# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## The effect of combined aerobic exercise and barley β-glucan on lipid profile and blood glucose of women with diabet type two

## Protocol summary

**Summary**

The main purpose of this study is to investigate the effect of combined aerobic exercise and barley β-glucan on lipid profile and blood glucose of women with diabet type two. Design and method of study: This study is an interventional and not blinded research. Twenty- four female volunteers, with age average 49 years fasting blood glucose between 110- 280 mg.dL-1 are selected purposefully and after completion of questionnaires, are selected and randomly (based on random numbers table) will be divided into three groups of 8 participants: aerobic training with diet, diet and control groups. The group diet use one number bread with 4 gram barley every day for 12 week. The aerobic training with diet group in addition to participate in weekly group sessions for diet (barley bread) took part advanced walking session aerobic training program with intensity 60-70 pertcent of maximal heart rate; 2 to 3 times in week and the duration of each time was 20-60 minutes in 12 week. In the control group, activity is not performed regularly. Inclusion Criteria: Suffering from type 2 diabetes; blood glucose between 110- 280 mg.dL-1. Exclusion criteria: any acute disease during the study period; Absence from a training protocol session. Primary outcome: the blood glucose, triglyceride, cholesterol, LDL and HDL will be evaluated 24 hours before and 48 hours after training program.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017041933542N1**
Registration date: **2017-11-08, 1396/08/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-11-08, 1396/08/17

**Registrant information**

**Name**
Fatemeh Mokhtari
**Name of organization / entity**
University of Isfahan
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3793 2571
**Email address**
f.esfarjani@ui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Isfahan University

**Expected recruitment start date**

2012-12-05, 1391/09/15

**Expected recruitment end date**

2013-03-05, 1391/12/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of combined aerobic exercise and barley β-glucan on lipid profile and blood glucose of women with diabet type two

**Public title**

Effects of exercise and consumption of barley bread on type 2 diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria: suffering from type 2 diabetes; blood glucose between 110- 280 mg.dL-1 Exclusion criteria: any acute disease during the study period; Absence from a training protocol session

**Age**
From **35 years** old to **50 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **24**

**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**
Ethics Committee of Esfahan university

**Street address**
Isfahan University, Hezar jarib St, Isfahan

**City**
Esfahan

**Postal code**

**Approval date**
2012-11-30, 1391/09/10

**Ethics committee reference number**
IR.MUI.REC.1391.4.001

## Health conditions studied

**1**

**Description of health condition studied**
Type 2 diabetes

**ICD-10 code**
E11

**ICD-10 code description**
Non-insulin-dependent diabetes mellitus

## Primary outcomes

**1**

**Description**
Glucose blood

**Timepoint**
Before and after 12 weeks of intervention

**Method of measurement**
Blood test

**2**

**Description**
Lipid profiles (TG, TC, HDL-C and LDL-C)

**Timepoint**
Before and after 12 weeks of intervention

**Method of measurement**
Blood test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: The aerobic training with diet group in addition to participate in weekly group sessions for diet (barley bread) took part advanced walking session aerobic training program with intensity 60-70 pertcent of maximal heart rate; 2 to 3 times in week and the duration of each time was 20-60 minutes in 12 week.

**Category**
Other

**2**

**Description**
Intervention group 2: The group diet use one number bread with 4 gram barley every day for 12 week.

**Category**
Other

**3**

**Description**
Control group: In the control group, activity is not performed regularly.

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Charity of Hazrat Vale Asr

**Full name of responsible person**
Fatemeh Mokhtari

**Street address**
Jabal Ameli St, Kozeh Square, khomeini Shahr

**City**
Khomeini Shahr

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Esfahan University
**Full name of responsible person**
Dr Fahimeh Esfarjani
**Street address**
Isfahan University, Hezar jarib St, Isfahan
**City**
Esfahan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Esfahan University
**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**
University of Isfahan
**Full name of responsible person**
Fatemeh Mokhtari
**Position**
MS in Exercise Physiology
**Other areas of specialty/work**
**Street address**
Isfahan University, Hezar jarib St, Isfahan
**City**
Isfahan
**Postal code**
81746-73441
**Phone**
+98 31 3793 4283
**Fax**
**Email**
Fa.moztar@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
University of Isfahan
**Full name of responsible person**
Fatemeh Mokhtari
**Position**
MS in Exercise Physiology
**Other areas of specialty/work**
**Street address**
Isfahan University, Hezar jarib St, Isfahan
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
University of Isfahan
**Full name of responsible person**
Fatemeh Mokhtari
**Position**
MS in Exercise Physiology
**Other areas of specialty/work**
**Street address**
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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*