

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effects of low-calorie balanced diet containing wholegrain bread and wholegrain rice on indicators of metabolic syndrome in obese and overweight patients.

Protocol summary

Summary

The aim of this study is to determine the effect of low-calorie balanced diet containing wholegrain bread and wholegrain rice on indicators of metabolic syndrome in obese and overweight patients. This study is a randomized clinical trial. In this study, obese and overweight people are invited. The number of samples was 80. Sampling is done on the basis of the balanced block. Participants based on balanced block, will be divided into two groups. Wholegrain bread and wholegrain rice with low-calorie balanced diet will be given to the intervention group. In the second group, ordinary bread and ordinary rice with low calorie balanced diet will be given. intervention is 12 weeks. At the beginning and end of the intervention, blood samples will be taken. And the parameters measured. Weight, waist circumference and blood pressure will be measured monthly. Inclusion criteria: At least three of the indicators have metabolic syndrome : abdominal obesity; high blood sugar; high blood fat and blood pressure; People with obesity and overweight(body mass index greater than 25); Willingness to cooperate Exclusion: disease leading to hospitalization; Or discharge from the hospital; the person is under a special regime; pregnant and lactating women; professional athletes; People with type 1 diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062422905N1**

Registration date: **2016-09-25, 1395/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-25, 1395/07/04

Registrant information

Name

Mohadese Tondro

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy Shiraz University of Medical Sciences

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of low-calorie balanced diet containing wholegrain bread and wholegrain rice on indicators of metabolic syndrome in obese and overweight patients.

Public title

Effects of low-calorie balanced diet containing wholegrain bread and wholegrain rice on indicators of metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least three of the indicators have metabolic syndrome include: Abdominal obesity; High blood sugar; High blood fat; Blood pressure; People with obesity and overweight (BMI greater than 25); Willingness to cooperate
Exclusion: Disease leading to hospitalization or discharge from the hospital; The person is under a special regime; Pregnant and lactating women; Professional athletes; People with type 1 diabetes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Deputy Shiraz University of Medical Sciences

Street address

Zand Blvd

City

Shiraz

Postal code**Approval date**

2015-10-11, 1394/07/19

Ethics committee reference number

IR.SUMS.REC.1394.118

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

Obesity

ICD-10 code

E_66

ICD-10 code description

Obesity due to excess calories

2**Description of health condition studied**

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

3**Description of health condition studied**

Hypertension

ICD-10 code

I15

ICD-10 code description

Secondary hypertension

4**Description of health condition studied**

Hyperlipidaemia

ICD-10 code

E78

ICD-10 code description

Disorders of lipoprotein metabolism and other lipidaemias

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

waist circumference

Timepoint

Early intervention, Fourth Week, Eight Week, End of intervention

Method of measurement

by meter.centimeter

2**Description**

fasting blood sample

Timepoint

The beginning and end of the intervention

Method of measurement

measured by enzymatic spectrophotometry analysis.basiis mg/dl

3**Description**

blood pressure

Timepoint

Early intervention, Fourth Week, Eight Week, End of intervention

Method of measurement
mmHg,with an automatic sphygmomanometer

4

Description
lipid profile

Timepoint
The beginning and end of the intervention

Method of measurement
measured by enzymatic spectrophotometry
analysis.basis mg/dl

5

Description
Weight

Timepoint
Early intervention, Fourth Week, Eight Week,End of
intervention

Method of measurement
scales Seca (made in Germany) and 1.0 kg
accuracy.basis kg.

Secondary outcomes

1

Description
body mass index

Timepoint
The beginning and end of the intervention

Method of measurement
Measured height and weight

Intervention groups

1

Description
Intervention group:200 gram wholemeal bread and 100
gram wholegrain rice with a balanced low calorie diet for
12 weeks.

Category
Treatment - Other

2

Description
control Group: bread and white rice with a balanced low
calorie diet for 12 weeks.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Clinic
Full name of responsible person

Mousa Salehi,PhD of Nutrition

Street address
Bargh St, Ghasrodasht Ave
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Dputy of Shiraz University of Medical
Science

Full name of responsible person
Dr.Seyed Basir Hashemi

Street address
Zand Blvd

City
Shiraz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source
Research Dputy of Shiraz University of Medical Science

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Musa Salehi

Position
PhD/Associate Professor

Other areas of specialty/work

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Mousa Salehi

Position

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty