

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of biscuit fortified with whey protein and dietary fiber on biochemical and behavioral factors of appetite, anthropometric indices, and glycemic profile in overweight or obese adults

Protocol summary

Study aim

Determine the effect of biscuit fortified with whey protein and dietary fiber on biochemical and behavioral factors of appetite, anthropometric indices, and glycemic profile in overweight or obese adults

Design

In this study, 100 subjects will be selected, who will be overweight or obese, and follow the inclusion criteria. Then they will be allocated to intervention groups, thorough balanced block randomization method.

Settings and conduct

Participants will be invited to study thorough announcement. Sampling will be done in Imam Reza clinic. Participants will be randomly allocated to a group of intervention or control. Blinding protocol will done to blind participants and researcher from allocation of subjects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male and female gender; age 20 -50 years old; BMI higher than 25 kg/m². Non-inclusion criteria: follow weight loss diet during 6 months ago; psychological disorders related to eating disorders; use of multivitamin-mineral supplements and herbal medications; chronic disease and use drugs, which affected the metabolism, body composition and appetite; food allergy; pregnancy and lactation; alcohol and tobacco use.

Intervention groups

Participants allocated to 1) intake of biscuit fortified with whey protein and dietary fiber , 2) intake of biscuit fortified with whey protein , 3) intake of biscuit fortified with dietary fiber, or 4) intake of non fortified biscuit as control group. All participants will follow a diet with reduction of 500 kcal of total energy.

Main outcome variables

Energy intake; appetite score; serum level of ghrelin, leptin, glucagon like peptide, serotonin, fasting blood

sugar, insulin, lipid profiles, and weight, waist circumference, waist to height ratio, body mass index, fat mass, mood indices, and quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180509039596N2**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Zahra Hassanzadeh-Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1007

Email address

zhasanzadeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of biscuit fortified with whey protein and dietary fiber on biochemical and behavioral factors of appetite, anthropometric indices, and glycemic profile in overweight or obese adults

Public title

Effect of whey protein and dietary fiber on appetite and weight management

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female gender Age 20 -50 years old BMI higher than 25 kg/m2

Exclusion criteria:

Follow weight loss diet during 6 months ago
Psychological disorders related to eating disorders Use of multivitamin-mineral supplements and herbal medications Chronic disease and use drugs, which affected the metabolism, body composition and appetite
Food allergy Pregnancy and lactation Alcohol and tobacco use

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization method will be used to random allocation, and randomization unit will be a subject. At first, we will design blocks with different sequences of A, B, C, and D. Then we will select a block, in a draw. Each block contain a sequence of A, B, C, and D which determine intervention groups. Participants and researchers will not be notified the packages content.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, clinical assessor, and researcher will be blind. Participants, clinical assessor, and researcher don't know subjects allocated to which group. Participants will be identified by A, B, C, and D letters.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.SUMS.REC.1396.173

Health conditions studied**1****Description of health condition studied**

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Energy intake and appetite

Timepoint

Baseline, 14, 28, 42, and 60 days after intervention

Method of measurement

Food record questionnaire, and appetite assessment questionnaire

Secondary outcomes**1****Description**

Ghrelin

Timepoint

Baseline and end of intervention

Method of measurement

Elisa kit

2

Description

Leptin

Timepoint

Baseline and end of intervention

Method of measurement

Elisa kit

3

Description

Serotonin

Timepoint

Baseline and end of intervention

Method of measurement

Elisa kit

4

Description

Glucagon-like peptide-1 (GLP-1)

Timepoint

Baseline and end of intervention

Method of measurement

Elisa kit

5

Description

Fasting blood glucose

Timepoint

Baseline and end of intervention

Method of measurement

Auto Analyzer Biochemistry

6

Description

Insulin

Timepoint

Baseline and end of intervention

Method of measurement

Elisa kit

7

Description

Blood lipids including total cholesterol, low density lipoprotein, high density lipoprotein, and triglyceride

Timepoint

Baseline and end of intervention

Method of measurement

Auto Analyzer Biochemistry

8

Description

Body weight

Timepoint

Baseline and end of intervention

Method of measurement

weight scale

9

Description

Waist circumference

Timepoint

Baseline and end of intervention

Method of measurement

Strip meter

10

Description

Waist to height ratio

Timepoint

Baseline and end of intervention

Method of measurement

Strip meter

11

Description

Fat mass percentage

Timepoint

Baseline and end of intervention

Method of measurement

Bioelectrical impedance analysis (BIA)

12

Description

Mood indices

Timepoint

Baseline and end of intervention

Method of measurement

Emotionality Activity Sociability (EAS) questionnaire

13

Description

Quality of Life

Timepoint

Baseline and end of intervention

Method of measurement

Quality of Life questionnaire

14

Description

Body mass index

Timepoint

Baseline and end of intervention

Method of measurement

Weight scale and strip meter

15

Description

Fat free mass

Timepoint

Baseline and end of intervention

Method of measurement

Bioelectrical impedance analysis (BIA)

Intervention groups

1

Description

Intervention group: Whey protein and dietary fiber enriched biscuits. Biscuits will be consumed during 60 days of intervention duration. Participants will take 14 grams pre day whey protein. Dietary fiber will be added to biscuits as wheat bran, 15% of wheat flour.

Category

Treatment - Other

2

Description

Intervention group: Whey protein enriched biscuits. Biscuits will be consumed during 60 days of intervention duration. Participants will take 14 grams pre day whey protein.

Category

Treatment - Other

3

Description

Intervention group: Dietary fiber enriched biscuits. Biscuits will be consumed during 60 days of intervention duration. Dietary fiber will be added to biscuits as wheat bran, 15% of wheat flour.

Category

Treatment - Other

4

Description

Control group: Biscuit without whey protein or dietary fiber. Biscuits will be consumed during 60 days of intervention duration.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Specialized Clinic

Full name of responsible person

Zahra Hassanzadeh-Rostami

Street address

Zand street, Namazi square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

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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

Zahra Hassanzadeh-Rostami

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Shiva Faghih

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Associate professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Hassanzadeh-Rostami

Position

PhD Student

Latest degree

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Other areas of specialty/work

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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

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

Data Dictionary

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