Research Protocol

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Comparative Effects of Neuromuscular Joint Facilitation and Conventional Physiotherapy on Pain, Balance, and Functional Performance in patients with Knee Osteoarthritis: A Randomised Controlled Trial Protocol

Physiotherapy Section

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ABSTRACT

Introduction: Globally, Knee Osteoarthritis (KOA) is a major contributor to pain, impairment, and decreased mobility. While traditional physical therapy emphasises mobility, strengthening, pain management, and function, it cannot adequately address neuromuscular deficiencies that impact joint stability. Neuromuscular Joint Facilitation (NJF) is a movement-based method that improves muscle activation, coordination, and proprioception.

Need of the study: KOA is commonly associated with pain, impaired balance, and reduced functional ability. While conventional physiotherapy has been shown to improve pain and functional outcomes, it may not sufficiently address underlying neuromuscular and proprioceptive deficits. Additionally, there is limited comparative evidence regarding the effectiveness of NJF, particularly in improving balance among individuals with KOA. Therefore, this study is needed to compare the effectiveness of NJF and conventional physiotherapy in enhancing balance, reducing pain, and improving functional ability in this population.

Aim: To compare the effectiveness of NJF and conventional physiotherapy techniques in reducing pain, improving balance, and function in Grade 2 and 3 KOA patients.

Materials and Methods: A single-blinded, randomised controlled trial will be conducted at the tertiary care multispeciality hospital in Mullana, Ambala, Haryana, from January 2025 to December 2026. A total of 60 participants will be enrolled. The study will recruit patients aged 40-70 years, both male and female, with KOA, who meet the inclusion criteria. Numeric Pain Rating Scale (NPRS) for pain, Western Ontario and McMaster Universities OA index (WOMAC) for function, and Single Leg Stance test (SLS) for balance will be the outcome measures. The experimental group will receive NJF, including PNF diagonal patterns, PNF stretching, and joint composition movements; the control group will receive conventional physiotherapy exercises, three times a week for four weeks. Paired t-test and independent t-test will be used for intra-group and inter-group comparisons, respectively. If data are not normally distributed, the Wilcoxon signed rank test and the Mann-Whitney U test will be applied, and the chi-square test will be used for categorical variables with significance set at $p<0.05$.

Keywords: Muscle strength, Pain management, Proprioception, Quality of life

INTRODUCTION

The KOA is a major global health concern, ranking among the leading contributors to disability worldwide, with an increasing burden due to ageing and rising obesity levels [1]. Joint stiffness, decreased proprioception, discomfort, and quadriceps muscle weakness are common symptoms of KOA. These problems may eventually cause disability by a progressive deterioration in functional capacities like walking and climbing stairs [2]. OA management aims to limit impairment, improve function, reduce pain, educate patients, and slow the disease progression. According to research, these people can have neuromuscular deficiencies; incorporating neuromuscular exercises is vital for improving the overall efficacy of training outcomes [3]. NJF is a new kinesiology-based exercise that incorporates joint composition movement and the facilitatory element of proprioceptive neuromuscular facilitation, to enhance joint mobility through resistance, active, and passive exercises [4,5]. Some research has indicated that neuromuscular facilitation techniques can improve proprioception and muscle strength, both of which are essential for reducing the risk of falls and increasing mobility [5,6].

Conventional physiotherapy includes range-of-motion exercises, muscle strengthening, stretching, and pain-relieving modalities aimed at reducing symptoms and improving physical function in individuals with KOA. Although these interventions have demonstrated effectiveness in reducing pain and improving functional outcomes, they may not specifically target sensorimotor control and proprioceptive deficits associated with KOA. Therefore, interventions incorporating neuromuscular and proprioceptive training may provide additional benefits in improving joint stability and balance performance [7,8].

The NJF may be more effective than conventional physiotherapy in the management of KOA. For example, PNF treatment significantly improved muscular strength and proprioception compared to standard therapy in a clinical trial of patients with early-stage KOA [9]. Furthermore, a study examining NJF's immediate impact on pain perception and walking performance in older adults with KOA reveals that NJF enhances walking ability and reduces pain [3].

The present study is designed to compare the relative effectiveness of a NJF programme and conventional physiotherapy treatment on pain intensity, balance control and physical function in subjects with Grade 2 and 3 KOA over four weeks using the NPRS, SLS outcomes, and WOMAC.

REVIEW OF LITERATURE

The KOA is a common musculoskeletal disorder that significantly impairs physical function and overall quality of life, often limiting mobility and the ability to perform daily activities independently [8].

Lall S et al., compared the effects of NJF and quadriceps strengthening exercises on pain, physical function, posture, and balance in individuals with KOA. Sixty participants were randomly assigned to either the NJF group or the quadriceps strengthening group. Outcome measures included the NPRS, 30-Second Chair Stand Test (30s-CST), and SLS. The authors concluded that both NJF and quadriceps strengthening exercises were effective in improving pain, functional performance, and balance in individuals with KOA [3].

Huo M et al., investigated the effects of NJF on lower limb muscle strength in healthy young individuals. The study included participants divided into the NJF group and the PNF group. The results demonstrated significant improvement in maximal hip flexor and extensor muscle strength in the NJF group at both angular velocities (60°/sec and 180°/sec) following intervention compared to baseline values ($p<0.05$). The authors concluded that NJF has an immediate positive effect on hip muscle strength and neuromuscular activation [4].

Ge M et al., investigated the immediate effects of NJF on muscle force at the knee. The findings revealed that the NJF group demonstrated a significant improvement in both maximal knee flexor and extensor muscle strength compared to the control group after receiving the intervention. Specifically, mean maximal extensor force increased across angular velocities (at 60°: 66.0±6.1 to 69.3±7.6; at 180°: 64.5±7.4 to 66.2±8.0; at 300°: 57.3±14.5 to 61.8±12.7). Similarly, changes were observed in maximal flexor force values. The authors concluded that NJF enhanced joint alignment and neuromuscular coordination, leading to greater muscle fibre recruitment and activation, which ultimately contributed to increased muscle strength [10].

Nakata K et al., evaluated the immediate effect of NJF on patients with KOA. The results indicated that post-intervention, the NJF group showed decreased Visual Analogue Scale (VAS) (22.6±15.8 to 0.0±0.0), increased walking velocity (62.5±14.9 to 68.0±15.4 m/min) and step length (0.53±0.10 to 0.64±0.13 m), with reduced cadence (117.6±12.0 to 106.2±10.2 steps/min) compared to the control group. The authors concluded that NJF would be effective in reducing pain and improving gait parameters, contributing to better functional mobility in KOA [11].

Although previous studies have demonstrated the beneficial effects of NJF on muscle strength, gait and pain in KOA. Most of these studies have focused on isolated outcomes such as muscle strength, gait or immediate effects on muscle force. Additionally, limited research has been conducted to directly compare NJF with conventional physiotherapy interventions, particularly in patients with grade II and III KOA. Therefore, the present study aims to address this research gap by comparing the effectiveness of NJF and conventional physiotherapy in reducing pain and improving balance and functional performance among individuals with Grade II and III KOA.

Primary objective:

- To evaluate the effectiveness of NJF in reducing pain, improving functional ability, and balance control in individuals with Grade 2 and 3 KOA.
- To evaluate the effectiveness of conventional physiotherapy techniques in reducing pain, improving functional ability, and balance control in individuals with Grade 2 and 3 KOA.

Secondary objective:

- To compare the effectiveness of NJF vs conventional physiotherapy techniques in reducing pain, improving functional ability, and balance control in individuals with Grade 2 and 3 KOA.

Null Hypothesis (H_0): There is no significant effect of NJF as compared to conventional physiotherapy in pain reduction, improving balance or functional outcomes in individuals with Grade 2 and 3 OA.

Alternative Hypothesis (H_1): The NJF demonstrated significantly greater improvements in pain reduction, balance, and functional outcomes compared with conventional physiotherapy in individuals with Grade 2 and Grade 3 KOA.

MATERIALS AND METHODS

A single-blinded, randomised controlled trial will be conducted at a multispeciality tertiary care hospital, Mullana-Ambala, Haryana, from January 2025 to December 2026. Ethical approval has been obtained from the institutional ethical committee with reference number IEC-3091. Written informed consent will be obtained from all participants before their enrollment in this study. This study has been duly registered with the Clinical Trial Registry-India (CTRI) under the identification number CTRI/2025/04/084557.

Inclusion criteria:

- Age group between 40-70 years;
- General population suffering from grade II & III OA. (Kellgren -Lawrence grading scale) [12] Kellgren-Lawrence grading will be obtained from existing X-ray reports interpreted by qualified radiologists/orthopaedic consultants and will be used solely for confirming diagnosis and eligibility criteria;
- NPRS ≥ 4;
- Participants willing to participate.

Exclusion criteria:

- Participants having an open wound around the knee area;
- Any knee trauma or lower limb fracture (<6 months);
- Other musculoskeletal problem (tendon & ligament tear);
- Rheumatoid arthritis;
- Any known neurological disorder;
- Person with known psychological problems (Depression, Anxiety, etc.);
- Severe cardiovascular issues will be excluded from the study.

Sample size calculation: G* power version 3.1.9.4 is utilised to calculate the required sample size. The effect size was calculated using NPRS mean and standard deviation values (Group-1: 5.73±1.40, Group-2: 6.71±1.23) from the previously published study [3]. The effect size (Cohen's d) was calculated using the mean difference between Groups and the pooled standard deviation, as shown below:

$$SD_{pooled} = \sqrt{\frac{SD_1^2 + SD_2^2}{2}}$$

Sample size estimation formula is provided by: $\{n = 2(Z_{\alpha/2} + Z_{\beta})^2/d^2\}$

Where:

- $Z_{\alpha/2}$ = corresponding to the chosen significance level ($\alpha = 0.05$)
- Z_{β} = corresponding to the desired power ($1-\beta = 80\%$)
- d = corresponding to the effect size (Cohen's d) = 0.74

$$n = \frac{2(1.96+0.84)^2}{(0.74)^2}$$

$$n = \frac{15.68}{0.5476} = 28.63$$

n = 28.63 = 29

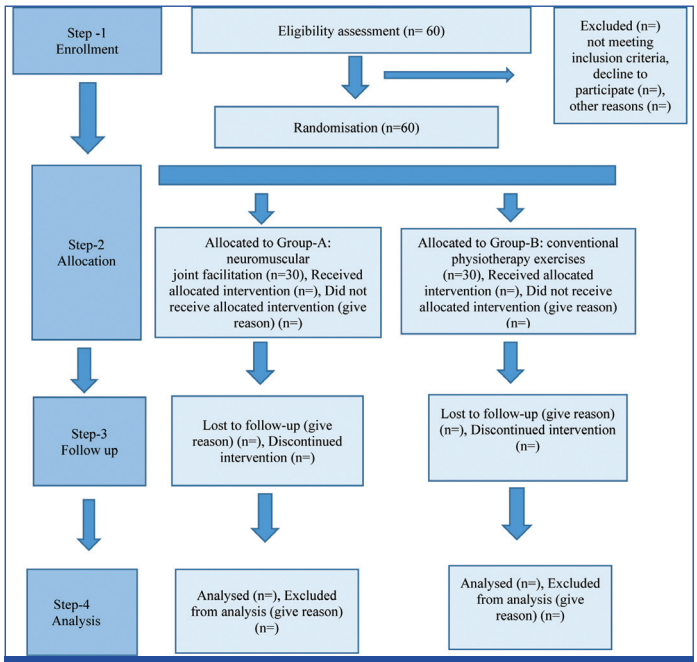
Therefore, 29 participants per group. The total sample size will be 58 participants.

A 3% dropout is considered. So, the total sample size will be 60, 30 participants in each group.

Participants will be randomly assigned to either Group-A (NJF group) or Group-B (conventional group) using simple random sampling. Allocation concealment will be maintained by using sealed, opaque

envelopes, which an individual independent of the research process will draw from. Participant blinding will be maintained by not disclosing group allocation or the study hypothesis to them. Participants will only be informed that the exercises are part of physiotherapy treatment for KOA and will not be told about the differences between the interventions. They will be treated in separate cabins to prevent interaction during sessions. Additionally, pre- and post-assessment values will not be shared with them. Thus, participants will remain unaware of their treatment allocation, ensuring single blinding. Due to the nature of the interventions, blinding of the treating physiotherapist and outcome assessor is not feasible.

The flow of participants through the study is illustrated in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Intervention: Patients in Group-A (Experimental Group) will receive NJF, while patients in Group-B (Control Group) will receive conventional treatment [Table/Fig-2].

The interventions are explained below:

Primary outcomes:

1. **Numeric Pain Rating Scale (NPRS) [13]:** The NPRS is a tool used to assess pain intensity. It is an 11-point scale ranging from "0", which signifies the absence of pain, to "10", representing the worst pain imaginable. Individuals are asked to state a number that best represents the severity of discomfort they felt during the previous 24 hours, and this value is recorded as their pain score. Test-retest reliability for NPRS is in the order of 0.64 to 0.86.
2. **Single Leg Stance (SLS) test [14]:** This test evaluates balance by examining the individual's ability to maintain stability of the supporting knee during a stationary standing position. During this procedure, the duration the participant can maintain a SLS with hands placed on the hips is recorded. The maximum test duration is 30 seconds. The test is terminated if any of the following occur: a) the unsupported leg touches the ground surface; b) The stance foot changes position from its original placement; c) The non-weight-bearing leg touches the weight-bearing leg; d) The hands fail to remain placed on the hips throughout the assessment.

Secondary outcomes:

1. **The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [15]. WOMAC** is a standardised self-reported assessment tool developed to measure pain severity, joint stiffness and functional limitations in individuals with OA, especially affecting the knee and hip joints. This questionnaire comprises 24 items categorised into three domains: five items assessing pain, two evaluating stiffness, and 17 measuring physical function. Higher scores reflect worse symptoms and increased functional limitations, making WOMAC a crucial tool in both clinical practice and research for evaluating treatment outcomes in OA.

   All outcome measures will be assessed at baseline and post-intervention, i.e., at the end of the fourth week.

STATISTICAL ANALYSIS

Data will be analysed using SPSS version 27.0. Demographic characteristics will be summarised using descriptive statistics. Normality will be assessed using the Shapiro-Wilk test. For normally distributed data, paired and independent t-tests will be used for within-group and between-group comparisons, respectively. For non-normally distributed data, the Wilcoxon signed-rank test and Mann-Whitney U test will be used for within-group and between-group comparisons, respectively. The chi-square test will be applied to categorical variables. A p-value <0.05 will be considered statistically significant. [Table/Fig-3] presents the study schedule.

Group	Sample size	Intervention	Description	Duration per session	Frequency	Total Duration
A	30	**Neuromuscular Joint Facilitation (NJF)**	NJF protocol included PNF diagonal patterns (D1, D2) performed in supine with gradual resistance; hold-relax stretching for hamstrings; joint movement exercises, including heel slides and dynamic knee Flexion-Extension; and passive tibiofemoral joint mobilisation with the knee at 20 to 30 degrees. Repetitions and resistance will be progressively increased from week 1 to week 4.	30-40 mins	3 times per week	4 weeks
B	30	**Conventional physiotherapy exercises**	Conventional physiotherapy included heel slides, calf stretching, Quadriceps and hamstring isometric exercises, step-up and step-down exercises and mini squats. Exercises will be performed in supine and standing positions with a gradual increase in repetitions and holding time from week 1 to week 4.	30-40 min	3 times per week	4 weeks

[Table/Fig-2]: Intervention protocol for experimental and control groups.

	Study Period					
	Enrollment	Randomisation	Intervention Phase			
Time-point	**0 week**	**0 week**	**Week 1**	**Week 2**	**Week 3**	**Week 4**
Enrollment						
Eligibility screening	•					
Written informed consent	•					

Clinical evaluation	•					
Allocation		•				
Interventions						
NJF treatment			•	•	•	•
Conventional treatment			•	•	•	•
Assessments						
Demographic data		•				•
NPRS		•				•
WOMAC		•				•
SLS		•				•

[Table/Fig-3]: Study schedule.
NPRS: Numeric pain rating scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; SLS-Single Leg Stance test; "•" indicates denotes completion of the respective activity

Handling of missing data: Data analysis will follow the Intention-To-Treat (ITT) approach.

Author contributions: All authors made substantial contributions to Data curation, conceptualisation, methodology, writing, project administration, Supervision, software, resources, editing, visualisation, and review.

Data Sharing Plan: Owing to the ethical constraints involving participant confidentiality, the dataset is not openly available, but can be shared by the corresponding author if a justified request is made.

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