# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
drtariqrafiq149@yahoo.com

**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

### 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 group,s 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
**City**
Lahore
**Postal code**
54000
**Phone**
+92 42 99330101
**Email**
ms.raic@pessi.gop.pk

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology
**Full name of responsible person**
Dr Farid Ahmad Chaudhary
**Street address**
Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology, Punjab Employees Social Security Institution, Multan Chongi, Multan Road Lahore
**City**
Lahore
**Postal code**
54000
**Phone**
+92 42 99330101
**Email**
ms.raic@pessi.gop.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**
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
**City**
Kuala Lumpur
**Postal code**
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

**Street address**
Rehmatul-Lil-Alamine Post Graduate Institute of Cardiology, Punjab Employees Social Security Institution, Multan Chongi, Multan Road Lahore

**City**
Lahore

**Province**
Punjab

**Postal code**
54000

**Phone**
+92 42 99330103

**Fax**

**Email**
drtariqrafiq149@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
University of Malaya

**Full name of responsible person**
Mohamad Shariff A Hamid

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Physical Medicine

**Street address**
Sports Medicine Department, University of Malaya Medical Centre, Kuala Lumpur, Malaysia

**City**
Kuala Lumpur

**Province**
Selangor

**Postal code**
59100

**Phone**
+60 3-7967 6669

**Email**
ayip@um.edu.my

## Person responsible for updating data

**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

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

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Lahore

**Province**
Punjab

**Postal code**
54000

**Phone**
+92 42 99330101

**Fax**

**Email**
drtariqrafiq149@yahoo.com

## 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