Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

Effect of the Gut Makeover diet with or without yoga on weight management in obese women with food addiction

Protocol summary

Study aim
Determining the effect of GM diet with or without Yoga on weight management in obese women

Design
An open label clinical trial with 136 eligible individuals in 4 groups, with parallel design, Random assignment using random blocks method using 4 Blocks

Settings and conduct
The population of this study includes obese and healthy women working in colleges and medical centers affiliated to Iran University of Medical Sciences and Shahid Beheshti University of Medical Sciences between the ages of 18-50. People in the first group receive a 500-calorie diet less than their energy intake, the second group will receive a 500-calorie diet in the GM diet, the women in the third group will receive a calorie restricted diet with yoga, and the fourth group will receive a calorie restricted diet in the GM diet .

Participants/Inclusion and exclusion criteria
Inclusion criteria: obese women aged 18-50 years old with body mass index of 30-40 kg / m 2; food addiction; no gout and chronic illnesses; no appetite and weight loss medications; no antibiotics in the last three weeks; no supplement intake; non-adherence to specific diet; no weight loss of 3 kg or more over the past 2 months; no neurological disorders; no pregnancy or lactation; regular menstrual cycle; no allergies; no desire to participate study. Exclusion criteria: acquired any acute illness; pregnancy during the study period; failure to follow intervention; migration; exclusion.

Intervention groups
4 groups (Calorie restriction group, GM calorie restriction group, Calorie restriction group with yoga, and GM calorie restriction group with yoga)

Main outcome variables
Anthropometric indices; body composition; serotonin plasma concentration; oxytocin plasma concentration; BDNF plasma concentration; appetite rate; stress level; food addiction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090822002365N24**
Registration date: **2020-01-15, 1398/10/25**
Registration timing: **prospective**

Last update: **2020-01-15, 1398/10/25**
Update count: **0**

Registration date
2020-01-15, 1398/10/25

Registrant information

Name
Mohammad Reza Vafa

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8670 4734

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-12-05, 1399/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of the Gut Makeover diet with or without yoga on weight management in obese women with food addiction

Public title
The effect of Gut Makeover diet with or without yoga on weight management

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Obese women with 18-50 years old BMI: 30-40 kg/m2 Food addiction based on YFAS questionnaire Lack of gout and chronic diseases such as diabetes, cardiovascular, liver, etc. Not taking drugs that affect appetite and weight No use of antibiotics in the last three weeks Not taking vitamin supplements and minerals Not following a specific diet No weight loss of 3 kg or more during the past 2 months No psychiatric illness Not being pregnant or breast-feeding Have a regular menstrual cycle No food allergies Willingness to participate in the study

Exclusion criteria:
Having any acute illness Pregnancy during the study period Failure to follow the intervention Immigration Exclusion from the study based on participants' personal preference

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **136**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample of the study included women working in colleges and medical centers affiliated to Iran University of Medical Sciences and Shahid Beheshti University of Medical Sciences. With a sample size of 136 people, 34 blocks of 4 will be produced using the online site (www.sealedenvelope.com) and participants will be assigned to one of four study intervention groups.

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 Iran University of Medical Sciences

Street address
Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

City
Tehran

Province
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Postal code
1449614535

Approval date
2019-12-15, 1398/09/24

Ethics committee reference number
IR.IUMS.REC.1398.918

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 changes

Timepoint
Weight changes was measured at baseline (before intervention) and at the end of week 8.

Method of measurement
Obesity status will be assessed by anthropometric indices (weight, body mass index, waist, hip circumference and waist to hip ratio) and body composition indices (body fat percentage, body fat free mass percentage, body fat weight, fat free mass, visceral fat percentage, visceral fat content in kg)

Secondary outcomes

1

Description
Plasma Serotonin Concentration

Timepoint
At the beginning of the study and after the intervention (end of week 8)

Method of measurement
The measurements will be performed by ZellBio kit (Made in Germany) by ELISA method.

2

Description
Plasma Oxytocin Concentration
Timepoint
At the beginning of the study and after the intervention (end of week 8)
Method of measurement
The measurements will be performed by ZellBio kit (Made in Germany) by ELISA method.

3

Description
BDNF plasma concentration
Timepoint
At the beginning of the study and after the intervention (end of week 8)
Method of measurement
It will be measured by Kate ZellBio (Made in Germany) ELISA method.

4

Description
Appetite
Timepoint
At baseline and after intervention (end of week 8)
Method of measurement
People's appetite will also be measured using the standardized Simplified Nutritional Appetite Questionnaire (SNAQ).

5

Description
Food addiction rate
Timepoint
At baseline and after intervention (end of week 8)
Method of measurement
Food addiction assessment will be performed by Yale Food Addiction Questionnaire (YFAS).

6

Description
Stress level
Timepoint
At baseline and after intervention (end of week 8)
Method of measurement
People's stress levels will be assessed by a 14-item Cognitive Stress Scale.

Intervention groups

1

Description
Intervention group 1: The group receiving a calorie restricted diet in the GM diet (a restriction of 500 calories less than their energy intake in the GM diet), for 8 weeks. The GM diet is divided into two 4-week phases and each phase is as follows: During the first 4 weeks, people are advised to: - Get three main meals a day without a snack. - The 12-hour meal period between dinner and breakfast. During this time, people are fasting and only allowed to drink water.- Eat 5 units of vegetables and 2 units of fruit group daily.- At each meal, receive a rich source of protein (animal source such as fish, eggs, Or nuts and seeds) .- Eat between 20 and 30 different types of plant sources (fresh edible plants, fruits, vegetables) each week. - Use olive oil and coconut oil as baking oil. - Chewing the food thoroughly in the mouth so that each bite is chewed 20 times in your mouth. - Do not calculate and limit your intake of calories. People are also recommended during the next 4 weeks: - can get ghee in a permissible amount. - Eat foods containing probiotic such as fermented milk (kefir) and increase intake of prebiotic-containing vegetables such as bananas, fennel, onions, garlic, and leeks. Also, during the next 4 weeks, participants must remove the following sources from their daily diet: - refined sugar, grains (such as wheat, rice, barley) and legumes (such as beans and lentils), caffeine, dairy (can be put on a diet after two weeks if it has no side effects). Two weeks before starting the GM diet participants are advised to remove all probiotic-containing products from their daily diet. Also, other types of probiotic-containing foods should be excluded from their diet during the study.
Category
Lifestyle

2

Description
Intervention group 2: Calorie restriction (500 calories less than energy need per person) with yoga. Yoga therapy: The intervention program includes asanas, pranayama, and relaxation strategies that will be held 3 sessions per week. These meetings will not be ongoing for the better recovery of the participants. The exercise program will also be determined based on issues including overload, repetition, intensity, timing, and type of exercise. In this study, yoga training courses and movement levels are increased each week based on the ability of the participants. Finally, it will reach 75 minutes in the final week.
Category
Lifestyle

3

Description
Intervention group 3: Restriction of calorie intake (500 calories less than the energy they need) in GM diet with yoga therapy
Category
Lifestyle

4

Description
Control group: During the study, subjects in the control group will received a daily restricted diet (500 calories less than the energy they need.)
Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Schools and Medical Centers affiliated to Iran University of Medical Sciences and Shahid Beheshti Un

Full name of responsible person
Dr. Mohammad Reza Vafa

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Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person
Dr Seyyed Abbas Motelian

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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, Iran University of Medical Sciences

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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Vafa

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
A part of the data will be shared, such as primary outcomes.
When the data will become available and for how long
Four months after the publication of the results.
To whom data/document is available
Researchers and students of university
Under which criteria data/document could be used
Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.
From where data/document is obtainable
Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com
What processes are involved for a request to access data/document
Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com
Comments