

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of powder of flaxseed on weight, appetite, appetite hormones, and mental fatigue of Overweight and obesity children aged 7 to 18 years

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of flaxseed powder on weight, appetite and appetite hormones and mental fatigue in overweight and obese children aged 7-18 years.

##### Design

Two arm parallel group randomized, controlled trial (Study phase: 3) sample size: 70

##### Settings and conduct

Seventy eligible children were selected based on available sampling from Shiraz health centers. Subjects were randomly divided into intervention and control groups by drawing method. At the beginning of the study, blood samples were taken to determine the amount of appetite control hormones and the appetite questionnaire, mental fatigue was completed. Then, flaxseed and puffed wheat (control) were distributed for 4 weeks. After 4 weeks, blood samples were taken again and the appetite and mental fatigue questionnaires were completed. Also, 24-hour food intake was taken at the beginning and at the end of the study to control and consider Disturbing edible variables.

##### Participants/Inclusion and exclusion criteria

The participants were children aged 7-18 years that had overweight and obesity. The inclusion criteria included the healthiness of these participants and their willingness to cooperation. Non-inclusion criteria: Children who had a particular diet. Children who used flaxseed for at least a week ago. Children who have been given supplementation or an appetite suppressant drug.

##### Intervention groups

The intervention group used 20 grams of flaxseed powder on yogurt, salad and food each day for 4 weeks. The control group used 25 grams of puffed wheat each day for 4 weeks. The intervention and control had the same calories.

##### Main outcome variables

The major outcomes of this study included weight, appetite, appetite hormone (PPYY), and mental fatigue in

overweight and obese children aged 7-18 years.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190408043204N1**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **retrospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

##### Registration date

2019-04-28, 1398/02/08

##### Registrant information

##### Name

Zohreh Gholami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3754 5024

##### Email address

gholami\_z@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

2018-12-22, 1397/10/01

##### Actual recruitment end date

2019-01-30, 1397/11/10

##### Trial completion date

2019-03-16, 1397/12/25

### Scientific title

Effect of powder of flaxseed on weight, appetite, appetite hormones, and mental fatigue of Overweight and obesity children aged 7 to 18 years

### Public title

Effect of flaxseed in improvement of appetite and mental fatigue

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy overweight and obesity children aged 7 to 18 years  
Tendency to cooperate

#### Exclusion criteria:

Children who had a particular diet. Children who used flaxseed for at least a week ago. Children who have been given supplementation or an appetite suppressant drug.

### Age

From **7 years** old to **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **70**

Actual sample size reached: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Drawing method: Initially, we categorized the participants into four groups: obese children, overweight children, obese adolescents and overweight adolescents. Then, by using the drawing method, we randomized each group for allocation to either intervention or control group; In the drawing, individuals are allocated into intervention group for even times and into control for odd times.

### 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 Shiraz University of Medical

Sciences

### Street address

Street Zand, opposite Felestin Street, Central building of Shiraz University of Medical Sciences

### City

Shiraz

### Province

Fars

### Postal code

71348-14336

### Approval date

2018-02-07, 1396/11/18

### Ethics committee reference number

IR.SUMS.REC.1396.172

## Health conditions studied

### 1

#### Description of health condition studied

Overweight and obesity

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

Weight in kilograms

#### Timepoint

At first (before intervention) and end (after 4 weeks of intervention) of study

#### Method of measurement

Digital scales by accuracy of 0.1 kilograms

## Secondary outcomes

### 1

#### Description

Appetite questionnaire score

#### Timepoint

At first (before intervention) and end (after 4 weeks of intervention) of study

#### Method of measurement

Simple Appetite Questionnaire (8 Questions)

### 2

#### Description

Appetite hormone (PPYY)

#### Timepoint

At first (before intervention) and end (after 4 weeks of intervention) of study

#### Method of measurement

PPYY hormone measuring kit

### 3

**Description**

Mental fatigue score

**Timepoint**

At first (before intervention) and end (after 4 weeks of intervention) of study

**Method of measurement**

Multidimensional Fatigue Inventory (MFI)

## Intervention groups

### 1

**Description**

Intervention group: This group consumed 20 grams of flaxseed each day for four weeks in full powder form.

**Category**

Prevention

### 2

**Description**

Control group: This group consumed 25 grams of puffed wheat each day for 4 weeks.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Shiraz Health Center (Valfajar)

**Full name of responsible person**

Zohreh Gholami

**Street address**

West Saheli Street, Next to the Governorate

**City**

Shiraz

**Province**

Fars

**Postal code**

71357-66563

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+98 71 3234 0884

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gholami\_z@sums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Masoumeh Akhlaghi

**Street address**

Street Zand, Opposite Flestine Street, Central building of Shiraz University of Medical Sciences

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**Province**

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**Postal code**

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**Phone**

+98 71 3230 5410

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info@sums.ac.ir

**Web page address****Grant name**

sg- Grant of Shiraz University of Medical Sciences

**Grant code / Reference number**

sg -96 -39 گرنٹ

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Masoumeh Akhlaghi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Razi Blvd, School of Nutrition and Food sciences

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**Province**

Fars

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## Person responsible for scientific inquiries

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

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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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