

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Effects of ketogenic diet on weight management and appetite status in overweight or obese adults with food addiction and weight regain

Protocol summary

Study aim

Determining the effects of ketogenic diet on weight management and appetite in overweight or obese individuals with weight regain and food addiction

Design

Clinical trial with control group, with parallel, randomized groups, on 50 obese or overweight adults. Excel software rand function was used for randomization.

Settings and conduct

Candidates are asked to attend the nutrition clinic of Shahid Beheshti University at the beginning and end of the project. After filling out the required consent and questionnaires, blood samples are taken, the physical composition of the volunteers is measured with an InBody device, stool samples are taken from the volunteers. And finally a proper diet is given to people.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy adults who are obese or overweight with weight regain with food addiction
Exclusion criteria: Gout and chronic diseases such as diabetes, cardiovascular, liver, etc. Neurological diseases (depression, bipolar disorder, and obsessive-compulsive disorder) Follow a special diet, use drugs that affect appetite and weight, and use any probiotic product in one recent month of antibiotic use in the last month.

Intervention groups

Obese or overweight adults with recurrent weight regain with food addiction Ketogenic diet for intervention group
Dietary control group with calorie restriction

Main outcome variables

plasma serotonin level, plasma BDNF level, eating behavior, weight, body mass index, waist circumference, hip circumference, waist to hip ratio, fat mass percentage Body, percentage of lean body mass, weight of body fat mass, body weight of lean body mass, percentage of visceral body fat, amount of visceral body fat, appetite, Bacteroides abundance, Lactobacillus abundance, Bifidobacterium abundance, Megamonas abundance, Eubacterium abundance, Akkermansia

abundance, Urine ketone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220418054574N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Ali Zamanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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alitimeeeee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Effects of ketogenic diet on weight management and appetite status in overweight or obese adults with food addiction and weight regain
Public title	Effect of kettogenic diet on weight management and aptite
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Overweight or obese people between 18-60 years old Body mass index 40-26 kg / m2 Food addiction based on YFAS4 questionnaire Weight regain One-third to two-thirds of the weight lost in 1 year, or almost all of them in 5 years Do not be pregnant or breastfeeding Exclusion criteria: gout and chronic diseases such as diabetes, cardiovascular, liver, etc. mental illness (depression, bipolar disorder and obsessive-compulsive disorder) Failure to follow a specific diet take drugs that affect appetite and weight use any probiotic products in a recent month use antibiotics during the last month
Age	From 18 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 50
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, participants were classified into two groups with overweight (26-30) and obesity grade 2 (30-40) by stratified blocked randomization method and based on BMI and randomly assigned to One of the groups TRF or control group. Separate randomization is done based on BMI within each group. The size of the blocks is 4, with two assignments to the intervention group (A) and two allocations to the control group (B). There are 6 different permutations of AABB, ABAB, BBAA, BABA, ABBA, BAAB.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address	No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran
City	Tehran
Province	Tehran
Postal code	1981619573
Approval date	2022-04-18, 1401/01/29
Ethics committee reference number	IR.SBMU.NNFTRI.REC.1401.003
Health conditions studied	
<u>1</u>	
Description of health condition studied	Obesity
ICD-10 code	E66.0
ICD-10 code description	Obesity due to excess calories
Primary outcomes	
<u>1</u>	
Description	weight
Timepoint	before intervention and 8 weeks after intervention
Method of measurement	seca scale
<u>2</u>	
Description	Body Mass Index
Timepoint	before intervention, 4 weeks and 8 weeks after intervention
Method of measurement	Calculation (kg/m2)
<u>3</u>	
Description	Waist circumference
Timepoint	before intervention, 4 weeks and 8 weeks after intervention
Method of measurement	

Meter strip

4

Description

Fat Mass

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Bio Impedance Analyzer

5

Description

Fat Free Mass

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Bio Impedance Analyzer

Secondary outcomes

1

Description

serum serotonin level

Timepoint

before intervention, 8 weeks after intervention

Method of measurement

Elisa

2

Description

serum BDNF

Timepoint

before intervention, 8 weeks after intervention

Method of measurement

Elisa

3

Description

gut microbiota

Timepoint

before intervention, 8 weeks after intervention

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: Get a ketogenic diet with calorie restriction for 8 weeks

Category

Treatment - Other

2

Description

Control group: Get low calorie diet with calorie restriction

for 8 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

nutrition clinic of Shahid Beheshti university of medical science

Full name of responsible person

Ali Zamanian

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Baran Ave., Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition

Full name of responsible person

Dr. Azita hekmatdust

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition

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

Province
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Person responsible for general inquiries

Contact

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable