

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Sep 2023

### Effect of time restricted feeding on anthropometric measures, body composition, eating behavior, stress, brain derived neurotrophic factor (BDNF) levels, and lipopolysaccharide binding protein (LBP) levels in food addicted obese women: a randomized clinical trial

#### Protocol summary

##### Study aim

determination of the effect of time restricted feeding on anthropometric measures, body composition, eating behavior, stress, brain derived neurotrophic factor levels, and lipopolysaccharide binding protein levels in food addicted obese women

##### Design

participants first divided into two groups based on Body Mass Index (BMI) grade-1 obesity BMI=29.9-34.9 and grade-2 obesity BMI=34.9-39.9, then individuals in each group is assigned to intervention or the control group by randomized blocking method.

##### Settings and conduct

The population of this study obese women referred to the nutrition clinic of shahid beheshti university. Sample size 60 subjects (30 in the intervention group and 30 in the control group). Intervention Individuals will take weight loss diet with or without time restriction for 8 weeks based on the group they are in

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Body Mass Index between 30- 39.9 kg/m<sup>2</sup> inclination to participate in the study confirmation of food addiction based on YALE food addiction questionnaire age between 20-60y. Exclusion criteria having any kind of disease being on a weight loss diet in the last 2 months pregnancy or lactation menopause smoking using vitamin and/or mineral supplements continuous using any kind of drugs continuous using (more than 1 time/week) any probiotic products in the last month using any kind of antibiotics in the last three months using weight or appetite reducing drugs Sports activity that lasted more than three weeks from the start

##### Intervention groups

Individuals will receive weight loss diet with an intake time restricted to 10 am to 8 pm in intervention group or weight loss diet without time restriction in intake in

control group for 8 weeks based on the group they are in.

##### Main outcome variables

weight, body composition, eating behavior, stress, BDNF and LBP levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131228015968N7**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

##### Registration date

2020-10-25, 1399/08/04

##### Registrant information

##### Name

Atoosa Saidpour

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
School of nutrition

##### Country

Iran (Islamic Republic of)

##### Phone

-

##### Email address

a.saidpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-08-21, 1399/05/31

**Expected recruitment end date**

2022-08-22, 1401/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of time restricted feeding on anthropometric measures, body composition, eating behavior, stress, brain derived neurotrophic factor (BDNF) levels, and lipopolysaccharide binding protein (LBP) levels in food addicted obese women: a randomized clinical trial

**Public title**

Effect of time restricted feeding on anthropometric measures, body composition, eating behavior, stress, brain derived neurotrophic factor (BDNF) levels, and lipopolysaccharide binding protein (LBP) levels in food addicted obese women: a randomized clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

BMI between 30- 39.9 kg/m<sup>2</sup> inclination to participate in the study confirmation of food addiction based on YALE food addiction questionnaire age between 20-60y

**Exclusion criteria:**

having any kind of disease being on a weight loss diet in the last 2 months pregnancy or lactation menopause smoking using vitamin and/or mineral supplements continuous using any kind of drugs continuous using (more than 1 time/week) any probiotic products ( probiotic supplement, probiotic yogurt or probiotic cheese) in the last month using any kind of antibiotics in the last three months using weight or appetite reducing drugs

**Age**From **20 years** old to **60 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, participants were classified into two groups with obesity grade A (30-34.9) and obesity grade 2 (34.9-39.9) 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**

2020-10-05, 1399/07/14

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1399.03

**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, 4 weeks 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, 4 weeks and 8 weeks after intervention

### **Method of measurement**

Bio Impedance Analyzer

## 5

### **Description**

Fat Free Mass

### **Timepoint**

before intervention, 4 weeks and 8 weeks after intervention

### **Method of measurement**

Bio Impedance Analyzer

## **Secondary outcomes**

## 1

### **Description**

serum BDNF

### **Timepoint**

before intervention, 8 weeks after intervention

### **Method of measurement**

Elisa

## 2

### **Description**

serum LBP

### **Timepoint**

before intervention, 8 weeks after intervention

### **Method of measurement**

Elisa

## 3

### **Description**

Eating behavior

### **Timepoint**

before intervention, 8 weeks after intervention

### **Method of measurement**

The Three-Factor Eating Questionnaire

## 4

### **Description**

stress

### **Timepoint**

before intervention, 8 weeks after intervention

### **Method of measurement**

PSS-14

## **Intervention groups**

## 1

### **Description**

Intervention group: receives low calorie diet with intake time restricted to 10 A.M to 8 P.M for 8 weeks

### **Category**

Treatment - Other

## 2

### **Description**

Control group: receives low calorie diet without any restriction in intake time for 8 weeks

### **Category**

Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

nutrition clinic of Shahid Beheshti university of medical science

#### **Full name of responsible person**

Hanieh Irani

#### **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**

hanie.irani95@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. Morteza Abdollahi

**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**

morabd@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**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**

Hanieh Irani

**Position**

Msc. student of clinical 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**

hanie.irani95@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

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7384

**Email**

Atoosa.saidpour@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hanieh Irani

**Position**

Master student of clinical 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**

hanie.irani95@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