

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Pilates training on serum levels of Irisin, Ghrelin, lipid profile and appetite in women with type 2 diabetes

Protocol summary

Study aim

Investigating the effect of 12-week Pilates exercises on serum Irisin level, Ghrelin level, lipid profile and appetite in women with type 2 diabetes

Design

A clinical trial is randomized with a control group and an intervention group, with parallel groups, a single blind which is performed on 30 people. The online randomization site kitset.ir/numbers/random is used for randomization.

Settings and conduct

Place of the study: Jenan Diabetes Center, Najaf Abad.
Study population: Women with type 2 diabetes (members of Jenan Diabetes Association). Single blind test: Participants were blinded, people in the control group did not know about the exercises in the exercise group, and the exercise group did not know about the control group. The subjects in both groups are blind. Sampling is random, and the sampling method is semi-experimental.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 35 to 55 years old- fasting blood sugar equal to or more than 126 to 250, history of at least one-year diabetes, use of oral medicine, ability to do exercise, use of oral diabetes medicine. Exclusion criteria: having back pain and neck pain - using injectable insulin - exercising regularly

Intervention groups

Intervention group: It includes 15 women with type 2 diabetes who meet the inclusion criteria and undergo 12-week Pilates training, 3 sessions per week, 50 minutes per each session, with an intensity of 70 to 80% of the maximum heart rate. Control group: There is no intervention for them.

Main outcome variables

Irisin, Ghrelin, Lipid profile and appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230628058611N1**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Azam Talebi Najafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4262 9350

Email address

a.talebi98@shu.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-03-06, 1402/12/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Pilates training on serum levels of Irisin, Ghrelin, lipid profile and appetite in women with type 2 diabetes

Public title

The effect of Pilates training on type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age: Between 35 to 55 years old Fasting Blood Sugar: Equal to or more than 126 to 250 History: At least one year history of Diabetes Ability to do exercise Use of oral medication

Exclusion criteria:

Doing exercise regularly Having back pain and neck pain Use of injectable insulin

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

How to randomize: The online random number generation site at the address kitset.ir/numbers/random was used and the no duplicate numbers were ticked and 15 numbers were selected among 30 subjects and numbers of 15,9,28,8,16,13,12,30,11,3,21,29,26,5,1 were placed in the test group and numbers of 14,6,18,7,4,27,20,10,2,23,17,19,25,24,22 were placed in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participant: People in the control group do not know about the exercises of the training group, and the training group does not know about the control group. The subjects are blind in both groups. Coach: He doesn't know about the training group. The outcome evaluator: He doesn't know about being two groups and the protocol of exercise. Data analyzer: It has no relationship with subjects, coach, and training protocol

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Najafabad Azad University

Street address

Najafabad Azad University, University Boulevard, Najafabad

City

Najafabad

Province

Isfahan

Postal code

8514143131

Approval date

2022-06-30, 1401/04/09

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1401.042

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Diabetes mellitus type 2

Primary outcomes

1

Description

Irisin

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

2

Description

Ghrelin

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

3

Description

Low density lipoprotein

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

4

Description

High density lipoprotein

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

5

Description

Cholesterol

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

6

Description

Triglyceride

Timepoint

Before and 48 hours after the study

Method of measurement

Laboratory kits

7

Description

Amount of appetite

Timepoint

Before and 48 hours after the study

Method of measurement

(Questionnaire) Visual analog scale

Secondary outcomes

1

Description**Timepoint****Method of measurement**

Intervention groups

1

Description

Intervention group: It includes 15 women with type 2 diabetes (members of Jenan Diabetes Association) who meet the inclusion criteria of the study and undergo 12-weeks Pilates training, 3 sessions per week, 50 minutes per each session, with an intensity of 70 to 80% of the maximum heart rate.

Category

Rehabilitation

2

Description

Control group: It includes 15 women with type 2 diabetes (members of Jenan Diabetes Association) who meet the

inclusion criteria of the study and this group continues their daily life and does not have any special plan.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Jenan Diabetes Center

Full name of responsible person

Azam Talebi Najafabadi

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No. 35, Abdulahi Deadend, Riyazi St., Shariati St.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mahdi Rafiei

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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

Najafabad Azad University

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University of Najafabad

Full name of responsible person

Azam Talebi Najafabadi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport physiology

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Latest degree

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Other areas of specialty/work

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Isfahan

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable