Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 circumeference
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 fibe. 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.
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3212 7001
Email
Hassanzadeh_z8@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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
Street address
Nutrition and Food Sciences School, Razi Street
City
Shiraz
Province
Fars
Postal code

7153675541

Phone
+98 71 3725 1001

Email
Hassanzadeh_z8@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Shiva Faghih

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Nutrition and Food Sciences School, Razi Blvd.

City
Shiraz

Province
Fars

Postal code
7153675541

Phone
+98 71 3725 1001

Email
Shivafaghih@gmail.com

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
Master

Other areas of specialty/work
Nutrition

Street address
Nutrition and Food Sciences School, Razi Blvd.

City
Shiraz

Province
Fars

Postal code
7153675541

Phone
+98 71 3725 1001

Email
Hassanzadeh_z8@yahoo.com

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