Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Proprioceptive Neuromuscular Exercises in improving Knee Range of Motion, Functional Ability, and Balance in Total Knee Arthroplasty Patients; A Randomized Clinical Trial

Protocol summary

Study aim

To determine the effect of Proprioceptive Neuromuscular Facilitation exercises in improving knee ROM, functional activity and balance in total knee arthroplasty patients.

Design

two arm parallel group randomized trial with patients and data analyzer blinded

Settings and conduct

The study will be conducted at Physiotherapy department of Rehman Medical Institute, Peshawar. The participants will be blinded by not informing them what group they are in, similarly the statistician will be blinded by keeping the allocation of participants concealed.

Participants/Inclusion and exclusion criteria

Participants who had unilateral total knee replacement surgery 1 week ago and were able to walk for 10 meters on ground at a comfortable speed, and having MMSE score of 24 or more were included in the study while the participants who had total knee replacement previously, re-operation for total knee replacment (revision arthroplasty or manipulation under anesthesia), past surgical history of any orthopedic procedure at lower limbs, history of fractures at lower limbs, multiple medical comorbidities such as metabolic disorders, cancers, cardiovascular conditions, Cognitive and neurological disorders i.e. stroke, neuropathy, neuromuscular disorders and individuals on Beta Blockers and uncontrolled Hypertension were excluded.

Intervention groups

Participants in the control group will receive traditional stretching and exercises using isotonic contractions while those in experimental group will be engaged in stretching using PNF techniques such as Rhythmic Initiation, Combination of isotonic and Hold Relax, along with the exercises given to the control group, each for 30 minutes, conducted 5 times a week for 2 weeks.

Main outcome variables

Knee Range of Motion, Functional activity and Balance are the outcome variables, which are to be assesed via goniometer, time up & go test, and mini berg balance scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241230064219N1**
Registration date: **2025-05-11, 1404/02/21**
Registration timing: **prospective**

Last update: **2025-05-11, 1404/02/21**
Update count: **0**

Registration date

2025-05-11, 1404/02/21

Registrant information

Name

Munazza Shah

Name of organization / entity

Khyber Medical University

Country

Pakistan

Phone

+92 334 9234131

Email address

munazza.shah@rmi.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-15, 1404/02/25

Expected recruitment end date

2025-06-15, 1404/03/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Proprioceptive Neuromuscular Exercises in improving Knee Range of Motion, Functional Ability, and Balance in Total Knee Arthroplasty Patients; A Randomized Clinical Trial

Public title
Effectiveness of Proprioceptive Neuromuscular Exercises in patients that have undergone Total Knee Replacement Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with unilateral Total Knee Arthroplasty Procedure Participants who underwent 1 weeks after Total Knee Arthroplasty surgery Patients who can walk for 10 meters on ground at a comfortable speed (with or without assistive device) Patients having Mini Mental State Examination score of 24 or more
Exclusion criteria:
Individuals who had undergone total knee replacement previously. Individuals who had a re-operation for total knee arthroplasty (revision arthroplasty or manipulation under anesthesia). Past surgical history of any orthopedic procedure at lower limbs. History of fractures at lower limbs. Individuals with multiple medical comorbidities such as metabolic disorders, cancers. Individuals with cardiovascular conditions such as Ischemic heart disease or Peripheral Vascular Disease. Individuals with Cognitive and neurological disorders i.e. stroke, neuropathy. Individual with neuromuscular disorders i.e., Multiple Sclerosis. Individuals on Beta Blockers and uncontrolled Hypertension. Individuals with multiple musculoskeletal conditions other than knee Osteoarthritis
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
randomization will be conducted to ensure unbiased allocation of participants into study groups. The method of randomization employed will be block randomization, which will help maintain equal group sizes throughout the enrollment period. The unit of randomization will be individual participants, allowing for precise control over group characteristics. To enhance balance across key baseline variables, stratified randomization will be implemented. Randomization strata will be based on factors such as age group and gender, ensuring that these characteristics are evenly distributed between the intervention and control groups. The randomization process will be carried out using computer software designed for clinical trials, i.e. random.org, which can generate a reproducible and tamper-proof sequence. The random sequence will be generated in advance using a pre-defined algorithm within the software, ensuring unpredictability and integrity in the allocation process. To protect against selection bias, allocation concealment will be maintained throughout the process. This will be achieved using sealed, opaque, and sequentially numbered envelopes, which will be prepared and opened only after the participant has been enrolled in the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will adopt a double-blind design, in which both the participants and the outcome assessor will be blinded to group allocation. Participants will not be informed of whether they are receiving the experimental intervention or the control condition. To support this, both interventions will be matched in terms of appearance, duration, and general format, thereby minimizing the chances that participants could infer their group allocation based on the nature of the treatment received. All instructions and interactions will be standardized across groups. The assessor, responsible for collecting both pre-intervention and post-intervention data, will remain fully blinded to the group assignment of each participant. The assessor will not participate in intervention delivery, will not have access to the randomization list or allocation codes, and will interact with participants only during scheduled data collection sessions i.e. at the start of the intervention and two weeks after the intervention is given. All participants will be identified by coded IDs, and documents of data collection will be anonymized to avoid revealing group identity. To further ensure the maintenance of blinding, participants will be explicitly instructed not to disclose any information about their intervention to the assessor during the data collection process. In addition, separate personnel will handle randomization and intervention delivery to prevent information leakage. To evaluate the effectiveness of blinding, a post-study assessment of blinding integrity will be conducted. The assessor will be asked to guess participants' group assignments to determine whether blinding was preserved throughout the study. Any cases of suspected or actual unblinding will be recorded, along with their potential impact on study results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Institute of Physical Medicine and Rehabilitation, Khyber Medical University

Street address
Phase V, Hayatabad, Peshawar

City
Peshawar

Postal code
25000

Approval date
2024-11-08, 1403/08/18

Ethics committee reference number
KMU/IPMR/ORIC/2024/96

Health conditions studied

1

Description of health condition studied
The condition under study is knee osteoarthritis. Systematic analysis for a Global burden of disease study done in 2021, shows that OA was the 7th ranked cause of Years lost due to disability (YLD's) in adults aged over 70 years and knee was the most common site of Osteoarthritis. While the post-operative recovery process differs from person to person, most of the patients report a marked improvement in the outcomes such as pain however, it has been found that muscle atrophy, neuromuscular impairments and balance deficits can persist for longer periods of time as indicated in a systematic review conducted by Ravi et.al. Post-operative mobility is strongly influenced by knee range of motion (ROM). A reduction in knee ROM not only weakens lower extremity muscle strength over time but also causes joint stiffness.

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Range of Motion: The knee flexion and extension Range of Motion.

Timepoint
before intervention and 2 weeks after intervention

Method of measurement
Range of Motion will assessed using a goniometer with patient in supine position and in saggital plan of movement.

Secondary outcomes

1

Description
Secondary outcome variable is Functional Activity. Being bed ridden in the initial phases after total knee replacement detrimentally effects the level of functional activity as many patients avoid to move at all.

Timepoint
before intervention and 2 weeks after intervention

Method of measurement
The Timed Up and Go (TUG) test will be used to assess functional activity. It is a highly reliable tool with inter- and intra-rater reliability scores of r=0.98 to 0.99. At the starting point, participants will be seated in an chair. When the signal to begin is given, they must get up from the chair, move three meters to a point, quickly turn towards the TKR side, and then get back in the chair. The time to complete the task will be recorded.

2

Description
Balance

Timepoint
before intervention and 2 weeks after intervention

Method of measurement
Short form of Berg Balance scale will be used to assess the balance performance of the participants.

Intervention groups

1

Description
Control group: Participants in the control group will receive exercises such as (1) knee flexion with assistance from a belt in supine lying, (2) quadriceps on fulcrum in supine lying, (3) heel slides in supine lying (4) straight leg raise in hooked lying (5) knee extension with assistance from a belt in hook lying, (6) seated knee extension, and (7) Seated Knee flexion while sliding the foot on the ground using isotonic contractions. These exercises will be performed under the supervision of a skilled physical therapist in a physical therapy OPD setting, for a duration of 30 minutes, with exercise sessions conducted 5 times a week for 2 weeks

Category
Treatment - Other

2

Description
Interventional Group: Participants in the Experimental or interventional group will receive same exercises given to the control group but these exercises will be performed using techniques of Proprioceptive Neuromuscular facilitation called Rhythmic Initiation (RI), Combination of isotonic (CI) and Hold Relax (HR). Exercises such as (1) knee flexion with assistance from a belt in supine lying, (2) quadriceps on fulcrum in supine lying, (3) heel slides

in supine lying (4) straight leg raise in hooked lying (5) knee extension with assistance from a belt in hook lying, (6) seated knee extension, and (7) Seated Knee flexion while sliding the foot on the ground will be performed in a manner that each exercise position is held for 10 seconds with a rest period of 10 seconds. Each exercise will have 2 sets and each set will have 6 repetitions and a time period of 1 minute as rest between each set. The exercise sessions will be conducted 5 times a week for 2 weeks under the supervision of a skilled physical therapist in a physical therapy OPD setting.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy and Rehabilitaton Department Rehman Medical Institute

Full name of responsible person
Hoor Kakar

Street address
5-B/2, Phase-V, Hayatabad Peshawar, KP, Pakistan

City
Peshawar

Postal code
25000

Phone
+92 91 5838334

Fax
+92 91 5838333

Email
info@rmi.edu.pk

Web page address
https://www.rmi.edu.pk/#

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khyber Medical University Peshawar

Full name of responsible person
Dr Mujeeb ur Rahman (PT)

Street address
Phase V, Hayatabad, Peshawar

City
Peshawar

Postal code
25000

Phone
+92 91 9217703

Fax
+92 91 9217703

Email
mujeeb.rahman@kmu.edu.pk

Web page address
https://kmu.edu.pk/

Grant name

Grant code / Reference number

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

Title of funding source
Khyber Medical University Peshawar

Proportion provided by this source
100

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Institute of Physical Medicine and Rehabilitation, Khyber Medical University

Full name of responsible person
Munazza Shah

Position
Scholar of Master's Program

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
D-2, PTCL Colony opposite Bagh-e-Naran, sector k-2, phase 3 Hayatabad Peshawar

City
Peshawar

Province
Khyber Pakhtunkhwa

Postal code
25000

Phone
+92 91 5812299

Email
shah.munazza997@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Institute of Physical Medicine and Rehabilitation, Khyber Medical University

Full name of responsible person
Munazza Shah

Position
Scholar of Master's Program

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
D-2, PTCL Colony opposite Bagh-e-Naran, sector k-2, phase 3 Hayatabad Peshawar
City
Peshawar
Province
Khyber Pakhtunkhwa
Postal code
25000
Phone
+92 91 5812299
Email
shah.munazza997@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Institute of Physical Medicine and Rehabilitation, Khyber Medical University
Full name of responsible person
Munazza Shah
Position
Scholar of Master's Program
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
D-2, PTCL Colony opposite Bagh-e-Naran, sector k-2, phase 3 Hayatabad Peshawar
City
Peshawar
Province
Khyber Pakhtunkhwa
Postal code
25000
Phone
+92 91 5812299
Email
shah.munazza997@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