

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Phone

+98 71 3234 0884

Email

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

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Web page address**Grant name**

sg- Grant of Shiraz University of Medical Sciences

Grant code / Reference number

sg -96 -39 گرنت

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

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1001

Email

msm.akhlaghi@gmail.com

Person responsible for scientific 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

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Email

gholami_z@sums.ac.ir

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

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

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Gholami

Position

Master student

Latest degree

Master

Other areas of specialty/work

Nutrition