Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Whole Wheat and Barley Bread on Appetite Control, Energy Intake, Anthropometric Indices, Body Composition, Blood Pressure, and Some Biochemical Markers in Obese or Overweight Individuals with Type 2 Diabetes

Protocol summary

Study aim
Comparison of the effects of consuming whole wheat and barley bread on appetite control, energy intake, anthropometric indices, body composition, blood pressure, and some biochemical markers in obese or overweight individuals with type 2 diabetes

Design
A randomized, controlled, single-blind, clinical trial with 3 parallel groups, on 93 patients, randomized with a stratified block method based on the age confounder.

Settings and conduct
93 eligible individuals invited through a public call or referred to health education centers of Shiraz University of Medical Sciences, after being informed and obtaining informed consent, will be randomly assigned to 3 groups. Participants receive the breads belonging to their group, which are labeled with the letters A, B, and C in line with the groups to blind the participants, and consume them daily for 8 weeks. Anthropometric and biochemical indices, body composition, appetite score and dietary intake are assessed before and after the study.

Participants/Inclusion and exclusion criteria
Overweight or obesity individuals aged 18 and above and with diabetes. Conditions of non-entry: Insulin use, daily consumption of whole bread, pregnancy or breastfeeding, smoking or alcohol use, following special diets, chronic digestive disorders, antibiotics taken or hospitalization within the past month, taking fiber supplements routinely or within the past month, individuals requiring a low-residue diet. Exclusion criteria: Consuming less than 80% of breads, become pregnant or hospitalized, experience active infections or trauma

Intervention groups
1- First intervention group: Receive 1.5 pieces of whole wheat bread daily for 8 weeks, 2- Second intervention group: Receive 2 pieces of whole barley bread daily for 8 weeks, 3- Control group: Receive 1.5 pieces of white wheat bread daily for 8 weeks.

Main outcome variables
Anthropometric and glycemic indices

General information

Reason for update

Acronym
WBOD

IRCT registration information
IRCT registration number: **IRCT20250507065638N1**
Registration date: **2025-06-25, 1404/04/04**
Registration timing: **prospective**

Last update: **2025-06-25, 1404/04/04**
Update count: **0**

Registration date
2025-06-25, 1404/04/04

Registrant information

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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

2025-08-01, 1404/05/10

Expected recruitment end date

2026-03-15, 1404/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Whole Wheat and Barley Bread on Appetite Control, Energy Intake, Anthropometric Indices, Body Composition, Blood Pressure, and Some Biochemical Markers in Obese or Overweight Individuals with Type 2 Diabetes

Public title

Comparison of the Effects of Whole Wheat and Barley Bread on health-related indicators in Obese or Overweight Individuals with Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Overweight or obesity individuals aged 18 and above who either meet one of the diagnostic criteria for type 2 diabetes or have been diagnosed with diabetes and are taking medication to control their blood glucose

Exclusion criteria:

Insulin use Daily consumption of whole bread when examining people's dietary habits before the study began Pregnancy or breastfeeding Smoking or alcohol use Following special diets such as ketogenic, vegetarian, weight control diet, diabetic diet, etc. Chronic digestive disorders including chronic diarrhea, Crohn's and ulcerative colitis, and celiac disease Antibiotics taken within the past month Hospitalization within the past month Taking fiber supplements routinely or within the past month Individuals requiring a low-residue diet

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the stratified block method will be used, in which individuals are classified based on the age confounder (<55 or ≥55 years) and then, by using the Random Allocation Software, they will be randomly divided into 3 groups of whole wheat bread (A), whole barley bread (B), and white bread (C) as the control group in a 1:1:1 ratio. 1- Group 1: Receiving 1.5 pieces of whole wheat bread daily for 8 weeks 2- Group 2: Receiving 2 pieces of whole barley bread daily for 8 weeks 3- Group 3: Receiving 1.5 pieces of white wheat bread daily for 8 weeks as the control group For allocation concealment, an out-of-study person will give individuals sealed envelopes that determine whether they are in the intervention or control group. Breads will be in the same shape and individuals will not be aware of their grouping. Only the principal investigator will know the type of loaves and the groupings.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind trial, meaning that the patients will not be aware of the type of intervention they will receive until the end of the study. The breads will be identical in appearance, and participants wont know their group assignment. During the intervention, the researchers will label the products and groups using codes, so participants remain unaware of the specific intervention they are receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shiraz University of Medical Sciences

Street address

Nutrition and Food Sciences School, Razi Blvd., Shiraz

City

Shiraz

Province

Fars

Postal code

7153675500

Approval date

2025-06-08, 1404/03/18

Ethics committee reference number

IR.SUMS.REC.1404.126

Health conditions studied

1

Description of health condition studied

Obese or overweight individuals with type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied
Obese or overweight with type 2 diabetes
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Body mass index
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating using the formula using height and weight

2

Description
Waist circumference
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
meter

3

Description
Body weight
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
scale

4

Description
Waist-to-height ratio
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By dividing the waist measurement by height

5

Description
Waist-to-hip ratio
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By dividing the waist measurement by hip measurement

6

Description
Body shape index
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating with the formula using body mass index, waist circumference and height

7

Description
Body roundness index
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating using the formula with using waist circumference and height

8

Description
Body fat mass
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

9

Description
Skeletal muscle mass
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

10

Description
Body fat percentage
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

11

Description
Appetite score
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Visual Analogue Scale questionnaire

12

Description
Energy intake
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
24-hour dietary recall (24hr)

13

Description
Fiber intake
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
24-hour dietary recall (24hr)

14

Description
Macronutrients intake
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
24-hour dietary recall (24hr)

15

Description
Micronutrients intake
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
24-hour dietary recall (24hr)

16

Description
Fasting blood sugar
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kit and autoanalyzer

17

Description
2-hours postprandial glucose
Timepoint
At the beginning of the study and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kit and autoanalyzer

18

Description
Hemoglobin A1C
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kit and autoanalyzer

19

Description
Homeostasis model assessment-estimated insulin resistance (HOMA-IR) index
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating using the formula with using glucose and insulin

20

Description
Fasting insulin
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

Secondary outcomes

1

Description
High-sensitivity C-Reactive Protein
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

2

Description
Systolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Digital sphygmomanometer

3

Description
Diastolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement

Digital sphygmomanometer

4

Description
Triglyceride
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kits and autoanalyzer

5

Description
HDL (high-density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kits and autoanalyzer

6

Description
LDL (low-density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kits and autoanalyzer

7

Description
Total cholesterol
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Colorimetric method with Pars Azmoon kits and autoanalyzer

8

Description
Atherogenic index of plasma
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating with the formula using triglyceride and high-density Lipoprotein

Intervention groups

1

Description
First intervention group: Daily intake of 1.5 pieces of whole wheat lavash bread for 8 weeks (The composition of whole wheat lavash bread was determined by Bitaran Laboratory. The average weight of the bread is approximately 70 grams, which contains 59.18% by weight of carbohydrates and 2.04% by weight of fiber.) In this study, we will try to ensure that individuals in each group receive approximately 61-68 grams of digestible carbohydrates daily through the intervention bread. The breads are prepared from the Amirieh Bread Free Baking Complex in Shiraz.
Category
Treatment - Other

2

Description
Second intervention group: Daily intake of 2 pieces of whole barley lavash bread for 8 weeks (The composition of whole barley lavash bread was determined by Bitaran Laboratory. The average weight of the bread is approximately 56 grams, which contains 61% by weight of carbohydrates and 1.93% by weight of fiber.) In this study, we will try to ensure that individuals in each group receive approximately 61-68 grams of digestible carbohydrates daily through the intervention bread. The breads are prepared from the Amirieh Bread Free Baking Complex in Shiraz.
Category
Treatment - Other

3

Description
Control group: Daily intake of 1.5 pieces of white wheat bread for 8 weeks (The composition of White wheat lavash bread was determined by Bitaran Laboratory. The average weight of the bread is approximately 70 grams, which contains 60.3% by weight of carbohydrates and 1.3% by weight of fiber.) In this study, we will try to ensure that individuals in each group receive approximately 61-68 grams of digestible carbohydrates daily through the intervention bread. The breads are prepared from the Amirieh Bread Free Baking Complex in Shiraz.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated to Shiraz University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
Research grant
Grant code / Reference number
32574
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 Mirshekaran
Position
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Latest degree
Bachelor
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

Yes - There is 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

Title and more details about the data/document

The data and information will be shared with others upon reasonable requests to the responsible and main researcher of the study.

When the data will become available and for how long

The data and information will be shared with others upon reasonable requests to the responsible and main researcher of the study.

To whom data/document is available

The data and information will be shared with others upon reasonable requests to the responsible and main researcher of the study.

Under which criteria data/document could be used

The data and information can be used by others upon reasonable requests to the responsible and main researcher of the study.

From where data/document is obtainable

The data and information will be shared with others upon reasonable requests to the responsible and main researcher of the study.

What processes are involved for a request to access data/document

The data and information will be shared with others upon reasonable requests to the responsible and main researcher of the study.

Comments