

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of proprioceptive and therapeutic exercises on pain, stiffness and functional disability among the patients with knee osteoarthritis

#### Protocol summary

##### Study aim

To assess the effectiveness of proprioceptive and therapeutic exercises on pain, stiffness and physical functioning among the patients with knee osteoarthritis.

##### Design

A Randomized control Trial with parallel group design of 54 patients, enrolled between August 2022 and October 2022, and followed for one month.

##### Settings and conduct

District head quarter hospital Mandi Baha ud Din and City hospital Jalal pur Jattan. The participants were chosen through lottery method (single blind).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 45-60 years old patients diagnosed of knee osteoarthritis. Exclusion criteria: Patients with diagnosed osteoporosis, history of traumatic injury and surgery of knee joint (within last 6 months) and Patients of knee osteoarthritis with recommended surgery of knee.

##### Intervention groups

After 20 minutes of local heating Group A received proprioceptive exercises. Exercises included One leg balance: every patient stood on the affected leg with upright posture with hip and knee flexion on the other leg and ankle joint were off from the surface. Two repetitions of this position were held for 1 minute followed by rest for 10 to 20 seconds. Blind advanced one leg balance: This was the same as the one leg stance except that the patient was commanded to completely close his/her eyes during the exercise. Group B was treated with therapeutic exercises. Straight leg raise (SLR), pillow squeeze, heel raise, and quadriceps setting. The exercises were done in three sets of 5 repetitions with a 3-min rest between the Each patient was treated four times a week for a period of 4 weeks. Pre-treatment, 2nd week and 4th week pain intensity, joint stiffness and physical difficulties were assessed by

using Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire.

##### Main outcome variables

Pain, Stiffness and Physical Functioning

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201021049094N3**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **retrospective**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

##### Registration date

2022-12-17, 1401/09/26

##### Registrant information

##### Name

Raheela Kousar

##### Name of organization / entity

The University of Lahore

##### Country

Pakistan

##### Phone

+92 53 3589155

##### Email address

raheelasaleem10@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-09, 1401/05/18

##### Expected recruitment end date

2022-12-09, 1401/09/18

**Actual recruitment start date**

2022-08-09, 1401/05/18

**Actual recruitment end date**

2022-12-09, 1401/09/18

**Trial completion date**

2022-12-10, 1401/09/19

**Scientific title**

Effectiveness of proprioceptive and therapeutic exercises on pain, stiffness and functional disability among the patients with knee osteoarthritis

**Public title**

Effectiveness of proprioceptive and therapeutic exercises on pain, stiffness and functional disability among the patients with knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

45-60 years old patients diagnosed of knee osteoarthritis

**Exclusion criteria:**

Patients with diagnosed osteoporosis History of traumatic injury and surgery of knee joint (within last 6 months) History of central or peripheral neuropathy Patients of knee osteoarthritis with recommended surgery of knee Patients with active synovitis

**Age**

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

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **54**

Actual sample size reached: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization by lottery method. Allocation concealment through sealed envelope. In a bowl we put closed slips of group A and group B. Participants fulfilling inclusion criteria will randomly pick up groups and then allocated through sealed envelopes.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

the patients were blind about their exercise group as they were not known either they were the member of Group A or Group B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethical committee of University of Lahore

**Street address**

University of Lahore, chenab campus adjacent to chenab bridge, Gujrat.

**City**

Gujrat

**Postal code**

50700

**Approval date**

2022-08-16, 1401/05/25

**Ethics committee reference number**

REG/GRT/22/AHS-85

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

Knee osteoarthritis: Knee OA is the most common form of arthritis related to functional disabilities in middle-aged and older adults. Clinically complaints of pain, decreased muscle strength, joint instability, joint stiffness, and proprioceptive deficits are exhibited by patients with degenerative knee OA, all of which lead to a decline or loss of function.

**ICD-10 code**

M17

**ICD-10 code description**

Osteoarthritis of knee

**Primary outcomes****1****Description**

Pain

**Timepoint**

Before intervention and 2, 4 weeks after intervention.

**Method of measurement**

Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

**2****Description**

Stiffness

**Timepoint**

Before intervention and 2, 4 weeks after intervention.

**Method of measurement**

Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

**3****Description**

Physical Functioning

## Timepoint

Before intervention and 2, 4 weeks after intervention.

## Method of measurement

Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group A: Proprioceptive Exercises (baseline: heating therapy)

#### Category

Rehabilitation

### 2

#### Description

Intervention group B: Therapeutic Exercises (base line: heating therapy)

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

D.H.Q hospital M.B.Din (Physical Therapy Department)

##### Full name of responsible person

Nosheen Sultan

##### Street address

D.H.Q hospital, old block jail road, M.B.Din

##### City

Mandi Baha ud Din

##### Postal code

50400

##### Phone

+92 349 9740755

##### Email

Nosheensultan1957@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

City hospital Jalal pur Jattan (Physical Therapy Department)

##### Full name of responsible person

Nosheen Sultan

##### Street address

City hospital tanda chok Jalal pur Jattan

##### City

Gujrat

##### Postal code

50780

##### Phone

+92 349 9740755

##### Email

Nosheensultan1957@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Self

##### Full name of responsible person

Nosheen Sultan

##### Street address

Heigherwala khurd, Tehsil: Phalia Distt: Mandi baha ud Din.

##### City

PAHRIANWALI ADD

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50300

##### Phone

+92 349 9740755

##### Email

Nosheensultan1957@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

University of Lahore Chenab campus Gujrat

##### Full name of responsible person

Nosheen Sultan

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

##### Street address

Heigherwala khurd, via pahrianwali tehsil: phalia Distt: M.B.Din.

##### City

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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**  
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Nosheensultan1957@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
University of Lahore, Chenab Campus Gujrat.  
**Full name of responsible person**

Nosheen Sultan  
**Position**  
Student  
**Latest degree**  
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**Other areas of specialty/work**  
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**Email**  
nosheensultan1957@gmail.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