

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of progressive resistance strength training on body mass index, quality of life and functional capacity in knee osteoarthritis

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of progressive resistance strengthening training on body mass index, quality of life and functional capacity in the overweight and obese knee osteoarthritis patients.

Design

Study will be single-blinded randomized controlled design

Settings and conduct

Study will be conducted at the Teaching Bay of Rehmatul-Lil-Alameen Postgraduate institute of cardiology, Punjab Employees Social Security Institution. The principle investigator will not be blinded. The participants receiving the intervention will be blinded by simply not informing them of their treatment allocation.

Participants/Inclusion and exclusion criteria

The inclusion criteria will be: (1) Overweight and obese knee osteoarthritis patients having osteoarthritis of one or both knees (2) Osteoarthritis grading scale of 2-mild or 3-moderate according to Kellgren and Lawrence radiographic scale (3) Symptoms of osteoarthritis for more than three months (5) Residing in the Urban community of Lahore . Exclusion criteria will be one or more of the following: (1) Flat feet (2) Knee surgery (3) Corticosteroid injection of knee (4) Spinal deformities (5) Cardiac problem or (6) Hormonal problem

Intervention groups

Intervention groups will be Rehabilitation Protocol Group and the Control Group. The patients in the Rehabilitation Protocol Group will perform the progressive resistance strengthening training in non-weight bearing sitting and lying positions following the instructions of daily care for duration of 12-weeks. The patients in the Control Group will follow the instructions of daily care for duration of 12-weeks.

Main outcome variables

Primary outcome measures will be body mass index and quality of life. Secondary outcome measure will be the functional capacity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191221045846N3**

Registration date: **2020-07-20, 1399/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-20, 1399/04/30**

Update count: **0**

Registration date

2020-07-20, 1399/04/30

Registrant information

Name

Muhammad Tariq Rafiq

Name of organization / entity

Punjab Employees Social Security Institution

Country

Pakistan

Phone

+92 42 99330101

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-16, 1399/04/26

Expected recruitment end date

2020-10-15, 1399/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of progressive resistance strength training on body mass index, quality of life and functional capacity in knee osteoarthritis

Public title

The role of strength training in treatment of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Overweight and obese knee osteoarthritis patients having osteoarthritis of one or both knees Osteoarthritis grading scale of 2-mild or 3-moderate according to Kellgren and Lawrence radiographic scale Symptoms of osteoarthritis for more than three months Residing in the Urban community of Lahore

Exclusion criteria:

Flat feet Knee surgery Corticosteroid injection of knee Spinal deformities Cardiac problem Hormonal problem.

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be single blinded randomized controlled design. The method of allocation generation will be done by a computerized random-number generator. The sequence will be generated by the process of simple randomization. Simple randomization will be based on a single sequence of random assignments. Three research coordinators will be involved in data collection. The one coordinator will be involved in baseline data collection and two coordinators will be involved in the assessment of outcomes. Participants will be blinded of other groups intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

The coordinators collecting data will be independent individuals from trials and will be unaware of the group allocation. There will be different coordinators at the initial and final evaluation. Individuals performing the statistical analysis will be blinded by labelling the groups with non-identifying terms (such as X and Y).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee RAIC PESSI (Rehmatul-Lil-Alameen Postgraduate Institute of Cardiology, Punjab Empl

Street address

Multan Chongi Multan Road Lahore,

City

Lahore

Postal code

54000

Approval date

2020-03-30, 1399/01/11

Ethics committee reference number

RAIC PESSI/Estt/2020/2419

Health conditions studied**1****Description of health condition studied**

Osteoarthritis of knee

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Body Mass Index

Timepoint

At pre-test and post-test (after 12-weeks of intervention) measurements

Method of measurement

Calculated by the formula Weight (kg)/Height(meter square)

2**Description**

Quality of life

Timepoint

At pre-test and post-test (after 12-weeks of intervention) measurements

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index summary score of pain, stiffness and physical function

Secondary outcomes

ms.raic@pessi.gop.pk

1

Description

Functional capacity

Timepoint

At pre-test and post-test (after 12-weeks of intervention) measurements

Method of measurement

Gait Speed Test will be used for the assessment of functional capacity

Intervention groups

1

Description

Intervention group: The participants in the intervention group will perform the training sessions of progressive resistance strength training of lower limb muscle groups following the instructions of daily care for duration of 12-weeks. Each training session started with 10 minutes warm up, 45-60 minutes of progressive resistance strength training of lower limb muscle groups training, and 10 minutes cool down at the end of training session.

Category

Treatment - Other

2

Description

Control group: The participants in the control group will follow the instructions of daily care for duration of 12-weeks. Instructions of daily care are general guidelines of eating and care of knee in order to prevent the cartilage destruction.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching Bay of Rehmatul-Lil-Alameene Post Graduate Institute

Full name of responsible person

Dr Farid Ahmad Chaudhary

Street address

Teaching Bay of Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology, Punjab Employees Social Security Institution, Multan Chongi, Multan Road Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology

Full name of responsible person

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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

50

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

Other

2

Sponsor

Name of organization / entity

University of Malaya

Full name of responsible person

Mohamad Shariff A Hamid

Street address

Sports Medicine University Malaya Medical Centre, Kuala Lumpur, Malaysia

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59100

Phone

+60 3-7949 8065

Email

ayip@um.edu.my

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

50

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Punjab Employees Social Security Institution

Full name of responsible person

Muhammad Tariq Rafiq

Position

Consultant Senior Physiotherapist

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Ph.D.

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Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Consultant Senior Physiotherapist

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available