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"Effectiveness of Percutaneous Electrical Nerve Stimulation Versus Trigger Point Dry Needling In Tibiofemoral Osteoarthritis: A Protocol For A Randomized Controlled Trial"

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Abstract

Introduction: Osteoarthritis (OA) degrades cartilage in the knee, resulting in discomfort and impaired physical function. Percutaneous Electrical Nerve Stimulation (PENS) and Trigger Point Dry Needling (TrP-DN) provide effective pain alleviation. PENS modulates nerve impulses, whereas TrP-DN stimulates muscles and connective tissue. Knee osteoarthritis symptoms may improve with these methods.

Aim and Objectives: This randomized controlled experiment will assess the efficacy of percutaneous electrical nerve stimulation (PENS) with trigger point dry needling in managing tibiofemoral osteoarthritis with TENS as controlled group with common use of exercise.

Method: This randomized controlled experiment will compare three different physiotherapeutic modalities in mild to moderate primary tibiofemoral OA. 180 patients of 50-69 year will be randomized to one of the three treatments, trigger point dry needling, PENS and TENS (control intervention). All three groups will perform self-exercise. The KOOS, (Knee Injury and Osteoarthritis Outcome Score), will be the primary outcomes measure.

Result: Data collection for the ClinicalTrials.gov-registered experiment (CTRI/2022/05/042523) is ongoing, projected to conclude by mid-year. Long-term outcome data collection spans January 2023 to July 2024. Following recruitment completion, KOOS scoring and statistical analysis will assess and compare PENS, dry needling, and TENS efficacy.

Conclusion: Upon completion the analysis, we will able to understand the comparative effectiveness of the PENS and dry needling.

Keywords: PENS, KOOS, pain management, dry needling, osteoarthritis.

Introduction

Osteoarthritis (OA) is the predominant kind of arthritis, marked by the gradual breakdown of articular cartilage, leading to pain and significant disability. Arthritis of the knee, more specifically tibio-femoral articulation is most often involved. There are two distinct classifications of knee osteoarthritis, namely primary and secondary [1]. Primary osteoarthritis refers to the degeneration of the articular cartilage without any identifiable underlying cause. Subsequent osteoarthritis arises due to either an atypical accumulation of force within the joint, as observed in cases of post-traumatic events, or abnormalities in the articular cartilage, as observed in rheumatoid arthritis (RA) [1,2].

One of the commonest ways to clinically identify OA is by American College of Rheumatology clinical criteria for knee osteoarthritis (American College of Rheumatology 2007) which includes knee pain plus presentation of at least three of the following: age > 50 years, morning joint stiffness that usually resolved within 30 minutes, crepitus with active motion of the knee, bony tenderness, bony enlargement, or no palpable warmth of the synovium [3]. A report from Global Burden of Disease (2010) pointed out that the knee OA is one of the leading causes of disability globally and ranked as 11th highest contributing factor to global disability. Knee OA alone increased DALY increased to 0.69% in 2010 from 0.42% in 1990s. [4]

Incidence of Knee osteoarthritis is projected to escalate in tandem with the escalating life expectancy and obesity rates. it has been reported that approximately 13% of women and 10% of men aged 60 years and above experience symptomatic knee osteoarthritis [5]. The prevalence of OA knee in Indian population is even higher, reaching upto 28.7% in the population above 40 according to some authors [6]. With advancing age OA affects more people, reaching up to 40% among individuals aged 70 and above. Although males have a slightly lower incidence of knee osteoarthritis compared to females. Osteoarthritis (OA) is one of the 50 most prevalent consequences of diseases and injuries worldwide, impacting more than 250 million individuals, which accounts for 4.1% of the global population. Orthopedic osteoarthritis (OA) accounts for 83.2% of the overall global disease burden [7].

Dry needling is a skilled intervention utilized by the physiotherapists that penetrates the skin and stimulate target tissues to bring about therapeutic effects using a slender filiform needle. Dry needling is a treatment technique grounded in neurophysiological evidence, which necessitates the proficient manual evaluation of the neuromuscular system[8]. Dry needling is employed to treat neuro-musculo-skeleto-fascial pathologies. However, most often dry needling is used to deactivate trigger points.

Myofascial trigger points are consistently found in OA knee. It has been estimated that a significance amount of OA knee pain originates from trigger points with their prevalence reaching as high as 92% [9]. Extensive documentation exists regarding the advantages of trigger point dry needling in the management of knee osteoarthritis. Studies provide evidence that dry needling enhances pain management, diminishes muscle tension, restores the normal functioning of motor end plates in terms of biochemical and electrical processes, and expedites the process of returning to active rehabilitation. Amani et al., 2022 stated that implementing a single session of DN can result in a reduction in pain intensity among individuals with mild to moderate knee osteoarthritis (KOA) [10].

Percutaneous Electrical Nerve Stimulation is a relatively newer modality in the field of physiotherapy. In simple terms, it is a combination of Dry Needling and TENS. It can be argued that PENS has the potential benefits of Dry Needling as well as TENS. This modality is relatively recent and is primarily used for pain relief. It has demonstrated significant potential in reducing pain associated with osteoarthritis. Research has demonstrated that PENS offer considerably superior and enduring pain relief with minimal adverse reactions. There exist two principal mechanisms for pain relief that can be activated: the Pain Gate Mechanism and the Endogenous Opioid System. The pain gate mechanism alleviates pain by stimulating the A delta and A beta sensory fibers, resulting activation of multiple analgesic pathways including, but not limited to segmental inhibition, serotonergic inhibition, noradrenergic inhibition and Diffused Noxious Inhibitory Control (DNIC) [11]

Therapeutic Exercises are one of the most important nonpharmacological interventions for osteoarthritis. The American Academy of Orthopedic Surgeons has recommended regular self-exercises for the management of osteoarthritis knee. The primary objective of exercise is to mitigate pain and disability through the enhancement of muscle strength, joint stability, range of motion, proprioception endurance, and aerobic fitness. An uncomplicated regimen of exercises performed at home has been proven to greatly enhance self-reported knee pain and functionality [12].

To manage a diverse range of painful conditions, transcutaneous electrical nerve stimulation (TENS) is a cost-

effective and noninvasive intervention. Prior research has demonstrated that TENS enhances heat and pressure pain thresholds in individuals without any health issues, while simultaneously diminishing mechanical and heat hyperalgesia in animals with arthritis [13].

So, in this study, TENS will be used in patients with knee osteoarthritis and is taken as a control group. It is compared with both the test groups that plans to use dry needling and PENS. Both DN and PENS have been found effective, but which one is more beneficial is not known. This study aims to find out if one is better than the other.

Materials and Methods

Research Design

This study will use a randomized controlled trial (RCT) design to examine the effectiveness of 2 experimental interventions, PENS and Dry needling with a control intervention, i.e. TENS in managing knee osteoarthritis. RCTs are considered the gold standard in clinical trials for assessing the effectiveness of interventions while minimizing biases.

Participants

The study population will consist of people between 50 to 69 years who will be diagnosed with tibiofemoral osteoarthritis and will fulfill the selection criteria.

Inclusion Criteria	Exclusion criteria
Mild to moderate ACR-diagnosed primary tibiofemoral OA.	A history of surgical procedures performed on the knee that was causing pain.
Both male and female patients.	A history of surgical procedures performed on the knee that was causing pain.
Between the ages of 50 and 69 years..	Previous six-month lower limb surgery.
Long-standing knee pain for over 3 months.	Had physiotherapy, manual therapy, or other local therapy in the past six months that could alter treatment efficacy or result.
Capacity to walk without assistance for a distance of six meters.	Treatment-area peripheral neuropathy.
Mild to moderate ACR-diagnosed primary tibiofemoral OA.	Contraindications and concerns for dry needling as indicated in the 2013 APTA reference manual.
	Exacerbation of acute symptoms
	A history of surgical procedures performed on the knee that was causing pain.

A sample size of 180 people was selected by sample size estimation. The participants will be chosen by random sampling assigned to one of three arms of this trial. To make sure that the groups were evenly distributed randomization will be done. In case of dropout additional samples with the same selection criteria will be taken. It was planned to recruit participants from hospitals and outpatient departments (OPDs) affiliated with Garden

City University. A broad collection of persons who had been diagnosed with knee osteoarthritis was the target population for these settings that had been selected. Figure 1 shows the research flow and study process in details.

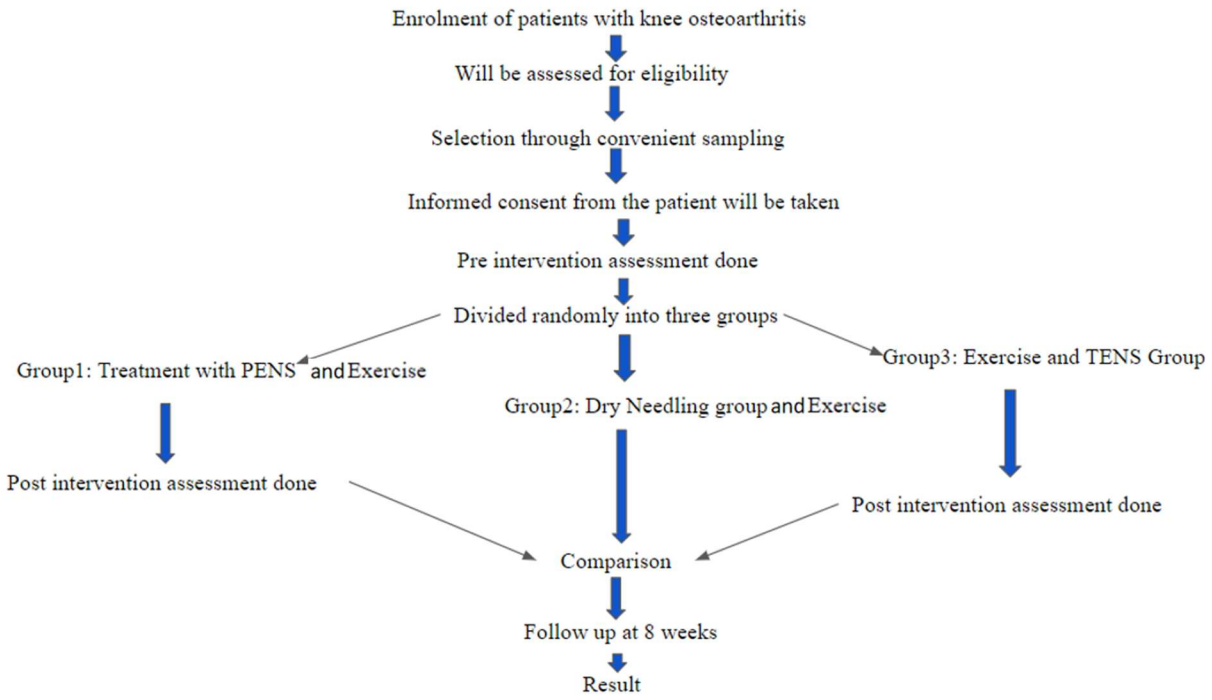

Figure 1: Research Work Flow

Outcome measures

The knee injury and osteoarthritis outcome score, also known as the KOOS Scale, is the primary outcome measure for this study. This is a validated instrument used to evaluate knee function and symptoms in patients with osteoarthritis. The KOOS is a self-reported outcome measure assessing the patient's opinion about the health, symptoms, and functionality of their knee. The maximum score a patient can achieve in each subscale is 100, indicating no knee problems. The minimum score is zero, indicating severe knee problems. KOOS demonstrates adequate content validity, internal consistency, test-retest reliability, construct validity and responsiveness for age- and condition-relevant subscales. [14]

Developed in the late 1990s by researchers from Sweden, KOOS has become widely used in both clinical and research settings due to its thorough evaluation of multiple domains related to knee function and quality of life.

The KOOS questionnaire comprises 42 items organized into five subscales or domains:

1. Pain: This domain assesses the intensity and frequency of knee pain experienced by the individual. Questions within this subscale inquire about the severity of pain during various activities or movements, as well as pain at rest or during the night.

2. Symptoms: The symptom domain evaluates other knee-related symptoms besides pain, such as stiffness, swelling, and grinding sensations (crepitus). It aims to capture the breadth of symptoms that may affect individuals with knee issues.

3. Function in Daily Living (ADL): This domain focuses on the individual's ability to perform activities of daily living that involve the knee joint, such as walking, stair climbing, and standing up from a chair. It assesses the degree to which knee problems impact everyday tasks.

4. Function in Sport and Recreation (Sport/Rec): This subscale addresses the individual's ability to participate in more demanding physical activities, including sports and recreational pursuits. It evaluates the impact of knee problems on activities that require higher levels of mobility and function.

5. Knee-Related Quality of Life (QOL): The quality of life domain assesses the overall impact of knee issues on the individual's quality of life, including factors such as emotional well-being, social functioning, and limitations in daily activities due to knee problems.

Each item in the KOOS questionnaire is scored on a Likert scale, typically ranging from 0 to 4 or 0 to 5, with higher scores indicating better knee health or fewer limitations. The scores from each domain can be analyzed separately or combined to provide an overall assessment of knee function and quality of life.

KOOS is valuable for clinicians in assessing the severity of knee conditions, monitoring treatment progress, and guiding treatment decisions. It also serves as a research tool, allowing for standardized assessment of outcomes across different studies and populations. Overall, KOOS provides a detailed and comprehensive evaluation of knee health from the patient's perspective, aiding in patient-centered care and research efforts related to knee injuries and osteoarthritis.

The secondary outcome was measured by including the use of a pressure algometer algometer to determine the pressure pain threshold (PPT) in the knee. Pressure alometry is found to be a suitable tool in measuring pain in OA knee. [15].

PPT will be determined by using a handheld pressure algometer with a 1 square cm probe area. with an increasing of the pressure rate of 20 Kpa/s. Measurements will be performed at 1 cm distal from the medial knee joint line with the knee flexed at 90 degree. The participants will not be allowed to see the algometer display. The pressure will be gradually increased with the probe and as soon as the assessee experiences a painful sensation, he/she can indicate so. The algometer will be immediately released and the force (in Kpa) will be recorded. [16] For algometry assessor blinding will be done.

All assessments were used at the baseline, after six weeks of treatment and then after the intervention the follow up measures are taken.

Blinding

Due to the nature of this study, it is not possible to fully blind the patient or the clinician providing the intervention to the treatment received. The patient will be blinded to whether they are in the experimental group or in the control group. Outcome measures collected at baseline, end of intervention and at follow-up examinations will be done by independent assessors and the treating clinicians will be blinded to these results.

Interventions

Trigger point dry needling will be done using standard disposable stainless steel filamentous needles with .25 cm diameters. The length of the needles will be chosen as per the depth of the target muscles. The patients will be assessed for trigger points in Quadriceps, Tensor Fascia Lata, Hamstrings, and Gastrocnemius and will be needles accordingly. The number of needle insertions per muscle will depend on the number of MTrPs to be dry needled. Following insertion, the acupuncture needle will be withdrawn partially and advanced repeatedly to produce a local twitch response (LTR). If the LTR is elicited the needle is kept in the situ for 5 minutes before withdrawal. [17] otherwise the needle is left in the situ for 15 minutes. [18]

For PENS a USFDA-approved battery-operated TENS unit will be utilized. Four most painful points around the knee which may include muscles or non muscular structures will be chosen and needled with similar needles as dry needling. Following this the TENS leads will be attached to the metal needle handles using crocodile clips. A biphasic continuous waveform of frequency 2 Hz and pulse duration of 250 µs will be used with a maximum comfortable intensity. The duration of the session will be 15 minutes [19]. For TENS similar parameters as PENS will be used, i.e, 2 Hz, 250 µs biphasic continuous waveform with 15 minutes a session. All the three groups received interventions along with exercise. All three interventions will be administered twice a week for six weeks.

All the patients recruited will be given a home exercise program to be followed on a daily basis. It has been found that a home exercise program consisting of stretching, strengthening and range of motion exercise, whether supervised or unsupervised, are beneficial to the management of OA Knee [20]. The Exercises will start with the range of motion component, where patients will be performing full range of motion heel drag in supine for 10 repetition in a set for 2 sets [21].

The Strengthening part of the exercise was adapted from the home based strength training protocol of Chaipinyo K & Karoonsupcharoen O [22]. It aims to provide concentric and isometric contractions to quadriceps. In chair sitting from 90 Degree Knee flexion the patients will be asked to take the knee to full extension and then maintain 5 seconds maximum isometric hold. This would be done for 10 repetitions in a set, for 3 sets.

The stretching component is adapted from Makarm, W.K et. al's study [21]. It will involve hamstrings and quadriceps stretch. The quadriceps stretch involves prone knee bending, assisted by hand. The hamstring stretch involves towel assisted straight leg raise, till a stretch is felt at the back of thigh. Both stretches will be performed for 30 seconds, for 5 repetitions in each set, for two sets. The patients will be asked to maintain a maximum tolerable intensity.

Statistical analysis

This research used descriptive statistics to summarize baseline characteristics of the study population and suitable tests to compare intervention groups (e.g., t-tests, Mann-Whitney U tests, chi-square tests). For the primary outcome measure, Knee injury and Osteoarthritis Outcome Score (KOOS Scale), repeated measures analysis of variance (ANOVA) will be used to analyze within-group and between-group changes over time, with post-hoc tests for multiple comparison Pressure pain threshold will be analyzed similarly. Statistical significance will be determined at $p < 0.05$, and effect sizes with confidence ranges were presented. All analyses were done using SPSS, R, or SAS, and findings were presented using tables, figures, and summary statistics for interpretation and debate.

Result

Data Arrangement and analysis for this ClinicalTrials.gov-registered experiment (CTRI/2022/05/042523) is currently on-going and expected to finish by 2024. Once the recruitment is over, KOOS scoring will be done and subsequently statistical analysis will be carried out to evaluate the comparative efficacy of PENS and dry needling.

Table 1: Timeframe of the study

Action	2023				2024			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Recruitments of the patients	X	X	X	X				
Intervention & Data collection	X	X	X	X	X			
Data Arrangement					X	X		
Data Analysis					X	X		
Publication							X	X

Discussion

The present study aims to perform a randomized single-blind clinical trial to test the comparative efficacy between PENS and trigger point DN in patients with tibiofemoral osteoarthritis. This investigation seems pioneering, given the scarcity of previous research directly comparing these two interventions in this patient population. By providing evidence for their notion, it is possible to enhance other investigations and clinical practice for these patients.

While Knee osteoarthritis starts with articular erosion, myofascial trigger points (MTrPs) may contribute to pain beyond radiographic findings. Interventional studies show that myofascial treatment decreases pain and improves function [8]. In a study by Henry et al. (2012), upon testing 25 participants awaiting unilateral primary TKA all of them had active trigger points. Trigger point therapy produced significant decreases in pain and improvements in mobility in 92% of the patients immediately after the first visit and remained that way throughout the eight-week duration of the study. The treatment significantly decreased pain intensity and interference, improved functionality, and presented the possible role of myofascial pain in knee OA [9]. In another study Dor & Kalichman had demonstrated in a systematic review that presence of trigger points were consistent and highly prevalent in osteoarthritis patients [23]. This establishes the reason to look into the effective remedies to tackle trigger points in OA Knee.

The effects of trigger point dry needling in the treatment of knee osteoarthritis has been well documented [11, 24]. Jiménez-Del-Barrio et al. (2022) investigated the effectiveness of DN in reducing pain and improving physical function in patients suffering from OA over short-, medium-, and long-term periods. Through a systematic search total of 291 osteoarthritis patients were found, showing that DN leads to significant short-term improvements regarding pain intensity and physical function. The results underline the potential of DN in the short term and, on the other hand, strongly indicate the necessity of further rigorous research to demonstrate DN's benefits over a longer period [24]. Ughreja & Prem et al. (2021) performed a systematic review to assess the effectiveness of DN techniques in knee OA, as this treatment modality has been known to be effective in other types of myofascial pain syndromes and musculoskeletal conditions. Results demonstrate moderate-quality evidence of the benefit of the periosteal stimulation technique on pain and function in the short term [25]. Needling by physiotherapists have been found as a cost effective use of health care resources [26].

PENS being a more recent modality, the body of research around it is not as extensive. However, it has been associated with no morbidity, good pain relief, and increased function in patients with knee osteoarthritis [27].

He et al. (2019) conducted a study for the assessment of the efficacy and safety of percutaneous electrical nerve stimulation (PENS) for chronic knee pain (CKP) treatment, as it is evident for its benefits in neuromodulation and nerve regeneration. [28].

The comparison of DN with PENS in relation to tibiofemoral osteoarthritis remains very scant in the existing literature, which is a huge gap that needs to be addressed. Besides, a control group, when added to a study, improves the strength of the research design and helps to build more reliability and validity in its findings. This comparative approach, including a control group, is essential in providing a clear understanding of the efficacy and safety of these interventions in the management of TFOA. The findings from the study offer the potential of a huge benefit toward advancing knowledge and management of chronic knee pain and other related musculoskeletal conditions. By comparing treatment with DN and PENS, the study clarifies the efficacy and safety of these interventions in tibiofemoral osteoarthritis. Furthermore, including a control group adds strength to the research and provides reliable results that may stipulate optimal frequency and dosage for DN and PENS treatments. The study's outcomes may indicate new avenues of research for further exploration of DN's effects in OA and other related conditions, thus contributing to improvement in treatment approaches in these domains.

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