

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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)

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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

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

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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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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamideh Akbari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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:
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modanloo.mahnaz@gmail.com