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Research Protocol

Physiotherapy Section

Impact of Early Proprioceptive Training on Pain, Range of Motion, Muscle Strength, and Gait Post in Patients following Total Knee Replacement: A Research Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: In cases of Osteoarthritis (OA) affecting knee compartments, Total Knee Replacement (TKR) is highly effective but often leads to postsurgery challenges such as reduced knee flexion, strength, and Range of Motion (ROM). The purpose of this study is to fill in the information gaps regarding the best proprioceptive training settings for patients undergoing TKR. Although there is some discussion about the optimal method, early proprioceptive training is essential for enhancing gait, neuromuscular control, balance, and recovery outcomes. This study aims to improve customised rehabilitation techniques by examining the influence of important variables such as muscular strength and knee ROM. The ultimate goals are to improve recovery, prevent falls, and enhance the long-term quality of life for TKR patients.

Need of the study: While traditional TKR rehabilitation has been widely studied, research on early-stage proprioceptive rehabilitation is scarce, highlighting the need for more effective post-TKR rehabilitation techniques.

Aim: To investigate the effect of early intervention using proprioceptive training along with Combined Kinematic Chain Exercise (CCE) in subjects who have undergone TKR.

Materials and Methods: A Randomised Controlled Trial (RCT) will be conducted in the orthopaedic ward (IPD no. 33) of Acharya Vinoba Bhave Rural Hospital, Ravi Nair Physiotherapy College, Sawangi, Wardha, with a total sample size of 52. The duration of the study is from February 2024 to June 2025. Twenty-six participants will be allocated to each group. The patients will be divided into two groups: the control group (Group A), which will receive CCE, and the experimental group (Group B), which will receive proprioceptive exercises along with CCE. Both groups will undergo interventions six days a week for four weeks, with outcome measures assessed at baseline and after four weeks.

Primary outcomes will include pain {Numeric Pain Rating Scale (NPRS)}, ROM, gait parameters (X-sens), muscle strength, and gait (balance and functional mobility). These parameters will be assessed using frequency and percentage for categorical data, and mean and standard deviation for continuous data. Continuous outcome variables will be analysed using normality tests and summarised with descriptive statistics; significance will be tested using t-tests for normally distributed data and Mann-Whitney tests for non-normally distributed data. Categorical variables will be summarised by frequency and percentage, with efficacy analysed using Chi-square tests.

Keywords: Arthroplasties, Balance training, Knee joint, Posture balance, Rehabilitation, Walking

INTRODUCTION

The most frequent and persistent cause of disability and mobility dependency is Osteoarthritis (OA). Between 1990 and 2013, around 240 million individuals globally were affected by OA. Patients with OA typically experience symptoms for an average of 26.1 years [1]. OA, also known as degenerative joint disease, leads to pain and functional impairment, significantly reducing quality of life [2]. The inflammatory process in OA begins in the synovial membrane, where both humoral and cellular mediators, along with "Damage-Associated Molecular Patterns" (DAMPs), play critical roles [3].

Each year, around 1.5 million Total Knee Arthroplasties (TKA) are performed worldwide [4]. By 2030, TKA procedures are expected to increase by 601%, reaching 3.48 million annually [5]. TKA aims to alleviate joint discomfort, enhance mobility, and improve quality of life in patients with end-stage OA or rheumatoid arthritis, although postoperative pain remains an issue. Three-quarters of patients report mild pain, and 60% report severe pain after surgery [6]. OA in the knee leads to weakened muscles, tendons, and ligaments, as well as impaired proprioception, which increases the risk of discomfort or incapacity [7,8].

Recent research indicates that early-stage knee OA may reduce proprioception, which is provided by receptors in muscles, tendons, and joint capsules [9,10]. Studies show that Bicompartmental Knee Arthroplasty (BKA) offers superior outcomes in Active Daily Life (ADL) scores, Knee Injury and Osteoarthritis Outcome Score (KOOS) stiffness, The Knee Society Score (KSS) function, and postoperative knee ROM compared to TKA [11,12].

Rehabilitation following TKR, particularly focusing on quadriceps strength and ROM, plays a vital role in recovery, with no increased risk of injury during early rehabilitation [13-15].

Various rehabilitation techniques, including telerehabilitation and balance training, have shown promise in improving function and mobility in knee OA patients post-TKR [16,17]. Early proprioceptive and balance training can enhance functional outcomes, gait patterns, and overall rehabilitation, reducing the risk of falls and improving quality of life by supporting stability, mobility, and pain relief [18]. Early proprioceptive training is a key component of TKR physiotherapy, enhancing neuromuscular control and proprioception, which are often compromised following surgery [19]. Starting balance training early helps improve gait, reduce fall risks, restore stability, and promote proper weight distribution. This leads to better functional

outcomes, such as increased mobility and independence in daily activities, while also reducing pain and swelling. Overall, early proprioceptive training significantly improves the quality of life and accelerates recovery for TKR patients.

At present, there are no established standards regarding the ideal length, frequency, and intensity of proprioceptive training for TKR rehabilitation, nor is there any knowledge about the long-term impacts on balance, gait, and quality of life. By determining optimal proprioceptive training settings and investigating the effects of gait, knee ROM, balance, muscle strength, and physical condition on recovery, this study seeks to address these gaps. The study's unique approach is its individualised method, which aims to create focused rehabilitation regimens that can improve the quality of life and recovery outcomes for TKR patients.

Aim: To investigate the effect of early intervention using proprioceptive training along with CCE in subjects who have undergone TKR.

Primary objective:

1) To evaluate the effectiveness of early proprioceptive rehabilitation along with CCE on pain, ROM, muscle strength, and gait in subjects who have undergone TKR.
2) To evaluate the effectiveness of CCE on pain, ROM, muscle strength, and gait in subjects who have undergone TKR.

Secondary objective:

1) To compare the effectiveness of early proprioceptive rehabilitation alongside CCE on muscle strength, functional mobility, and balance in subjects who have undergone TKR.

Null hypothesis:

H0: There will be no significant difference in the effect of early-stage proprioceptive rehabilitation combined with CCE compared to CCE alone on pain, ROM, and muscle strength.

Alternative hypothesis:

H1: Early-stage proprioceptive rehabilitation combined with CCE will have a significant effect on pain, ROM, muscle strength, and gait in patients undergoing TKR.

REVIEW OF LITERATURE

Balance and proprioceptive impairments often persist after total joint replacement, leading to reduced functionality, altered gait, and difficulties with walking and postural control [18]. A literature review highlights varying outcomes, with some patients showing improvement through rehabilitation, while others experience long-term deficits.

Ozden F et al., provide clear information indicating that there is a lack of literature on step reaction time, proprioception, and gait performance on curved paths after Total Knee Arthroplasty (TKA). Using assessments such as the Figure-of-8 Walk Test (F8WT), L Test, and Tinetti Gait Test (TGT), this study investigated the association between proprioception, response time, and walking performance in older TKA patients. The findings demonstrated moderate relationships with both left and right leg proprioception, as well as substantial connections with Step Response Time (SRT), proprioception, and TGT scores for the F8WT. Regression models indicated that both the F8WT and the L Test were highly correlated with reaction time and balance. These results suggest that proprioception, balance, and reaction time are important factors in enhancing walking ability on curved pathways following TKA [20].

Guede-Rojas F et al., suggest that Strength Training (ST) is essential for enhancing muscle strength and possibly proprioception, arguing that proprioception is significantly compromised in Knee Osteoarthritis (KOA). According to a meta-analysis of RCTs, ST significantly improves knee proprioception compared to no intervention, particularly in Joint Position Sense (JPS) and Threshold to Detect Passive Motion (TTDPM), whereas the improvement in the knee JPS (active) category was not statistically significant. The author concludes that, while ST improves proprioception, further research is required to strengthen the evidence supporting its usefulness in clinical settings and to address its limitations [21].

Garner AJ et al., investigated compartmental strategies to examine the gait and patient-reported outcome measures of individuals who underwent partial knee arthroplasty and subsequently combined partial knee replacement. They concluded that comparing the compartmental approach to native compartment degeneration after partial knee arthroplasty leads to a gait that is closer to normal and higher patient satisfaction [22].

According to Wu J et al., proprioceptive training is a valuable recovery method for individuals who have undergone complete knee replacement surgery. The study illustrates the training's potential advantages in enhancing functional outcomes, balance, and overall recovery by methodically presenting the clinical impacts of the intervention. The conclusion emphasises the relevance of proprioceptive training in postoperative rehabilitation programmes, offering clinicians evidence-based recommendations to improve rehabilitation outcomes for TKA patients [19].

MATERIALS AND METHODS

The RCT design will be conducted in the orthopaedic ward, focusing on Total Knee Replacement (TKR) and Total Hip Replacement (THR) at Acharya Vinoba Bhave Rural Hospital, Ravi Nair Physiotherapy College, Sawangi, Wardha. A total of fifty-two participants will be enrolled, with twenty-six in each group. The study will take place from February 2024 to June 2025. The institutional ethical approval number has been obtained, with the reference number DMIHER (DU)/IEC/2024/182. The trial has been registered on the Clinical Trials Registry-India (CTRI) website, and the registration number is CTRI/2024/04/065377. Consent will be obtained from the participants.

Inclusion criteria:

1. Both male and female participants.
2. Patients who have undergone TKR.
3. Aged between 50 and 65 years.
4. Total Knee Replacement (TKR).
5. Those who have been referred to physiotherapy.
6. Uncemented and cemented implants.

Exclusion criteria:

1. Patients with superficial or deep sensory impairments.
2. Patients with hip problems who have undergone THR.
3. Patients with plantar fasciitis.
4. Current participation in another OA intervention study.
5. Severe physical disabilities (i.e., unable to walk, even with a walking aid).
6. Patients unwilling to participate in the study.

Sample size:

Formula using mean difference

$$n1=n2=2\frac{(Z_\alpha+Z_\beta)^2\sigma^2}{(\delta)^2}$$

Z_α=2.58

α=Type I error at 1% at both sides two tailed

Z_β=2.34=Power at 99%

Primary variable: Step Length (cm)

Mean Difference=2.49

Standard deviation=1.48 [23]

Minimum sample size required:

$$\text{Sample size } N=n1=n2=2\frac{(2.58+2.34)^2(1.48)^2}{(2.49)^2}=17 \text{ per group}$$

Total sample size required: 26 per group.

According to reference articles: An J et al., [23].

Outcome measures:

The outcomes measured in the present study are given in [Table/Fig-1].

Outcome measure	Scale/device
Pain	Numerical Pain Rating Scale (NPRS)
Knee ROM	Goniometer
Gait	X-Sens
Gait (balance and functional mobility)	TUG (The Time Up and Go)
Muscle strength	MMT by Kendall grading

[Table/Fig-1]: Outcome measures.

- Primary outcome:

1) Pain (NPRS)
   - Pain will be assessed three times: firstly, pre-rehabilitation; secondly, post-rehabilitation; and thirdly, after the home exercise programme.
   - Adults' pain intensity can be measured unidimensionally using the NPRS. Validity: It has been demonstrated that, in patients with rheumatic and other chronic pain syndromes (pain >6 months), there is a strong correlation between the NPRS and the Visual Analogue Scale (VAS), with a correlation range of 0.86 to 0.95 [24].
2) Knee Range Of Motion (ROM)
   - Using a universal goniometer, specifically a full circle goniometer from the brand Medisky Surgicals, we will assess the knee ROM both pre-intervention and post-intervention.
   - The knee will be assessed three times: first, pre-rehabilitation; secondly, post-rehabilitation; and thirdly, after the home exercise programme.
   - Goniometer procedure:

     Patient position: The patient should be lying supine with the hip and knee in a neutral position. A towel is placed under the distal thigh.

     Axis: Positioned over the lateral epicondyle of the femur.

     Stationary arm: Aligned with the lateral midline of the femur, aiming towards the greater trochanter.

     Moving arm: Aligned with the lateral midline of the fibula, aiming at the lateral malleolus.

     Stabilisation: The pelvis should be supported to prevent movement, and the femur should be stabilised by the clinician's hand if needed to avoid hip motion.
   - A goniometer is a popular tool for measuring the ROM at joints, measuring angles in different planes at the body's joints and is especially useful in rehabilitation. Studies show that goniometers are more accurate than X-rays for knee joint angles and have good to excellent reliability, especially for inexperienced users. However, reliability can vary depending on the specific joint and movement being measured [25].
3) Gait Parameters and Gait
   - The Xsens system measures various gait metrics such as stride length, step length, cadence, and gait speed.

     Stride length: Distance between heel contacts of the same foot.

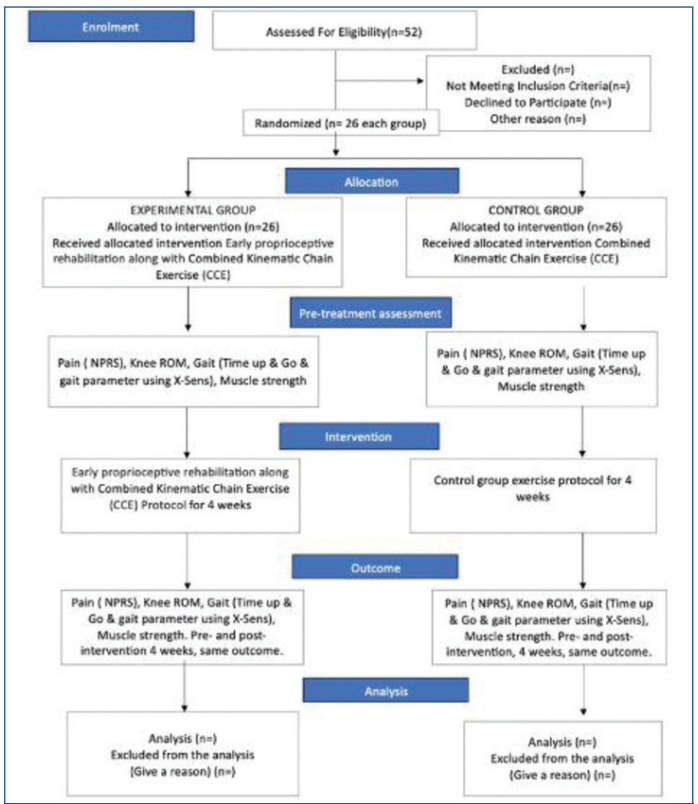
     Step length: Distance between consecutive heel contacts of opposite feet.

     Cadence: Steps taken per minute.

     Gait speed: Walking speed, calculated as distance travelled divided by time or as the product of step length and cadence.
   - The Xsens MVN Link, an Inertial Measurement Unit (IMU) system, is used for this purpose. It includes 17 IMUs attached to different body parts, such as hands, feet, legs, pelvis, shoulders, sternum, head, and arms, allowing for full-body motion capture. Each unit comprises a barometer, 3D accelerometers, 3D magnetometers, and 3D gyroscopes. Full details are available in the MVN User Manual [26].
4) Muscle strength:
   - Muscle strength will be assessed using manual muscle testing according to the Kendall grading system. Assessments will be conducted three times: before rehabilitation, after rehabilitation, and following the home exercise programme.
   - Manual Muscle Testing (MMT) is a technique used to assess a muscle's or muscle group's strength based on how effectively a movement is performed in response to gravity or manual resistance throughout the available ROM. It is a tool for assessing weakness and is useful in distinguishing between actual weakness and imbalance or low endurance. It may be referred to as manual muscle testing, muscular strength grading, motor testing, or by various other synonyms [27].
5) Gait (Balance and Functional Mobility)
   - The Timed Up and Go (TUG) test assesses walking skills, balance, and functional mobility. It has been validated by strong correlations with gait speed (r=0.75), postural sway (r=-0.48), step length (r=-0.74), Barthel Index (r=-0.79), and step frequency (r=-0.59) [28].

Study Procedure

A total of fifty-two patients will be allocated to two groups. Control group (Group A) patients will receive CCE, while experimental group (Group B) patients will undertake proprioception exercises alongside CCE. In [Table/Fig-2], the CONSORT chart illustrates the



[Table/Fig-2]: Consort chart showing study procedure.

study procedure. Both groups will receive interventions six days a week for four weeks. The outcome measures, including pain, ROM, muscle strength, and gait, will be assessed at baseline and after four weeks of intervention, as well as after four weeks of a home exercise programme.

Randomisation sequence: Participants will be allocated randomly using the sequentially numbered opaque sealed envelope method.

Allocation: Equal allocation superiority will be facilitated by a computer-generated random number system, utilising the sequentially numbered opaque sealed envelope method for sample allocation [29].

Blinding: This will be a single-blind study. The assessor will be blinded to the participants' group assignments. It is significant to note that the therapist is not blinded, as they are the ones providing the interventions to the patients. Similarly, the patients are not blinded because they are directly involved in the exercises and can see what they are performing. Therefore, the assessor is blinded to minimise bias when evaluating the outcomes.

Dependent variables: NPRS, TUG

Independent variables: Proprioceptive training and CCE

Intervention

Control group (Group-A)

The Control Group will receive CCE starting from day three and continuing for four weeks. The main focus will be on CCE training to improve physical function, balance ability, and gait. This group of patients will receive only CCE, as illustrated in [Table/Fig-3].

Week	Contents of program	Times
1 week	CCE [23] – 1. Quadriceps setting in the supine position 2. Ankle full exercise in a supine 3. Wallslide 4. Getting up and down from a chair	10 repetition×2 set
2-3 week	CCE- 1. Quadriceps setting while sitting 2. Getting up and down from a chair 3. Standing up and off heels 4. Wall squat 5. Stepping up and down the step box forward and sideward	10 repetition×2 set
Week	CCE- 1. Getting up and down from a chair 2. Hip abduction exercise while standing 3. Stepping up and down from a step box forward and sideward 4. Mini squat with a walker 5. Toe gait	10 repetition×2 set

[Table/Fig-3]: Week-wise protocol for control group (Group-A) [23].

Experimental Group (Group-B)

The Experimental Group will commence the treatment protocol from day one and continue for four weeks, focusing primarily on physical function, knee flexion, balance, and gait. The aim is to achieve early walking and improved balance through the implementation of proprioceptive exercises. This group of patients will receive both proprioception exercises and CCE. In the second week, proprioception exercises will be initiated alongside CCE, as illustrated in [Table/Fig-4] [30-32].

Home exercise program: Following discharge, the patients in the control group will continue their CCE rehabilitation at home. By employing exercises that target the lower limb of the kinematic chain, particularly the knee joint and the surrounding muscles, CCE aims to enhance functional mobility. The goal of this approach is to maintain knee strength, joint ROM, and stability—all of which are critical for performing ADLs, such as walking, standing up from a seated position, and ascending stairs. These patients can sustain the progress made during inpatient rehabilitation by continuing CCE at home, which aims to improve joint function, support muscular strength, and alleviate stiffness commonly associated with TKR recovery.

Week	Contents of program	Times
Week	• CCE [23]: 1. Quadriceps setting in the supine position 2. Ankle full exercise in a supine 3. Wall slide 4. Getting up and down from a chair	10 repetition×2 set
2-3 week	• CCE: 1. Quadriceps setting while sitting 2. Getting up and down from a chair 3. Standing up and off heels 4. Wall squat 5. Stepping up and down the step box forward and sideward • **Start proprioceptive training;** 1. Standing (eye open and eye closed) [30] 2. Two-leg stance [31] 3. Single leg stance stable surface (eye open - eye closed) [30] 4. Double leg squat with walker [31] 5. Single leg stance on balance pad progress (thick carpet-foam block- pillow-bosu) [30,32] 6. Double leg squat unstable surface i.e. balance pad [30]	10 repetition×2 set 10 repetition×2 set
4 week	• CCE: 1. Getting up and down from a chair 2. Hip abduction exercise while standing 3. Stepping up and down from a step box forward and sideward 4. Mini squat with a walker 5. Toe gait • **Proprioceptive training;** 1. Single leg stance with ball toss/foam [30,32]. 2. Side to side step on bosu [32] 3. Squat on bosu [31,32] 4. Lunges on bosu [32].	10 repetition×2 set

[Table/Fig-4]: Week-wise protocol for the experimental group (Group-B) [30-32].

The experimental group will also continue with CCE and proprioceptive training after discharge at home. Proprioceptive exercises challenge the body in various planes of movement (e.g., balancing on unstable surfaces, single-leg stances) to enhance joint awareness and neuromuscular control, ultimately improving balance, coordination, and stability. Patients receiving this training will be better equipped to adapt to changes in joint position, which is essential for steady and safe mobility, particularly on uneven terrain.

Proprioceptive training improves balance and control, while CCE develops muscular strength and increases joint mobility. This combination of proprioceptive exercises and CCE provides a dual emphasis. It is anticipated that this integrated approach will enhance functional outcomes more effectively compared to CCE alone, providing patients with greater stability and confidence.

The control group (Group A) participants will continue their CCE exercises at home after discharge, while the experimental group (Group B) patients will persist with their proprioceptive exercises alongside CCE exercise at home after discharge.

STATISTICAL ANALYSIS

The full analysis data set will include all the study participants with no missing values for any parameters in the data set. All data will be summarised with baseline characteristics. Demographic variables will be described by frequency and percentage for categorical data, and by mean and standard deviation for continuous data.

Statistical software SPSS 20 will be used for analysis. Outcome variables will be summarised for continuous variables with minimum, maximum, mean, standard deviation, standard error, and a 95% CI for parametric data. The continuous outcome variables will first be tested for normality using the Kolmogorov-Smirnov test at a 5% level of significance ($p \leq 0.05$). If the normality assumption is rejected, non-parametric tests will be employed to determine significance.

The t-test will be used to identify significant differences at a 5% level ($p \leq 0.05$) between the comparative groups: 1) Proprioceptive

rehabilitation with CCE; and 2) CCE (Control Group). The effect size will be measured at different assessment visits between the two groups for the variables of knee ROM and gait parameters using Xsens.

Non-normally distributed data will be described by mean, median, and the lower and upper quartiles for non-parametric testing. A significance level of $p<0.05$ will be applied, and the Mann-Whitney test will be used for testing significance. Categorical variables will be summarised by frequency (N) and percentage (%). The efficacy of categorical variables will be analysed using Chi-square analysis to determine overall efficacy.

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