

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of Nuts on the cognitive function in obese 8-10 year old girls in Kermanshah

Protocol summary

Study aim

Effect of the effect of Nuts on the cognitive function in obese 8-10 year old girls in Kermanshah

Design

This study was conducted in a clinical trial with a blinded one-blind, parallel-group, 90 girl aged 10-8 years with obesity who will be randomly assigned to the control and intervention groups.

Settings and conduct

This study will be conducted during 16 weeks on 90 girl aged 10-8 year old with obesity in Kermanshah. After explaining the purpose of the study and obtaining informed, the subjects will be evaluated for anthropometric indices, nutritional status and cognitive function. To evaluate the cognitive function, a Wechsler questionnaire for children and a BRIEF questionnaire (Behavioral Compliance Questionnaire for executive functions) will be used. Subjects will then be classified into control and intervention groups in such a way that participants will not be aware of the allocation of the groups. The intervention group will receive 30 grams nuts per day, and the control group will not take the placebo.

Participants/Inclusion and exclusion criteria

The age group of 8-10 years, at least 3 years of obesity, lack of underlying conditions such as diabetes, endocrine diseases and diseases of the cardiovascular system and liver and lack of professional sports.

Intervention groups

The first group will receive 30 grams of nuts containing 15 grams of walnuts, 7.5 grams of almonds and 7.5 grams of hazelnuts (divided in 2 doses per day), and the second group did not receive any placebo treatment.

Main outcome variables

cognitive functions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N2**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

Mehnoosh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

Email address

mehnoosh_samadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Nuts on the cognitive function in obese 8-10 year old girls in Kermanshah

Public title
Impact of nuts on cognitive function

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
At least 3 years old with obesity
Exclusion criteria:
Not having underlying diseases such as diabetes, endocrine disease, cardiovascular and liver disease Lack of professional exercise

Age
From **8 years** old to **10 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: cluster Referring to the education of Kermanshah, the city's schools list will be selected and 9 schools will be randomly selected. In each school, 5 people will be randomly assigned to the intervention group and 5 will be selected for the control group.

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
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date

2019-07-09, 1398/04/18

Ethics committee reference number
IR.KUMS.REC.1398.365

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Cognitive functions score in the Wechsler questionnaire and the BRIEF questionnaire (Behavioral Rating Schedule for Executable Functions).

Timepoint

Before the start of the study, 8 and 16 weeks after the start of the intervention

Method of measurement

Wechsler questionnaire and the BRIEF questionnaire (Behavioral Rating Schedule for Executable Functions).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention with 30 grams of nuts containing 15 grams of walnuts, 7.5 grams of almonds and 7.5 grams of hazelnuts (in two doses in the morning and evening) daily.

Category

Treatment - Other

2

Description

Control group: This group does not receive any intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Schools in Kermanshah

Full name of responsible person

Karam Ahmadian

Street address

Gomrek Street, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714897767

Phone

+98 83 3823 0218

Email

shimamoradi21@yahoo.com

Mehnoosh Samadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of Nutrition and Food Sciences, Above Farabi Hospital, Ilesar Square

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Phone

+98 83 3710 2009

Email

mehnoosh_samadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Building No. 2, Research Council Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3837 6892

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

No

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Reza amani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, school of Nutrition and Food Science, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

6104337945

Phone

+98 31 3792 3175

Email

r_amani@mail.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Sheikhi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Third Robat St,Shadi St,Pedrem Alley

City

Isfahan

Province

Isfahan

Postal code

8196743871

Phone

+98 31 3440 5545

Email

Sheikhi.fateme@gmail.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Trail that began to fall ill on 23th of September 2019 should have a release plan when recording its study protocol.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

No - There is not a plan to make this available