Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of The Effectiveness12-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. Randomizatin 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 Effectiveness12-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 to126 to 250 History of at least 1 year of diabetes Use of oral tablet Ablity 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
Isfehan

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 Assocation)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
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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; Najafabad
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Postal code
8514143131
Phone
+98 31 4229 2929
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
Street address
N0.274/5; Ayat Dead end alley; Nizam al-Mulk three-way; South Sheikh Bahai street
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Person responsible for scientific inquiries

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Person responsible for updating data

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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