

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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)

##### Phone

+98 21 7632 8409

##### Email address

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 keto-genic 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 / m<sup>2</sup>  
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

##### 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

### 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/m<sup>2</sup>)

### 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

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1981619573

###### **Phone**

+98 21 2237 6420

###### **Email**

alitimeeee@gmail.com

## **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

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1981619573

###### **Phone**

+98 21 2235 7483

###### **Email**

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

**Province**  
Tehran  
**Postal code**  
1981619573  
**Phone**  
+98 21 2235 7384  
**Email**  
Atoosa.saidpour@gmail.com

## 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  
**Street address**  
NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods  
(Gharb) twon, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1981619573  
**Phone**  
+98 21 2235 7483  
**Email**  
alitimeeeee@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Atoosa Saidpour  
**Position**  
PhD of Nutrition  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
No. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd., Qods  
(Gharb) twon, Tehran, Iran  
**City**  
Tehran

## Person responsible for updating data

### 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**  
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**Postal code**  
1981619573  
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**Email**  
alitimeeeee@gmail.com

## 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