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)

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+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

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

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

Purpose
Education/Guidance

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

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be a double-blind clinical trial, and 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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Approval date
2023-01-22, 1401/11/02

Ethics committee reference number
IR.SBMU.nnftri.Rec.1401.063

Health conditions studied

1

Description of health condition studied
Overweight and Obesity

ICD-10 code
E66.01

ICD-10 code description
Morbid (severe) obesity due to excess calories

Primary outcomes

1

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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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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1416643491
Phone
+98 21 8896 6130
Email
info@mkht.ir

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 Sadeghieh,Tehran

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1481795693

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Email
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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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1981619573

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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
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

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 updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Position
Associate professor

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Ph.D.

Other areas of specialty/work
Nutrition

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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