# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Oct 2026

## Comparison of high-fat and low-carbohydrate weight loss diet with standard weight loss diet on body composition, appetite and anthropometric measurements in overweight and obese children

## Protocol summary

**Study aim**

Comparison and determination the effects of high-fat and low-carbohydrate diet with Standard diet on body composition, appetite, and anthropometric measurements in overweight and obese children

**Design**

The clinical trial has two intervention groups, parallel groups, single blind and randomized.

**Settings and conduct**

Demographic questionnaire was used to measure social status, IPAQ-short form (The International Physical Activity Questionnaire) form was used to measure physical activity and The Appetite and Diet Assessment Tool(ADAT) and self-reported score were used to assess appetite. The three-day food record are filled out by the parents or children. Weight measurement is measured with a digital scale with 100 grams accuracy . The individual's height is measured with 0.5 cm accuracy . Waist and hip circumference is measured using a meter. Body composition is assessed with a Body impedance analysis (BIA). Diet sheet with supplementary recommendations to be given to the participant. To measure adherence each week, we will ask the person about their diet performing. Blinding: The evaluator is not aware of the participant's diet. location: Shiraz, Namazi Square, Imam Reza Clinic

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Children 9-18 years BMI for age above 85th percentile Exclusion criteria: Having a specific diet

**Intervention groups**

Control group: Low fat and high carbohydrate diet (Standard diet) (25% of total energy as fat, 20% of total energy as protein and 55% of total energy as carbohydrate) Intervention group: High-fat, low-carbohydrate diet (55% of total energy as fat, 20% of total energy as protein , and 25% of total energy as carbohydrate)

**Main outcome variables**

Height, weight, BMI, waist-to-hip ratio, waist circumference, hip circumference, appetite, adipose tissue, lean tissue, interstitial water

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20191121045464N1**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**

**Registration date**

2020-07-06, 1399/04/16

**Registrant information**

**Name**

Mohaddeseh Hasanzadeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3648 0127

**Email address**

hasanzade-m@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-07-05, 1399/04/15

**Expected recruitment end date**

2020-08-22, 1399/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of high-fat and low-carbohydrate weight loss diet with standard weight loss diet on body composition, appetite and anthropometric measurements in overweight and obese children

**Public title**

Comparison of the effects of two weight loss diets (High fat diet and Standard diet)

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

BMI(Body mass index) for age above 85th percentile
Parents' consent to participate in the project

**Exclusion criteria:**

BMI (body mass index) for age is normal

**Age**

From **9 years** old to **18 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **94**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals using the Permuted Block Randomization method will be divided into two groups. To create a random sequence in the block randomization approach, the website http://www.sealedenvelopepe.com will be used. The project methodologist is also given a random sequence to hide the allocation concealment. Then, the researcher communicates with the mentioned people based on the order of the participants entering the study and communicates with the said person about the random allocation of the participants to the study and asks about the random allocation of the participant to the specific group. For each intervention, a number (multi-digit code) is defined and entered on the envelope according to the random sequence created.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The trial is planned in such a way that the evaluator of weight and body composition does not understand which of the two groups (High-fat weight loss diet and Standard weight loss diet) belong to the participant.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences Central Building, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2019-12-12, 1398/09/21

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.694

## Health conditions studied

### 1

**Description of health condition studied**

Overweight and obesity

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Children's body mass index percentile

**Timepoint**

The first week and the sixth week

**Method of measurement**

Body weight in kilogram divided by the square of the height in meters

### 2

**Description**

Individual weight with minimum clothing and no shoes with 0.1 kg accuracy

**Timepoint**

The first week and the sixth week

**Method of measurement**

Scale

### 3

**Description**

Children's height in standing position without shoes with 0.5 accuracy

**Timepoint**

The first week and the sixth week

**Method of measurement**

Stadiometer

**4**

**Description**

Waist circumference measurement in the midline between the lower rib and the upper part of the iliac bone

**Timepoint**

The first week and the sixth week

**Method of measurement**

Meter

**5**

**Description**

Measuring the most articulated part of the hip

**Timepoint**

The first week and the sixth week

**Method of measurement**

Meter

**6**

**Description**

Waist to hip ratio

**Timepoint**

The first week and the sixth week

**Method of measurement**

Waist circumference divided by hip circumference

**7**

**Description**

Appetite score by ADAT questionnaire(The Appetite and Diet Assessment Tool)

**Timepoint**

The first week and the sixth week

**Method of measurement**

ADAT questionnaire(The Appetite and Diet Assessment Tool)

**8**

**Description**

Fat mass measured by Bioelectrical Impedance Analysis (BIA)with minimal clothing and no shoes

**Timepoint**

The first week and the sixth week

**Method of measurement**

Bioelectrical Impedance Analysis

**9**

**Description**

Lean body mass measured by Bioelectrical Impedance Analysis with minimal clothing and no shoes

**Timepoint**

The first week and the sixth week

**Method of measurement**

Bioelectrical Impedance Analysis (body weight - fat mass)

**10**

**Description**

Interstitial water measured by Bioelectrical Impedance Analysis with minimal clothing and no shoes

**Timepoint**

The first week and the sixth week

**Method of measurement**

Bioelectrical Impedance Analysis

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: High fat and low carbohydrate (55% of total energy as fat, 20% of total energy as protein 25% of total energy as carbohydrate ) and the amount of diet energy is 500 kcal below the individual requirement .Everyone will also be given dietary advice.The duration of the diet will be 6 weeks

**Category**

Treatment - Other

**2**

**Description**

Control group: Standard diet (55% of total energy as carbohydrate, 20% of total energy as protein 25% of total energy as fat ) and the amount of diet energy is 500 kcal below the individual requirement .Everyone will also be given dietary advice.The duration of the diet will be 6 weeks

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

کلینیک زیبا آفرین

**Full name of responsible person**

محدثه حسن زاده

**Street address**

4th floor,Kasra Building,Ordibehesht Ave,Mulla Sadra Street

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**Province**

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7134684499
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**Email**
mahdishealth@outlook.com
**Web page address**
http://mahdishealth.com/

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Maryam Mahmoodi
**Street address**
6th Floor, School of Nutrition and Dietetics, Hojjat Doust Alley, Naderi St, Keshavarz Blvd.
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1416643931
**Phone**
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**Email**
m-mahmoudi@sina.tums.ac.ir
**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**
Mohaddeseh Hasanzadeh
**Position**
Student of Master of science
**Latest degree**
Bachelor
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Nutrition
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

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

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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