

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of reduced-carbohydrate diet based on high fiber sources on food addiction and gut microbiota of obese adolescents

Protocol summary

Study aim

Determining the effect of reduced carbohydrate diet based on high fiber sources on anthropometric indices, metabolic parameters, food addiction and gastrointestinal microbiota in obese adolescents with food addiction

Design

Randomized clinical trial in parallel groups (control and intervention groups) with a sample size of 70 participants (35 participants in each group)

Settings and conduct

participants will be randomly assigned into two groups: control diet and reduced carbohydrate diet. Then they will receive their meal plan as a menu and detailed instructions. At the beginning and end of the study, weight, blood pressure, body fat percentage and dietary intakes will be recorded at the National Nutrition Research Institute. furthermore, blood and stool samples also will be collected. Participants will be followed up during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obese adolescents aged 19-12 years, with at least 3 symptoms of food addiction questionnaire and significant clinical disorder, willingness to participate in the study Exclusion criteria: taking antibiotics, taking supplements such as probiotics or prebiotics, participating in other weight loss programs and those with recent weight fluctuations, Suffering from any type of metabolic, renal, cardiovascular, thyroid, liver and gastrointestinal diseases, secondary obesity, history of eating disorders, current use Corticosteroid, use of medications to treat psychosis or mania-depression, history of surgery

Intervention groups

Individuals in the two groups receive a low-calorie diet with reduced carbohydrates based on high-fiber sources (intervention group) or a standard low-calorie diet (control group) for 3 months.

Main outcome variables

Weight, body mass index, body fat percentage, lipid profile, glucose, insulin, systolic and diastolic blood pressure, food addiction score, gut microbiota

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180805040703N2**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Golaleh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 9309

Email address

g_asghari@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of reduced-carbohydrate diet based on high fiber sources on food addiction and gut microbiota of obese adolescents

Public title
The effect of low carbohydrate diet on food addiction and gut microflora

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Adolescents 12-19 years old Obese, body mass index higher than 2 standard deviations from the average standard set for age and sex by the World Health Organization for children or adolescents between 5-19 years Has at least 3 signs of food addiction questionnaire symptoms and significant clinical disorder or discomfort Willingness to participate in the study
Exclusion criteria:
 Taking antibiotics for more than 3 days during the previous 3 months Taking medications or supplements such as probiotics or prebiotics that alter the gastrointestinal microbiota for more than 3 days in the past 1 month Participate in other weight loss programs in the previous 3 months and Suffering from any type of metabolic, renal, cardiovascular, thyroid, liver and gastrointestinal diseases Secondary obesity such as Cushing's syndrome, hypothyroidism, hypogonadal or pituitary obesity History of eating disorders Current use of corticosteroids for more than 5 days a month Use of medications to treat psychosis or manic-depressive illness such as lithium, carbamazepine, valproic acid History of surgery in the last 3 months (history of obesity surgery) History of weight fluctuations of more than 5 kg in the last 2 months

Age
From **12 years** old to **19 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block randomization method will be used. 70 participants will be assigned into two groups of diets (A intervention diet and B control diet) using a computer randomization list. This list will be created through the randomization.com website (<http://www.randomization.com>). Considering 6 blocks and 12 subjects in each block, a list of 72 subjects will be assigned to different groups, which 2 of them will be deleted due to the sample size of 70. Individuals are

assigned to two groups according to the order (from the first person number 1 to the last person number 70) who enter the study and according to the compiled randomization list. By researcher number 1, each person's number will be written on the envelope and the group will be placed inside a sealed envelope to ensure that the assigned order is hidden, and then the envelopes will be given to researcher number 2.

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 National Nutrition & Food Technology Research Institute

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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Province

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Postal code

1981619573

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1401.001

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

2

Description of health condition studied

food addiction

ICD-10 code

ICD-10 code description

3

Description of health condition studied

gut microbiota

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

weight

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Digital scales

2

Description

Body mass index

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

calculation

Secondary outcomes

1

Description

Food Addiction Score

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Yale Food Addiction Scale

2

Description

Abundance of actionbacteria

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

3

Description

Abundance of firmicutes

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

4

Description

Abundance of bacteroidetes

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

5

Description

Abundance of proteobacteria

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

6

Description

Abundance of verrucomicrobia

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

7

Description

Abundance of bifidobacterium

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

8

Description

Abundance of Escherichia

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

9

Description

Abundance of lactobacillus

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

10

Description

Abundance of bacteroides

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

11**Description**

Abundance of prevotella

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Polymerase chain reaction test

12**Description**

Percentage of body fat

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Bioelectrical impedance analysis

13**Description**

waist circumference

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

tape measure

14**Description**

Average of total daily calorie intake

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

15**Description**

Average total daily carbohydrate intake

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

16**Description**

Average total daily protein intake

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

17**Description**

Average total daily fat intake

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

18**Description**

Average total daily fiber intake

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

19**Description**

Average daily intake of saturated fatty acids

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

20**Description**

Average daily intake of unsaturated fatty acids

Timepoint

At the beginning of the study, 45 and 90 days after the start of the intervention (diet)

Method of measurement

24-hour food recall questionnaire

21**Description**

Fasting serum glucose concentration

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Colorimeter/ laboratory kit

22**Description**

Fasting serum insulin concentration

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

enzyme-linked immunosorbent assay/laboratory kit

23

Description

Total serum cholesterol level

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Colorimeter/ laboratory kit

24

Description

Serum triglyceride level

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Colorimeter/ laboratory kit

25

Description

serum Low density lipoprotein level

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

calculation

26

Description

serum high density lipoprotein level

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

Blood biochemical test / colorimetry

27

Description

Systolic blood pressure

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

sphygmomanometer

28

Description

Diastolic blood pressure

Timepoint

At the beginning and end of the study (3 months after starting the diet)

Method of measurement

sphygmomanometer

Intervention groups

1

Description

Intervention group: 3 months low calorie diet with reduced carbohydrates based on high fiber sources

Category

Treatment - Other

2

Description

Control group: Standard low calorie diet

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology, Growth and Metabolism Clinic

Full name of responsible person

Yasaman Khorshidi

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Sponsors / Funding sources

1

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Shahid Beheshti University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
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Yasaman Khorshidi
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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

There is no more information

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available