Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 apptite 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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alitimeeee@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 apptite

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

1

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

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Postal code
1981619573

Approval date
2022-04-18, 1401/01/29

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.003

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
weight

Timepoint
before intervention and 8 weeks after intervention

Method of measurement
seca scale

2

Description
Body Mass Index

Timepoint
before intervention, 4 weeks and 8 weeks after intervention

Method of measurement
Calculation (kg/m2)

3

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
Street address
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
Street address
No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran
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a_hekmat2000@yahoo.com
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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Zamanian

Position
Master student of nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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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
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