

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students: A Randomized Trial

#### Protocol summary

##### Study aim

Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students

##### Design

Randomized control trial with parallel groups

##### Settings and conduct

This study will be conducted among all elementary and high school students in Kermanshah. The calculated sample size will be 524 people who will be divided between two intervention and control groups using random method (Block Randomization). This study will be conducted as a randomized controlled clinical trial for 8 months, and the combined effect of nutritional education and physical activity on the treatment of obesity and overweight students will be measured. Anthropometric and physical activity will be evaluated at the beginning and end of the study.

##### Participants/Inclusion and exclusion criteria

Obese or overweight students in elementary and high school

##### Intervention groups

The intervention includes three components, i.e., nutrition education (students and parents), increased physical activity, and changing environment (food items offered in schools' canteens). Nutritionists will provide education to students, parents, and school teachers about healthy eating patterns with emphasis on the consumption of alternative and low-calorie foods, the Iranian food pyramid, and the consumption amount of each food group. Nutrition education will be imparted (a 30-minute session per week) by health instructors; physical activity will be done under the supervision of the school coaches (2 one-hour sessions per week). Parents' education (a 1.5-hour session) will be monthly.

#### Main outcome variables

Body mass index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180712040438N6**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **prospective**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

##### Registration date

2022-11-28, 1401/09/07

##### Registrant information

##### Name

Jalal Moludi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 2148

##### Email address

jmoludi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-11, 1401/09/20

##### Expected recruitment end date

2023-05-20, 1402/02/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students: A Randomized Trial

**Public title**  
Investigating the effect of nutritional and physical activity education on obesity

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Desire to cooperate Elementary and high school students  
Overweight or obese students with a high body mass index (body mass index equal to or higher than the 85th percentile)  
**Exclusion criteria:**  
Have a known neurological disease Having major systemic diseases such as malignancies Have known liver disease Taking medications that affect appetite and body weight, such as corticosteroids or other supplements Any possible injury related to the intervention during the study (such as physical harm during physical activity or following the provided diet)

**Age**  
From **7 years** old to **15 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **524**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method in this study is block randomization. Each of the randomly created sequences is recorded on a card and the cards are placed in the envelopes in order.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6719851552

#### Approval date

2022-10-11, 1401/07/19

#### Ethics committee reference number

IR.KUMS.REC.1401.301

## Health conditions studied

### 1

#### Description of health condition studied

Obesity or overweight

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Body mass index

#### Timepoint

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

#### Method of measurement

Dividing weight (in kilograms) by the square of height (in meters)

## Secondary outcomes

### 1

#### Description

Energy intake

#### Timepoint

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

#### Method of measurement

Three-day food recording

### 2

#### Description

Waist circumference

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

Tape measure

## **3**

### **Description**

Hip circumference

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

Tape measure

## **4**

### **Description**

The thickness of the skin fold in the triceps region

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

Caliper

## **5**

### **Description**

Physical activity

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

International physical activity questionnaire

## **6**

### **Description**

Stress, anxiety and depression

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

Depression anxiety stress scales

## **7**

### **Description**

Sleep quality

### **Timepoint**

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

### **Method of measurement**

Pittsburgh Sleep Quality Index

## **Intervention groups**

### **1**

### **Description**

Intervention group: In the intervention group, nutrition education will be provided to overweight and obese

children for 1 hour every week during the 8 months of intervention. These trainings will be with an emphasis on the consumption of alternative and low-calorie foods and the use of a healthy food plate. Students will be advised to do sports activities 3 times a week for one hour each time under the supervision of a sports coach. Educational pamphlets in the field of nutrition and following the food pyramid, as well as sports exercises, are provided to students and their parents at the beginning of the study.

### **Category**

Lifestyle

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

Elementary and high schools

#### **Full name of responsible person**

Jalal Moludi

#### **Street address**

Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry

#### **City**

Kermanshah

#### **Province**

Kermanshah

#### **Postal code**

6719851552

#### **Phone**

+98 83 3710 2003

#### **Email**

jmoludi@yahoo.com

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Kermanshah University of Medical Sciences

#### **Full name of responsible person**

Cyrus Jalili

#### **Street address**

Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry

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Kermanshah

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Kermanshah

#### **Postal code**

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#### **Phone**

+98 83 3710 2003

#### **Email**

jmoludi@yahoo.com

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Jalal Moludi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry

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Kermanshsh

**Province**

Kermanshah

**Postal code**

6719851552

**Phone**

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**Email**

jmoludi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Jalal Moludi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Email**

jmoludi@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Jalal Moludi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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Nutrition

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**Postal code**

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**Phone**

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**Email**

jmoludi@yahoo.com

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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

**Title and more details about the data/document**

Data collected for the primary outcomes will be shared

**When the data will become available and for how long**

Accessibility to data is possible 8 months after publication.

**To whom data/document is available**

The data will only be available for people working in academic institutions.

**Under which criteria data/document could be used**

The data of the present study will only be accessible by other researchers, for conducting Meta analysis

**From where data/document is obtainable**

Dr Jalal Moludi, Faculty of Nutrition Sciences and Food

Technology, Kermanshah University of Medical Sciences, +989399516766, j.moloudi@yahoo.com

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

Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.

**Comments**