# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jul 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**

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Iran (Islamic Republic of)

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**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

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Urmia

**Province**

West Azarbaijan

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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
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Ershad Boulevard, Ayatollah Modares Boulevard, Urmia
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## Sponsors / Funding sources

**1**

**Sponsor**
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Oroumia University of Medical Sciences
**Full name of responsible person**
Iraj Mohebbi
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Vice Chancellor for Research and Technology, Urmia University, University Headquarters, Resalat Boulevard, Emergency Stage
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**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**
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Asma Zamanian
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Masters student
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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