

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Measurement of hip muscle strength and their effects on pain and function in middle aged women in knee osteoarthritis: randomized control trial

#### Protocol summary

##### Study aim

To measure the strength of hip muscle and their effect on pain and function in middle aged women with knee OA.

##### Design

A double-blind, randomized controlled trial

##### Settings and conduct

Physical therapy department of WAPDA Teaching Hospital Complex Lahore, and Pakistan Society for the Rehabilitation of the Disabled, Lahore, Punjab, Pakistan

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Female only Aged 40 to 60 year, Pain intensity is not more than 8 on Visual analog scale (VAS), Pain intensity is not LESS than 2 on Visual analog scale (VAS), Unilateral knee osteoarthritis, Grade II to III by Kellgren- Lawrence scale of knee osteoarthritis.

Exclusion criteria: Male, Aged more than 61 and less than 39 year, Pain intensity is more than 8 and LESS than 2 on Visual analog scale (VAS), Bilateral knee osteoarthritis, Grade I to IV by Kellgren- Lawrence scale of knee osteoarthritis, Previous surgical/ steroid injection history with in last 6 months, Bony abnormalities, including bone fracture, osteochondritis, bipartite patella of knee.

##### Intervention groups

Intervention groups received hip strengthening exercises with knee strengthening exercises for 8 week, 4 session per week total 32 session each session last for 40 min.

##### Main outcome variables

Muscle Strength, Pain and Function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230124057196N3**

Registration date: **2024-09-26, 1403/07/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-09-26, 1403/07/05**

Update count: **0**

##### Registration date

2024-09-26, 1403/07/05

##### Registrant information

###### Name

mariam umer hayat

###### Name of organization / entity

The University of Lahore

###### Country

Pakistan

###### Phone

+92 321 4437350

###### Email address

mariamumerhayat@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-07-02, 1403/04/12

##### Expected recruitment end date

2024-12-02, 1403/09/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Measurement of hip muscle strength and their effects on pain and function in middle aged women in knee osteoarthritis: randomized control trial

## Public title

Measurement of hip muscle strength and their effects on pain and function in middle aged women in knee osteoarthritis: randomized control trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Female only Aged 40 to 60 year Pain intensity is not more than 8 on Visual analog scale (VAS) Pain intensity is not LESS than 2 on Visual analog scale (VAS) Unilateral knee osteoarthritis Grade II to III by Kellgren- Lawrence scale of knee osteoarthritis

### Exclusion criteria:

Male Aged more than 61 and less than 39 year Pain intensity is more than 8 and than 2 on Visual analog scale (VAS) Bilateral knee osteoarthritis Grade I to IV by Kellgren- Lawrence scale of knee osteoarthritis Previous surgical/ steroid injection history with in last 6 months Bony abnormalities, including bone fracture, osteochondritis, bipartite patella of knee

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: **84**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The participant of study was randomly allocated in experimental and control group by lottery method after recruitment of sample participants

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participant, Care provider and Data analyzer did not know which participant belonged to which group

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

THE UNIVERSITY OF LAHORE

#### Street address

1-Km Defense Road, near Bhuptian Chowk, Lahore, Punjab

#### City

LAHORE

#### Postal code

54000

#### Approval date

2024-07-18, 1403/04/28

#### Ethics committee reference number

REC NO 268/24

## Health conditions studied

### 1

#### Description of health condition studied

Knee Osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Determined the strength of hip and knee muscles in knee osteoarthritis

#### Timepoint

Measurement of primary outcome before the intervention baseline at 0 week, in mid after 4th week and after 8th week at the end intervention

#### Method of measurement

Manual Muscle Testing (MMT)

### 2

#### Description

PAIN

#### Timepoint

Measurement of primary outcome before the intervention baseline at 0 week, in mid after 4th week and after 8th week at the end intervention

#### Method of measurement

Visual analogue scale (VAS) and pain by subscale of Knee Injury and Osteoarthritis Outcome Score(KOOS)

## Secondary outcomes

### 1

#### Description

FUNCTION

#### Timepoint

Measurement of Secondary outcome before the intervention baseline at 0 week, in mid after 4th week and after 8th week at the end intervention

#### Method of measurement

Function by subscale of Knee Injury and Osteoarthritis

Outcome Score(KOOS)

## Intervention groups

### 1

#### Description

Intervention group: Experimental group received hip and knee strengthening exercises for 8th week, 4 session per week on alternative days, frequency of exercise was 3 set with 10 repetition in each set, session completed in 40 min, 2 rest, Thera-Band with medium resistance to heavy resistance was used . Superficial heat by electric heating pad and TENS is used for 10 min as placebo before exercise.

#### Category

Rehabilitation

### 2

#### Description

Control group: received knee strengthening exercises for 8th week, 4 session per week on alternative days, frequency of exercise was 3 set with 10 repetition in each set, session completed in 40 min, 2 rest, Thera-Band with medium resistance to heavy resistance was used. Superficial heat by electric heating pad and TENS is used for 10 min as placebo before exercise.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

WAPDA TEACHING HOSPITAL COMPLEX LAHORE

##### Full name of responsible person

Abid Javaid

##### Street address

210-Ferozpur Road Lahore

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 37564705

##### Fax

+92 42 35232285

##### Email

abidminhas.pt@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Pakistan Society for the Rehabilitation of the Disabled

##### Full name of responsible person

Hassan Javed

##### Street address

111 Lahore – Kasur Rd, Lahore,

#### City

Lahore

#### Postal code

54000

#### Phone

+92 42 37423455

#### Email

info@transparenthands.org

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Lahore

##### Full name of responsible person

Mariam Umer Hayat

##### Street address

No 103 L DHA Raber Lahore Pakistan

##### City

Lahore

##### Postal code

54000

##### Phone

+92 321 4437350

##### Email

mariamumerhayat@gmail.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

SELF

#### 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

The University of Lahore

##### Full name of responsible person

Mariam Umer hayat

##### Position

M.phill

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

L 103 DHA Rahber Lahore Punjab

**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

+92 321 4437350

**Fax****Email**

mariamumerhayat@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mobility Quest

**Full name of responsible person**

Mariam Umer Hayat

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

L 103 DHA rahber phase 2 Lahore

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**Province**

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**Postal code**

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**Phone**

+92 321 4437350

**Email**

mariamumerhayat@gmail.com

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

Mobility Quest

**Full name of responsible person**

Mariam Umer Hayat

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

L 103 DHA rahber phase 2 Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

+92 321 4437350

**Email**

mariamumerhayat@gmail.com

**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**

There is no further information

**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