

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of The Effectiveness 12-Week of Pilates Exercise on Serum Levels of Adipulin, Furin, Glycosylated Hemoglobin, and Fasting Blood Sugar in Female with Diabetes Type 2

Protocol summary

Study aim

Assessment of the effect of 12-week Pilates Exercise on Serum levels of Adipulin, Furin Glycosylated hemoglobin, and fasting blood sugar in female with type 2 diabetes.

Design

Clinical trial with one intervention and one control group, with parallel groups, single blind, randomized among 30 patients. Randomization will be done via online randomization site Kitset.ir/numbers/random

Settings and conduct

Place of study: In the Jenan Diabetes Center of Najaf Abad, the study population: Women with type 2 diabetes (member of Jenan Diabetes Association); Type of blinding: single blinded, Blinded 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. Subjects are blinded in two groups, random sampling, and the method of research is semi-experimental.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 35-55 years old; FBS greater than or equal to 126 to 250; history of at least 1 year of diabetes; use of oral tablet; ability to exercise. Exclusion criteria: use of insulin; regular sports exercise; having back pain and neck pain

Intervention groups

Intervention group: including 15 woman with type 2 diabetes who meet the criteria for inclusion in the study and are subjected to 12 weeks of Pilates training, three sessions per week, each session lasting 50 minutes, with an intensity of 70 to 80% of the maximum heart rate. Control group: there will be no intervention in this group.

Main outcome variables

Adipulin; Furin; Glycosylated Hemoglobin (HbA1c); Fasting Blood Sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230601058355N1**

Registration date: **2023-10-05, 1402/07/13**

Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**

Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

ZAHRA Montazeri nagafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 232 1077

Email address

montazeri.nja2017@shu.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effectiveness 12-Week of Pilates Exercise on Serum Levels of Adipulin, Furin, Glycosylated Hemoglobin, and Fasting Blood Sugar in Female with Diabetes Type 2

Public title

The Effect of Pilates in Diabetes 2

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 35-55 years old FBS greater than or equal to 126 to 250 History of at least 1 year of diabetes Use of oral tablet Ability to exercise

Exclusion criteria:

Regular sports exercise Having back pain and neck pain Use of insulin

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization: the online random number generation site at the address Kitset.ir/numbers/random was used, the number check was not repeated and 15 numbers were selected from among 130 subjects and in the subject group: numbers: 1, 3, 5, 6, 9, 10, 11, 13, 14, 15, 20, 24, 27, 29, 30 and in the control group numbers: 2, 4, 7, 8, 12, 16, 17, 18, 19, 21, 22, 23, 25, 26, 28 were included.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinded 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. Subjects are blinded in two groups. Blinded Coach: He does not know about the training group. Blinded outcome assessor: He does not know about the two groups and the training protocol. Blinded data analyst: unrelated to subjects, trainer, 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 Najaf-Abad Azad University

Street address

Najafabad Azad University; Daneshgah Blvd;
Najafabad

City

Najafabad

Province

Isfahan

Postal code

8514143131

Approval date

2022-04-28, 1401/02/08

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1401.031

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Adipulin

Timepoint

Before and 48 hours after the intervention

Method of measurement

Laboratory Kits

2

Description

Furin

Timepoint

Before and 48 hours after the intervention

Method of measurement

Laboratory Kits

3

Description

Glycosylated hemoglobin

Timepoint

Before and 48 hours after the intervention

Method of measurement

Laboratory Kits

4

Description

Fasting Blood Sugar

Timepoint

Before and 48 hours after the intervention

Method of measurement

Laboratory Kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including 15 Woman with type 2 diabetes (member of Jenan Diabetes Association) who meet the inclusion criteria and are subjected to 12 weeks of Pilates training, three sessions per week, each session lasting 50 minutes, with an intensity of 70 to 80% of the maximum heart rate.

Category

Rehabilitation

2

Description

Control group: including 15womman with type2 diabetes (member of jenan diabetes Association)who meet the inclusion criteria continue their daily life They do not have a specific program.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Genan Diabetes Center

Full name of responsible person

Zahra Montazeri Najafabadi

Street address

N0.274/5; Ayat Dead end alley; Nizam al-Mulk three-way; South Sheikh Bahai street

City

Najafabad

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Postal code

8517753188

Phone

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Email

montazeri.nja2017@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahdi Rafie

Street address

Najafabad Azad University; Daneshgah Blvd;
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Phone

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Email

INFO@JAUN.AC.IR

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Montazeri Najafabadi

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiology

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

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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

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