Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of low-calorie diet rich in whole grains and legumes on appetite control, improvement of hedonic eating behavior, lipid and glycemic profile, Serum levels of serotonin and insulin and hs-CRP in Obese women with hedonic eating behavior

Protocol summary

Study aim

Determination of the effect of a low-calorie rich diet on whole grains and legumes on appetite control, improved hedonic eating behavior, lipid and glucose profile, serum levels of serotonin and insulin, and hs-CRP in obese women and hedonic eating behavior

Design

A clinical trial with a control group, with parallel groups and a randomized single blind

Settings and conduct

The purpose of this study was to investigate the effect of whole grain and legume consumption. It is also located in the city of Urmia in Imam Khomeini Medical Center. Public gathering is also being used at Imam Khomeini Medical Center and the city level. Initially, the body composition analysis for each woman is performed using the BIA machine and the hedonic eating behavior questionnaire is filled in, then a diet is given to them according to their weight, and the women go to another day for testing and dieting. Subsequent referrals are from 6 to 12 weeks. Participants in this study are blinded and unaware that they are in the intervention and control groups because the intervention and control groups each visit the Imam Khomeini Medical Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with Hedonic Eating Behavior, BMI> 25, 19 to 45 years؛ exclusion Autoimmune, Heart, Diabetes, Cancer, Hypertension, Gastrointestinal,dyslipidemy,Pregnancy and Lactation, Other Diet,Antibiotics Use for 3 months and pills that affect appetite

Intervention groups

The intervention group received a daily diet of 500 kcal reduction plus at least 4 whole grains and 3 legumes daily and the control group received a diet of only 500 kcal lower daily

Main outcome variables

Triglycerides, total cholesterol, high density lipoprotein and low density lipoprotein, fasting blood sugar, body mass index, C-reactive protein, body composition,HOMA IR, QUICKI, appetite, serotonin, systolic blood pressure, Diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044563N2**
Registration date: **2020-03-21, 1399/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-21, 1399/01/02**
Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name
Asma Zamanian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4409 2875
Email address
asma_wzm@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of low-calorie diet rich in whole grains and legumes on appetite control, improvement of hedonic eating behavior, lipid and glycemic profile, Serum levels of serotonin and insulin and hs-CRP in Obese women with hedonic eating behavior

Public title

The Effect of Low-Calorie diet rich in whole grains and legumes on Obese Women with Hedonic Eating Behaviors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with BMI ≥25 Hedonic eating behavior

Exclusion criteria:

Chronic diseases such as diabetes and coronary heart disease Cancer smoking Uncontrolled High Blood Pressure (above 100/160 mmHg) Pregnancy and lactation Use of antibiotic drugs for 3 months Digestive tract diseases Autoimmune disease Use of immunosuppressants Taking medication for dyslipidemia Use of medications that affect metabolism, blood sugar, appetite and food intake Taking non-steroidal anti-inflammatory drugs Observe a specific diet Take a diet to lose weight

Age

From **19 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using stratified block randomization And according to BMI, people are divided into two groups

Blinding (investigator's opinion)

Single blinded

Blinding description

The intervention and control groups each go to the clinic on separate days and receive their diet, and the control group, like the intervention group, assumes that the weight loss diet is the same for everyone, but this is the case. That the control and intervention groups did not know each other's diet because they received their diet separately

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Sero Highway, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-10-02, 1398/07/10

Ethics committee reference number

IR.UMSU.REC.1398.244

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

triglyceride

Timepoint

Blood triglyceride levels at baseline (before intervention) and at the end of the study at week 12

Method of measurement

Serum triglyceride concentration measurement by enzymatic method with BT1500

2

Description

High-density lipoprotein

Timepoint
Blood High-density lipoprotein levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum high-density lipoprotein concentration measurement by enzymatic method with BT1500

3

Description
Low-density lipoprotein
Timepoint
Blood Low-density lipoprotein levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum low-density lipoprotein concentration measurement by enzymatic method with BT1500

4

Description
Fasting blood sugar
Timepoint
Blood Fasting blood sugar levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum fasting blood sugar concentration measurement by enzymatic method of glucose oxidase with BT1500

5

Description
Total cholesterol
Timepoint
Blood Total cholesterol levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum total cholesterol concentration measurement by enzymatic method with BT1500

6

Description
C-reactive protein
Timepoint
Blood C-reactive protein levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum total cholesterol concentration measurement by enzymatic method with BT1500

7

Description
Appetite
Timepoint
In the first weeks, 6 and 12 study and each day for 3 days at noon meal (before eating the main meal and after eating for 3 hours will be filled as 1 hour, 2 hours and 3 hours after meal)
Method of measurement
Visual Analogue Scale

8

Description
Hedonic eating behavior
Timepoint
The first week and 12 studies were assessed using a questionnaire
Method of measurement
Using the Power of Food Scale Questionnaire

9

Description
Insulin
Timepoint
Blood Insulin levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Measurement of serum insulin concentration by immuno-radiometric method with BT1500

10

Description
Serotonin
Timepoint
Blood Serotonin levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum Concentration Determination by ELISA

11

Description
Body mass index
Timepoint
Body mass index measurement in the first week and 12 studies
Method of measurement
Using height and weight values

Secondary outcomes

1

Description
Weight
Timepoint
Weight measurement at baseline (before intervention) and at 1, 6 and 12 weeks
Method of measurement
The weight of a person with minimal clothing and no shoes is measured to the nearest with BIA

2

Description
Physical activity
Timepoint
Physical activity measurement at baseline (before intervention) and at 1, 6 and 12 weeks
Method of measurement
Measurement of physical activity at three levels of light,

moderate and vigorous using the International Physical Activity Questionnaire

3

Description
Systolic blood pressure
Timepoint
Systolic blood pressure measurement at baseline (before intervention) and at 1 and 12 weeks
Method of measurement
Using a calibrated digital barometer

4

Description
Diastolic blood pressure
Timepoint
Diastolic blood pressure measurement at baseline (before intervention) and at 1 and 12 weeks
Method of measurement
Using a calibrated digital barometer

5

Description
Height
Timepoint
Measurement of individuals height at baseline (before intervention)
Method of measurement
Using BIA

Intervention groups

1

Description
Intervention group: Low-calorie diet (500kg reduction per person daily requirement) plus at least 4 whole grains and 3 legumes per day for three months
Category
Treatment - Other

2

Description
Control group: Low-calorie diet (500kg reduction per person daily requirement) for three months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Training Center
Full name of responsible person
Majid Manafi
Street address
Ershad Boulevard, Ayatollah Modares Boulevard, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
81351-57157
Phone
+98 44 3345 9538
Fax
+98 44 3346 9935
Email
asma_wzm@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Vice Chancellor for Research and Technology, Urmia University, University Headquarters, Resalat Boulevard, Emergency Stage
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3193 7224
Fax
+98 44 3224 0642
Email
asma_wzm@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
1
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Asma Zamanian
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Kosar Dormitory,Urmia University of Medical Sciences,Nazlou, Serow Road
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
asma_wzm@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Majid Manafi
Position
Instructor and faculty member
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Sero Highway, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
0098 44 5714783734
Phone
+98 44 3223 4897
Email
majidmanafi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Asma Zamanian
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Kosar Dormitory,Urmia University of Medical Sciences,Nazlou, Serow Road
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 21 4409 2875
Fax
Email
asma_wzm@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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