# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

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**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 ethier 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**
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**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
**Postal code**
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

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## Person responsible for updating data

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University of Lahore, Chenab Campus Gujrat.

**Full name of responsible person**

Nosheen Sultan

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Physiotherapy

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**City**

Mandi Baha ud Din.

**Province**

Punjab

**Postal code**

50300

**Phone**

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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