Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and BDNF level in patients with type 2 diabetes

Protocol summary

Study aim

The aim of present study is to evaluate the effects of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and Brain-Derived Neurotrophic Factor (BDNF) level in patients with type 2 diabetes.

Design

This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. Eighty participants will randomly allocated to receive wheat germ per day (n = 40) or placebo (n = 40).

Settings and conduct

All participants aged 30–65 years with type 2 diabetes diagnosis will recruited from Isfahan Endocrine & Metabolism Research Center (IEMRC), Isfahan, Iran. Subjects will stratified according to gender and age (two levels: 30-50 years and 50-65 years). Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Wheat germ and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial.

Participants/Inclusion and exclusion criteria

The cases will enrolled in the study if they met these inclusion criteria: 1) Willingness to participation in the study; 2) Diagnosis of diabetes in the last 5 years; 3) Body Mass Index (BMI) <35. Individuals with history of cancer, cardiovascular disease, renal, hepatic and thyroid disorders or using insulin or oral agents inducing insulin secretion will excluded.

Intervention groups

Individuals will randomly divided into two groups to receive 20 g wheat germ or placebo (bread powder) per day for 12 weeks.

Main outcome variables

Weight; Waist circumference; BMI; Hemoglobin A1C; Total cholesterol; Triglyceride; Low-density lipoprotein; High-density lipoprotein; BDNF; Malondialdehyde; Total antioxidant capacity; Systolic blood pressure; Diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N1**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Reza Amnai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1378

Email address

r_amani@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and BDNF level in patients with type 2 diabetes

Public title
Effect of wheat germ consumption in treatment of diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participation in the study Diagnosis of diabetes in the last 5 years Body mass index <35
Exclusion criteria:
Using insulin or oral agents inducing insulin secretion Smoking Pregnancy and lactation Using anti-psychotic drugs Taking antioxidant supplements within the past 3 months before the intervention Having a history of cancer, cardiovascular disease, renal, hepatic and thyroid disorders
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
A stratified randomized permuted block (with block size 4) will generated by an independent bio-statistician. Subjects will stratified according to gender and age (two levels: 30-50 years and 50-65 years). Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Researchers will not informed about randomization process until completion of data analyses (concealment).
Blinding (investigator's opinion)
Double blinded
Blinding description
Wheat germ and its placebos (bread powder) will manufactured by Narin Company (Isfahan, Iran). All wheat germ and its placebo powders will provided by Narin Company in prepacked boxes numbered for each patient according to the randomization sequence. Wheat germ and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjarib Ave., Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2018-05-27, 1397/03/06
Ethics committee reference number
IR.MUI.REC.1397.3.074

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Colorimetric

2

Description
Hemoglobin A1C
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
High-performance liquid chromatography

3

Description
Insulin
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Digital scale

2

Description
Waist Circumference
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
non-stretching tape measure

3

Description
Systolic blood pressure
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Sphygmomonometer

4

Description
Diastolic blood pressure
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Sphygmomonometer

5

Description
Total cholesterol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

6

Description
Triglyceride
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

7

Description
Low density lipoprotein-cholestrol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

8

Description
High density lipoprotein-cholestrol
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Enzymatic method

9

Description
Brain derived neurotrophic factor
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

10

Description
Malodialdehyde
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

11

Description
Total antioxidant capacity
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

12

Description
Depression score
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

13

Description
Anxiety score
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

14

Description
Stress score
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

15

Description
Appetite
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: 20 g/day wheat germ for 12 weeks. Wheat germ will manufactured by Narin Company (Isfahan, Iran).
Category
Treatment - Other

2

Description
Control group: 20 g/day placebo (bread powder) for 12 weeks. Placebo will manufactured by Narin company (Isfahan, Iran).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine & Metabolism Research Center
Full name of responsible person
Reza Amani
Street address
Korram Ave,
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81746-73461
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Fax
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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Postal code
8174673461
Phone
+98 31 3668 8138
Email
sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Amani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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 collected deidentified for the primary outcome measure only will be shared.

When the data will become available and for how long
starting 12 months after publication.

To whom data/document is available
Available for people working in academic institutions

Under which criteria data/document could be used
The data will provide for educational use.

From where data/document is obtainable
Reza Amani PO Box: 81746-73461
r_amani@nutr.mui.ac.ir

What processes are involved for a request to access data/document
The data will send as soon as possible, after receiving the request.

Comments