

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of low calorie DASH diet in comparison with low calorie diet on food addiction and weight management in individuals with food addiction and weight regain 2 years after bariatric gastric surgery

Protocol summary

Study aim

Determining the effect of low-calorie dash diet compared to low-calorie diet on weight management and food addiction in people with food addiction and weight regain, 2 years after sleeve surgery

Design

A parallel-group, double-blind, randomized, controlled, low-calorie diet clinical trial on 98 obese and overweight subjects two years after sleeve surgery, randomized with blocks of 4

Settings and conduct

The desired samples are selected according to the entry and exit criteria from three selected hospitals in Tehran, including two government hospitals (Sina and Martyr Mustafa Khomeini) and one private hospital (Ibn Sina). In order to investigate food addiction and the level of anxiety and depression in people Validated questionnaires are used by the participants in the study. Then other evaluations such as physical activity, body composition measurements, food intake status, and blood sugar and insulin serum levels are collected for the participants in the study. The duration of the study is 16 weeks.

Participants/Inclusion and exclusion criteria

- At least 2 years have passed since surgery
- Weight gain again after surgery
- No or very mild food addiction before sleeve surgery
- Suffering from food addiction based on the Yale questionnaire
- Non-entry criteria:
- Suffering from any acute illness
- Suffering from chronic diseases such as diabetes, cardiovascular, liver, etc
- Taking drugs that affect appetite and weight

Intervention groups

Two groups of 49 people are randomly placed in the group receiving the dash diet and the low calorie diet

Main outcome variables

diet weight regain food addiction blood sugar appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N26**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	therefore the participants, researchers, and the data analyst will be unaware that each person in the group receiving a high-calorie diet or a low-calorie diet will receive it. Blinding will be done by a third person outside the study. Therefore, the research team will not know the details of the groups until the end of data collection and data analysis.
Scientific title The effect of low calorie DASH diet in comparison with low calorie diet on food addiction and weight management in individuals with food addiction and weight regain 2 years after bariatric gastric surgery	Placebo Not used
Public title The effect of DASH diet in comparison with low calorie diet on food addiction and weight management in individuals with food addiction and weight regain 2 years after bariatric gastric surgery	Assignment Parallel
Purpose Education/Guidance	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Willingness to participate in the study At least 2 years have passed since surgery Weight gain again after surgery No or very mild food addiction before sleeve surgery Suffering from food addiction based on the Yale questionnaire Exclusion criteria: Any acute illness Suffering from chronic diseases such as diabetes, cardiovascular disease Taking drugs that affect appetite and weight pregnancy	Secondary Ids empty
Age From 18 years old to 65 years old	Ethics committees 1
Gender Both	Ethics committee Name of ethics committee Research Ethics committees of National Nutrition & Food Technology Research Institute Street address No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town City Tehran Province Tehran Postal code 1981619573
Phase 3	Approval date 2023-01-22, 1401/11/02
Groups that have been masked • Participant • Investigator	Ethics committee reference number IR.SBMU.nnftri.Rec.1401.063
Sample size Target sample size: 98	Health conditions studied 1
Randomization (investigator's opinion) Randomized	Description of health condition studied Overweight and Obesity
Randomization description Participants in the study are selected by convenience sampling method. Patients are classified according to age and gender, and each person will be placed in a group receiving group of dash diet or low-calorie diet using 1:1, quadruple random blocks. Quadruple blocks are randomly designed through software such as (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Assigning A or B to the group of dash diet or low-calorie diet will be done by someone outside the research so that the researchers remain blind. According to the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for randomly assigning patients. After each patient enters, according to the quadruple blocks prepared in the first stage, each patient is randomly assigned to group A or B. Assignment process will be done consecutively until the sampling is completed.	ICD-10 code E66.01 ICD-10 code description Morbid (severe) obesity due to excess calories
Blinding (investigator's opinion) Double blinded	Primary outcomes 1
Blinding description This study will be a double-blind clinical trial, and	Description Weight Timepoint at the beginning of the study and 16 weeks later at the end of the study Method of measurement Scale

2

Description

food addiction

Timepoint

at the beginning of the study and 16 weeks later at the end of the study

Method of measurement

Food addiction questionnaire is not officially defined in DSM-5. But evidence has shown that there is considerable overlap between the characteristics of food addiction and the DSM-5 criteria for drug addiction. Therefore, the YFAS food addiction scale questionnaire, which is based on DSM-5 criteria, is widely used to diagnose food addiction. In the present study, food addiction was diagnosed by the YFAS questionnaire. The YFAS is a 25-item questionnaire, which examines eating behaviors based on seven diagnostic criteria for drug addiction (by DSM-5). People are diagnosed with food addiction if they have three or more of the seven criteria in the past year, along with the presence of a clinical disorder in the past 12 months. The total scores of this questionnaire are calculated from 0 to 7.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention period in this clinical trial will be 16 weeks. Intervention group 1: People receive DASH-low calorie diet. Considering that people have undergone surgery and the calories required in the second year of surgery are calculated to be 1000-1200 calories. According to the same guidelines, the amount of protein intake will be 60 to 100 grams of protein per day or equivalent to 1.1 to 2.1 grams per kilogram of body weight based on the level of activity of the person. 35 to 48 percent of the required energy will come from carbohydrates and the rest of the energy will come from fat. It was more than 30%. In the group receiving the DASH diet, the diet will be adjusted according to the DASH pattern. Patients are visited once every 2 weeks during the study period. At the beginning of the study, at the end of the 16th week, the level of anxiety and depression in the people participating in the study was used with validated questionnaires. Then other evaluations such as physical activity, body composition measurements, food intake status, and serum levels of blood sugar and insulin were collected for the participants in the study. The level of physical activity and food addiction will be evaluated using the Yale questionnaire.

Category

Lifestyle

2

Description

Intervention group 2: People on a low-calorie diet receive 1000-1200 calories per day. At the beginning of the study, at the end of the 16th week, the level of anxiety and depression in the people participating in the study was used with validated questionnaires. Then other evaluations such as physical activity, body composition measurements, food intake status, and serum levels of blood sugar and insulin were collected for the participants in the study. The level of physical activity and food addiction will be evaluated using the Yale questionnaire.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

Sina Hospital, Hasan Abad Square, Imam Khomeini St, Tehran.

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2

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

No 9, Mostafa Khomeini Hospital, Italia St, South Phalestine St, Keshavarz Blvd, valiasr Square

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3

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

Ayatollah Kashani Blvd, second floor of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

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soodehrazeghi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

90

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

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Coded data of the participants, study protocol, and report of the main output of the study would be available in case of researchers' reasonable request sending to principal investigator of the study 6 months after publishing the article.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

University researchers

Under which criteria data/document could be used

Have no condition

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

sending email

Comments