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 orthe 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 questionaire age between 20-60y
Exclusion criteria:
having any kind of disease beeing 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/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
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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
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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
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NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods (Gharb) twon, Tehran
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Person responsible for scientific inquiries

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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