

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of lower limb strength training and aerobic exercises in combination with lifestyle modification on strength, aerobic fitness and quality of life in patients with type II diabetes mellitus.

Protocol summary

Study aim

To evaluate the effectiveness of lower limb strength training and aerobic exercises in combination with lifestyle modification on strength, aerobic fitness and quality of life in patients with type II diabetes

Design

Parallel group randomized clinical trial and Randomization will be achieved through computer generated random allocation software.

Settings and conduct

District Head Quarter (DHQ) teaching Hospital Faisalabad, Tehsil Headquarter Hospital Gojra, AL Barkat Hospital Gojra, Hajra Tufail Hospital, Gojra. Patients and outcome assessor will be blinded. It will be assessor and participant who will be blinded about the type of intervention. Treatment will be given by principal /investigator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both male and female patients, Age: 40 to 60 years, Patient with diabetes type II diagnosed by physician Exclusion criteria: Unsafe blood pressure, Mental retardation, Any recent surgery (cardiac, musculoskeletal and neurological) ,Fracture ,Limb amputation and joint replacement ,Central nervous system dysfunction (stroke, Parkinson disease)

Intervention groups

The intervention group will include lower limb strength training, aerobic exercises, and a lifestyle modification program. Session duration will be 45 minutes, thrice a week, and 24 sessions over 8 weeks. The interventions of the control group will include lower limb strength training, aerobic exercises, and unguided lifestyle instructions. Session duration will be 45 minutes, thrice a week and 24 sessions over 8 weeks.

Main outcome variables

Strength, Aerobic fitness, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057434N7**

Registration date: **2024-03-10, 1402/12/20**

Registration timing: **prospective**

Last update: **2024-03-10, 1402/12/20**

Update count: **0**

Registration date

2024-03-10, 1402/12/20

Registrant information

Name

Zainab Sheraz

Name of organization / entity

Riphah International University, Faisalabad

Country

Pakistan

Phone

+92 301 7070941

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zainab.48@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-15, 1402/12/25

Expected recruitment end date

2024-05-22, 1403/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of lower limb strength training and aerobic exercises in combination with lifestyle modification on strength, aerobic fitness and quality of life in patients with type II diabetes mellitus.

Public title

Effects of lower limb strength training and aerobic exercise in combination with lifestyle modification in type II diabetes mellitus.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both male and female patients Age: 40 to 60 years
Patient with diabetes type II diagnosed by physician

Exclusion criteria:

Unsafe blood pressure Mental retardation Any recent surgery (cardiac, musculoskeletal and neurological)
Fracture Limb amputation and joint replacement Central nervous system dysfunction (stroke, Parkinson disease)

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through a computer software "Random allocation software Version 2. The total sample size will be entered with required number of participants to be allocated in two groups. An automated randomization list will be achieved with attrition rate included. The program starts running with the default settings. Users may run the program with the default settings or set the number of groups, the name of participants in each group and the sample size. Clicking the 'Generate' button produces the random sequence. Before generating the random sequence, the option window will be displayed and different randomization settings can be entered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done on part of outcome assessor who will be an experienced therapist. Patients will be assessed by him at the end of treatment session. He will be blinded about the type of intervention patient will receive. Patients will also be blinded about the type of intervention they will received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah International University
Faisalabad

Street address

Riphah International University, Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2024-03-01, 1402/12/11

Ethics committee reference number

RCRAHS/REC/24/9

Health conditions studied

1

Description of health condition studied

Diabetes mellitus II

ICD-10 code

E11. 9

ICD-10 code description

Diabetes mellitus II

Primary outcomes

1

Description

Strength

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 8 weeks treatment.

Method of measurement

Five times sit to stand test

Secondary outcomes

1

Description

Aerobic fitness

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 8 weeks treatment.

Method of measurement

Harvard step test

2

Description

Quality of life

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 8 weeks treatment.

Method of measurement

SF-36

Intervention groups

1

Description

Group A (Intervention group) consisting of 27 patients will receive an exercise session of 3 minutes warm-up that includes walking at a slow pace, followed by lower limb strength training and aerobic exercise. In the intervention group, patients will receive lower limb strength training in the form of resistance exercises which will consist of hip abduction/adduction with a sandbag worn on the ankle, step (hip and knee flexion/extension), and tiptoe (ankle flexion/extension) with sandbag worn on the ankle. Patients will perform these exercises in standing position with the assistance of a chair. For the 1st four weeks, the sandbag weighing 0.5 kg will be worn with each exercise and performed for 8-15 times. After 4 weeks, the weight of the sandbag will progress to 1kg till 8th week. The total time for lower limb strength training exercises will be 20 minutes. Aerobic exercises will consist of 10 minutes of stationary cycling and 10 minutes of step-ups. The patients will be instructed while doing step-ups, they will keep their back straight. The total time for aerobic exercises would be 20 minutes, followed by 2 minutes of cool-down exercises which will consist of breathing exercises. The total session duration for the Intervention group will be 45 minutes and will repeat thrice a week, 24 sessions over 8 weeks. Lifestyle modification program which will include: Mediterranean diet instructions like consumption of fruit and vegetables (one or two portions a day), whole grains, legumes, and nuts it will also include a moderate quantity of fish and dairy products while minimizing the intake of meat, processed and industrial food. Healthy sleep instructions according to the guidelines developed by the American Academy of Sleep Medicine includes: setting a bedtime that is early enough for a person to get at least 7-8 hours of sleep, making your bedroom quiet and relaxing before sleeping, limiting exposure to bright light in the evening, turning off electronic devices at least 30 minutes before bedtime, don't eat a large meal before bedtime, avoiding consuming caffeine in the afternoon or evening

Category

Treatment - Other

2

Description

Group B (Control Group) consisting of 27 patients will receive an exercise session of 3 minutes warm-up that will include walking at a slow pace, followed by lower

limb strength training and aerobic exercise. Lower limb strength training in the form of resistance exercises which will consist of hip abduction/adduction with a sandbag worn on the ankle, step (hip and knee flexion/extension), and tiptoe (ankle flexion/extension) with sandbag worn on the ankle. The patient will perform these exercises in a standing position with the assistance of a chair. For the 1st four weeks sandbag weighing 0.5 kg will be worn with each exercise and performed for 8-15 times. After 4 weeks, the weight of the sandbag will be progressed to 1kg till 8th weeks. The total time for lower limb strength training exercises will be 20 minutes. Aerobic exercises will consist of 10 minutes of stationary cycling and 10 minutes of step-ups. The Patients will be instructed while doing step-ups, they will keep their back straight. The total time for aerobic exercises would be 20 minutes, followed by 2 minutes of cool-down exercises which consist of breathing exercises. In unguided lifestyle instructions, the therapist will advise the patient to live a healthy life and eat a healthy diet without specific or detailed guidance or instructions. The total session duration for the Control group will be 45 minutes and will repeat thrice a week, 24 sessions over 8 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

District Headquarter Hospital, Faisalabad

Full name of responsible person

Maria Irshad

Street address

Mall Road, near Faisalabad Railway Station

City

Faisalabad

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38000

Phone

+92 302 7935249

Email

mariairshad098@gmail.com

2

Recruitment center

Name of recruitment center

Tehsil Headquarter Hospital, Gojra

Full name of responsible person

Anam Sabir

Street address

Jhang Road, Gojra

City

Gojra

Postal code

56000

Phone

+92 306 8835013

Email

anamsabirpml58@gmail.com

3

Recruitment center

Name of recruitment center

Hajra Tufail Hospital, Gojra

Full name of responsible person

Khadeeja

Street address

Mongi Bangla Road, Gojra, Toba Tek Singh District

City

Gojra

Postal code

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Phone

+92 305 9880245

Email

ah8490184@gmail.com

4

Recruitment center

Name of recruitment center

Al Barkat Hospital, Gojra

Full name of responsible person

Aqsa

Street address

Faisalabad Road, Gojra, Toba Tek Singh District,
Punjab

City

Gojra

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Phone

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Email

ma0176589@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self Funded

Full name of responsible person

Zainab Sheraz

Street address

House no. 32, street no. 2, Rehman Town, adjacent
Shahzad Colony, Satyana Road, Faisalabad

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zainab.48@hotmail.com

Web page address

<https://www.riphahfsd.edu.pk/>

Grant name

N/A

Grant code / Reference number

N/A

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

No

Title of funding source

N/A

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University, Faisalabad

Full name of responsible person

Zainab Sheraz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no. 32, street no. 2, Rehman Town, adjacent
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Riphah International University, Faisalabad

Full name of responsible person

Zainab Sheraz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Real patient is involved

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available