Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of walking and Pilates exercise at home on quality of life, functional capacity and anthropometric measurements in elderly women with diabetes type 2

Protocol summary

Study aim

Comparing the effect of walking and Pilates exercises at home on the quality of life in elderly women with diabetes

Design

This study is a randomized clinical trial. First, 100 qualified patients will be selected using convenience sampling. Then Participants will be allocated into two groups using Randomizer software.

Settings and conduct

This randomized clinical trial will be done on 100 diabetic patients. Due to the nature of the interventions, only the outcome assessor will be blinded. First, qualified patients will be selected using convenience sampling. Then Participants will be allocated into two groups by simple randomization method. Data was gathered in three times; before intervention, immediately and one months after intervention. Depending on the type of intervention, participants will go to the gym to participate in training sessions. After participating in 2 session training under supervision of sports expert, if they will be competent for doing exercise at home independently, they will done intervention at home 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria; At least one year of history of type 2 diabetes Age 60-75 years lack of disability lack of psychiatric disorders Exclusion criteria; Under diet to lose weight Being hospitalized Living in a nursing home Contraindication of physical exercises based on physician advice

Intervention groups

Intervention 1 (Walking): After holding two training sessions under supervision of a sports expert, participants will be asked to walk at home 45 minutes, 3 times a week for 12 weeks. Intervention 2 (Pilates exercises): After holding two training sessions under supervision of a sports expert, participants will be asked to do prescribed Pilates exercises at home 45 minutes, 3 times a week for 12 weeks.

Main outcome variables

Quality of life; Functional capacity; Anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140412017237N12**
Registration date: **2020-11-20, 1399/08/30**
Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**
Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

Mahnaz Modanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3245 6900

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-08-21, 1400/05/30

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

Scientific title
Comparison of the effect of walking and Pilates exercise at home on quality of life, functional capacity and anthropometric measurements in elderly women with diabetes type 2

Public title
The effect of walking and Pilates exercise at home on quality of life, functional capacity and anthropometric measurements in elderly women with diabetes type 2
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
History of Diabetes mellitus type 2 from 1 year ago 60-75 years old Lack of physical disability Lack of known psychiatric disorder Lack of diabetes complications
Exclusion criteria:
Under weight lost diet Contraindication of physical exercises based on physician advice Nursing home residents Hospitalization
Age
From **60 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The eligible patients as an unit of randomization will be allocated in two intervention groups (1:walking at home, 2: Pilates exercise at home) using Randomizer software by simple randomization.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the interventions, only the outcome assessor will be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Golestan University of Medical Sciences
Street address
Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard
City
Gorgan
Province
Golestan
Postal code
4934174515
Approval date
2020-09-27, 1399/07/06
Ethics committee reference number
ir.goums.rec.1399.208

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E10-E14
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Quality of life
Timepoint
Quality of life measurement before intervention and immediately and one months after intervention
Method of measurement
Quality of life questionnaire (SF-36)

Secondary outcomes

1

Description
Functional capacity
Timepoint
Measurement of functional capacity before intervention and immediately and one months after intervention
Method of measurement
Evaluated by TUG, 2-10MWT, STS5-3, OLS tests.

2

Description
Anthropometry

Timepoint
Measurement of anthropometric indicators before intervention and immediately and one months after intervention

Method of measurement
Measuring body dimensions in a static state, which includes height, weight, body mass index, waist circumference, pelvic circumference, waist-to-height ratio, waist-to-hip ratio, mass and body fat percentage of patients. Weight will be measured using a digital scale made in Iran with an accuracy of 100 grams, height, waist circumference, pelvic circumference using a tape measure made in Iran with an accuracy of 0.1 cm. Body fat percentage will be measured using the BIA by the OMRON BF-511.

Intervention groups

1

Description
Intervention group 1 (walking at home): Walking at home for 45 minutes, three times a week for 3 months, which will be performed by an experienced instructor after training.

Category
Other

2

Description
Intervention group 2 (Pilates exercises at home): A selection of Pilates exercises at the beginner and basic level of Pilates is done lying down and without special tools at home. These movements are accompanied by the coordination of inhaling and exhaling in the performance of the movement, which will be for 45 minutes, three times a week for 3 months, which will be performed by an experienced instructor after training.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
5th Azar Medical and Educational Center

Full name of responsible person
Nasser Saffar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Mohammad Reza Honarvar

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Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Mahnaz Modanloo

Position
Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work
Nursing

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Nursing Research Center, Golestan University of Medical Sciences, Hirkan Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Hamideh Akbari

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Endocrinologist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Title and more details about the data/document
All data will be shared after unidentifiable participants.

When the data will become available and for how long
6 months after publication the data files will be available.

To whom data/document is available
The data will be shared for people working in academic institutions.

Under which criteria data/document could be used
Meta analyses on data is permitted.

From where data/document is obtainable
Please contact to person responsible for general inquiries.

What processes are involved for a request to access data/document
The data will be available through email.

Comments
Please contact to both email address:
modanloo.mahnaz@goums.ac.ir
modanloo.mahnaz@gmail.com