

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

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/m² 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/m² 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

AgeFrom **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/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, 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