Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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+92 301 7070941

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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
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38000
Phone
+92 302 7935249
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mariairshad098@gmail.com

2

Recruitment center
Name of recruitment center
Tehsil Headquarter Hospital, Gojra
Full name of responsible person
Anam Sabir
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Jhang Road, Gojra
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Gojra
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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
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Mongi Bangla Road, Gojra, Toba Tek Singh District
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ah8490184@gmail.com

4

Recruitment center

Name of recruitment center
Al Barkat Hospital, Gojra
Full name of responsible person
Aqsa
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Faisalabad Road, Gojra, Toba Tek Singh District, Punjab
City
Gojra
Postal code
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Phone
+92 304 5514364
Email
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Self Funded
Full name of responsible person
Zainab Sheraz
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House no. 32, street no. 2, Rehman Town, adjacent Shahzad Colony, Satyana Road, Faisalabad
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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
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House no. 32, street no. 2, Rehman Town, adjacent Shahzad Colony, Satyana Road, Faisalabad
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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)
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