

**Other areas of specialty/work**

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bagheri.r@ajums.ac.irroooyya@yahoo.com

**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*