Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of functional cake in patients with metabolic syndrome

Protocol summary

Study aim
Evaluating the effect of cake preparation with oak flour with cake made with wheat flour following a balanced hypocaloric diet on nutritional status and metabolic profile in obese and overweight patients with metabolic syndrome

Design
90 patients are randomly divided into two groups as follows: Group A: The intervention group received 30 gr of oak cake twice a day + a balanced hypocaloric diet Group B: The control group received 30 gr of wheat cake twice a day + a balanced hypocaloric diet This process is followed for 10 weeks.

Settings and conduct
This was a randomized, double-blinded, 10-week study. Participants were randomly allocated to two groups receiving either oak cake (2×30 g)/day o or wheat (2×30 g)/day. All participants were put on a caloric-restricted diet throughout the 10-week study. Body composition and biochemical indices were assessed before and after the intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria were both sexes between 20-60 years of age, body mass index (BMI) of 25–35 kg/m2, having metabolic syndrome

Intervention groups
1: received 30 gr of oak cake twice a day + a balanced hypocaloric diet 2: received 30 gr of oak cake twice a day + a balanced hypocaloric diet

Main outcome variables
HOMA-IR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170506033836N2**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **retrospective**
Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date
2020-10-15, 1399/07/24

Registrant information

Name
Mohsen Mohammadi Sartang

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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mohamadism@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of functional cake in patients with metabolic syndrome

Public title
The effects of functional cake

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 20 to 60 years Body mass index (BMI) of

25–35 kg/m2 According to the ATP III definition, metabolic syndrome is present if three or more of the following five criteria are met: waist circumference over 102 cm (men) or 88 cm (women), blood pressure over 130/85 mmHg, fasting triglyceride (TG) level over 150 mg/dl, fasting high-density lipoprotein (HDL) cholesterol level less than 40 mg/dl (men) or 50 mg/dl (women) and fasting blood sugar over 100 mg/dl Stable body weight (weight change less than 3 kg in the last 3 months) Not participating in weight loss programs for the past 6 months

Exclusion criteria:

Diabetic patients receiving blood sugar-lowering drugs and insulin History of alcohol consumption Smoking Pregnant and lactating women People with mental illness, cancer, thyroid, cardiovascular, pulmonary, renal, hepatic, eating disorders Taking drugs that affect appetite, body weight and lipid metabolism or have anti-inflammatory effect

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization between the two groups will be done by block randomization. In this way, the size of the blocks is considered 4 and all possible scenarios are written for two groups A and B and this process is repeated until the number reaches 80 people. Then a number is given to each of the block components using a random number table. The numbers given to each of the block components represent the number assigned to each person in advance. This identifies the group assigned to each individual.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, Investigators, and associated research and laboratory personnel will remain blinded to patient allocation until after study completion.The designed placebo is completely similar to the intervention group in terms of color, size and model. For blinding the packs of cakes is coded in A and B sounds by the third party who is not involved in the research process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Baqiyatallah University of Medical Sciences, Tehran, Iran

Street address

Tehran, Vanak Square, Mulla Sadra Street

City

Tehran

Province

Tehran

Postal code

1111111111

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.002

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

2

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Anthropometric measures

Timepoint

Before and after the intervention

Method of measurement

Bioelectric impedance analysis

2

Description

blood pressure

Timepoint

Before and after the intervention

Method of measurement

digital sphygmomanometer

3

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Commercial kits

4

Description

Insulin

Timepoint

Before and after the intervention

Method of measurement

ELISA kit

5

Description

Insulin resistance index (HOMA-IR)

Timepoint

Before and after the intervention

Method of measurement

Formula

6

Description

Lipids profile

Timepoint

Before and after the intervention

Method of measurement

Commercial kits

7

Description

Malon de aldehyde (MDA)

Timepoint

Before and after the intervention

Method of measurement

Tubarbitoric acid method (TBARS)

8

Description

C-reactive protein

Timepoint

Before and after the intervention

Method of measurement

ELISA kit

9

Description

Adiponectin

Timepoint

Before and after the intervention

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Functional cake group containing oak powder.The caloric content of both oak and wheat cakes will be equal, so due to the higher calorie content of oak flour, 10 grams of oak flour is sweetened in the preparation of cakes containing oak flour and about 13.8 grams of wheat flour will be used in the preparation of cakes containing wheat flour.In this way, a cake with a weight of approximately 30 grams will be produced and standardized packaging

Category

Treatment - Other

2

Description

Control group: Ordinary cake group containing wheat powder

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

hospitals and clinics

Full name of responsible person

Mohsen Mohamadi

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Khalili street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person
Dr Siavoosh Babajafari

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mohsen Mohamadi

Position
Phd

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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

Laboratory data file can be published

When the data will become available and for how long

After the intervention

To whom data/document is available

For researchers and industry professionals

Under which criteria data/document could be used

The use of data is allowed in the industry

From where data/document is obtainable

Mohsen Mohammadi Sartang mohamadism@sums.ac.ir

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

The possibility of requesting is checked via email and will be answered within a week

Comments