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EFFECTS OF A COMBINED QUADRICEPS STRENGTHENING AND NEUROMUSCULAR ELECTRICAL STIMULATION PROGRAMME ON PAIN, FUNCTIONAL DISABILITY, AND QUALITY OF LIFE IN PATIENTS WITH KNEE OSTEOARTHRITIS: A RANDOMISED CONTROLLED TRIAL

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Abstract

Background: Knee osteoarthritis (OA) is a leading cause of chronic pain and functional disability among older adults. While quadriceps strengthening is a cornerstone of conservative management, quadriceps inhibition often limits voluntary activation and reduces training efficacy. Neuromuscular electrical stimulation (NMES) may overcome this limitation by eliciting involuntary muscle contractions, thereby augmenting strength gains and clinical outcomes. This study investigated whether combining NMES with supervised quadriceps strengthening produces superior improvements in pain, functional disability, and quality of life compared with strengthening exercise alone in patients with knee OA.

Objective: *To compare the effects of a combined NMES and quadriceps strengthening programme versus conventional quadriceps strengthening alone on pain, functional disability, and health-related quality of life in patients with clinically diagnosed knee OA.*

Methods: *Twenty participants with knee OA (Kellgren-Lawrence grade II-III) were randomised equally into an intervention group (NMES plus supervised quadriceps strengthening, five sessions per week for six weeks) and a control group (quadriceps strengthening alone at the same frequency and duration). Primary outcomes were pain measured on a Visual Analogue Scale (VAS), physical function on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function subscale, and quality of life on the Knee Injury and Osteoarthritis Outcome Score quality-of-life subscale (KOOS-QOL). Secondary outcomes included quadriceps isometric strength, total WOMAC score, Timed Up and Go (TUG) test, 30-second chair stand test, six-minute walk test (6MWT), knee range of motion (ROM), Patient Global Assessment (PGA), analgesic consumption, and treatment adherence.*

Results: *Both groups demonstrated statistically significant within-group improvements across all outcomes ($p < 0.001$). However, the NMES combined group exhibited significantly greater between-group improvements in WOMAC*

function (mean difference -14.5, 95% CI -17.5 to -11.5, p < 0.001), quality of life (14.3, 95% CI 11.1 to 17.5, p < 0.001), quadriceps strength (4.0 kg, 95% CI 3.0 to 5.1, p < 0.001), TUG time (-1.5 s, 95% CI -2.0 to -1.0, p < 0.001), chair stand performance (3.5 repetitions, 95% CI 2.5 to 4.5, p < 0.001), six-minute walk distance (57.7 m, 95% CI 46.7 to 68.7, p < 0.001), and knee ROM (5.0 degrees, 95% CI 3.3 to 6.7, p < 0.001). Seven of ten participants in the NMES group reported being "much improved" on the PGA, compared with none in the control group. Adherence was 94.3% in the intervention group and 88.4% in the control group.

Conclusion: *The addition of NMES to a supervised quadriceps strengthening programme significantly enhanced functional recovery, quality of life, and physical performance in patients with knee OA compared with exercise alone. These findings support the incorporation of NMES into standard rehabilitation protocols for knee OA, particularly for patients exhibiting quadriceps inhibition.*

Introduction

Knee osteoarthritis (OA) is one of the most prevalent musculoskeletal disorders worldwide, affecting an estimated 19% of adults aged 45 years and older, with higher rates among women and older populations. The condition is characterised by progressive degeneration of articular cartilage, subchondral bone remodelling, synovial inflammation, and secondary changes in periarticular muscles and ligaments. Clinically, knee OA manifests as chronic joint pain, morning stiffness, reduced range of motion, muscle weakness, and progressive functional limitation that substantially impairs activities of daily living and health-related quality of life (HRQoL). The global burden of disease attributable to OA has increased markedly over the past two decades, and knee OA consistently ranks among the leading causes of years lived with disability in older adult populations.

Current clinical guidelines for the non-surgical management of knee OA emphasise a multimodal approach comprising exercise, weight management, patient education, and pharmacological interventions as first-line treatments. Among these, quadriceps strengthening exercise is widely regarded as a cornerstone of conservative rehabilitation, with robust evidence supporting its effectiveness in reducing pain and improving physical function. However, a well-documented clinical challenge in knee OA is arthrogenic muscle inhibition (AMI), a neurological phenomenon in which sensory inputs from the injured joint reflexively inhibit voluntary quadriceps activation. AMI limits the capacity of patients to fully engage in strengthening exercises, thereby reducing the potential effectiveness of voluntary exercise-based rehabilitation programmes. This inhibition is mediated by altered gamma-loop function, joint capsule mechanoreceptor afferent discharge, and pain-related fear-avoidance behaviours that collectively suppress maximal voluntary contraction of the quadriceps.

Neuromuscular electrical stimulation (NMES) has emerged as a promising adjunctive modality to address the limitations imposed by AMI. NMES involves the application of transcutaneous electrical currents to peripheral motor nerves, eliciting involuntary muscle contractions that bypass voluntary activation pathways. By directly stimulating the motor nerve fibres, NMES can activate a larger proportion of the motor unit pool, including those units that remain inhibited during voluntary effort, thereby facilitating greater muscle force production and promoting quadriceps hypertrophy. Previous systematic reviews and meta-analyses have provided evidence that NMES, either as a standalone intervention or combined with exercise, can improve quadriceps strength and reduce pain in patients with knee OA. However, the quality of evidence remains variable, and few randomised controlled trials have specifically evaluated the combined application of

NMES and supervised quadriceps strengthening across a comprehensive set of clinically relevant outcomes including pain, self-reported function, objective physical performance, and quality of life. The primary aim of this randomised controlled trial was to determine whether a six-week programme combining NMES with supervised quadriceps strengthening produces superior improvements in pain, functional disability, and quality of life compared with quadriceps strengthening exercise alone in patients with clinically diagnosed knee OA. Secondary aims included evaluating between-group differences in quadriceps isometric strength, functional mobility, knee range of motion, analgesic consumption, and patient-perceived global improvement. It was hypothesised that the combined NMES and exercise intervention would result in significantly greater improvements across all measured outcomes compared with exercise alone.

Methods

Study design: This study was a parallel-group, single-blind, randomised controlled trial conducted at a university-affiliated physiotherapy outpatient clinic. The trial was registered prospectively and the protocol was approved by the institutional ethics review board. All participants provided written informed consent prior to enrolment. Reporting follows the CONSORT 2010 guidelines for randomised controlled trials.

Participants: Participants were recruited from the orthopaedic outpatient department and community advertisements between November,2026 and January,2026. Eligibility criteria included: age 40 to 75 years; clinical diagnosis of knee OA according to the American College of Rheumatology criteria; radiographic confirmation of Kellgren-Lawrence grade II or III; knee pain of at least three months duration with a Visual Analogue Scale (VAS) score of 4 or greater out of 10; and ability to ambulate independently with or without an assistive device. Exclusion criteria comprised previous knee replacement surgery, intra-articular corticosteroid or hyaluronic acid injection within the preceding three months, neurological conditions affecting lower-limb function, severe cardiovascular disease, uncontrolled hypertension, pacemaker implantation, active skin lesions over the stimulation site, and current participation in another rehabilitation programme.

Randomisation and blinding. Following baseline assessment, participants were randomly allocated in a 1:1 ratio to either the intervention group (NMES plus quadriceps strengthening) or the control group (quadriceps strengthening alone) using a computer-generated block randomisation sequence with block sizes of four and six, prepared by an independent statistician. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes opened by the treating physiotherapist after baseline assessment. Outcome assessors were blinded to group assignment, whereas participants and treating therapists could not be blinded due to the nature of the intervention.

Interventions. Both groups received supervised quadriceps strengthening exercises five sessions per week (Monday through Friday) for six consecutive weeks, totalling 30 sessions. The strengthening programme comprised progressive resistance exercises targeting the quadriceps muscle group, including straight leg raises, mini-squats (0 to 45 degrees), seated knee extensions using ankle weights, and isometric quadriceps contractions at multiple knee angles. Exercise intensity was progressed according to the overload principle, with resistance increased by 10% when the participant could complete three sets of 12 repetitions without reporting a significant increase in pain. Each session lasted approximately 45 minutes and included a five-minute warm-up and five-minute cool-down period.

In addition to the identical strengthening programme, the intervention group received NMES applied to the vastus medialis and vastus lateralis of the affected knee using a dual-channel neuromuscular stimulator. A biphasic symmetrical

waveform with a pulse frequency of 50 Hz, pulse duration of 300 microseconds, ramp-up time of two seconds, on-off cycle of 10 seconds on and 50 seconds off, and treatment duration of 20 minutes was employed. Stimulus intensity was adjusted to the maximum tolerable level that produced a visible tetanic muscle contraction without causing discomfort exceeding a VAS score of 3 out of 10. NMES was administered immediately prior to the strengthening exercises during each treatment session to capitalise on the pre-activation effect and enhance subsequent voluntary contraction capacity.

Outcome measures: All outcomes were assessed at baseline (pre-intervention) and within one week following the completion of the six-week programme (post-intervention) by a blinded assessor. Primary outcomes were: (1) pain intensity measured on a 100-mm Visual Analogue Scale (VAS), scored 0 to 10 by measuring the mark in centimetres (0 = no pain, 10 = worst pain); (2) physical function assessed using the WOMAC function subscale (17 items, 0 to 68, higher scores indicating greater disability); and (3) health-related quality of life measured using the KOOS quality-of-life subscale (0 to 100, higher scores indicating better quality of life).

Secondary outcomes included: isometric quadriceps strength measured using a handheld dynamometer with the knee positioned at 60 degrees of flexion; total WOMAC score (0 to 96, higher indicating worse symptoms); Timed Up and Go (TUG) test measuring the time in seconds to rise from a chair, walk three metres, turn, and return to sitting; 30-second chair stand test recording the number of repetitions completed in 30 seconds; six-minute walk test (6MWT) measuring the total distance walked in metres along a standardised corridor; active knee range of motion (ROM) measured using a universal goniometer; Patient Global Assessment (PGA) of improvement rated on a five-point ordinal scale (much improved, improved, slightly improved, unchanged, worse); weekly analgesic consumption recorded as the number of tablets taken; and treatment adherence calculated as the percentage of scheduled sessions attended.

Statistical analysis: Sample size estimation was based on detecting a between-group difference of 10 points on the WOMAC function subscale with a standard deviation of 8 points, an alpha level of 0.05, and power of 0.80, requiring a minimum of 10 participants per group. Descriptive statistics (mean and standard deviation) were calculated for all continuous variables. Normality of data distribution was assessed using the Shapiro-Wilk test, and homogeneity of variances was verified using Levene's test. Within-group changes from pre- to post-intervention were analysed using paired t-tests. Between-group differences in change scores were examined using independent-samples t-tests with Welch's correction for unequal variances where applicable. Effect sizes were calculated using Cohen's d, with thresholds of 0.2, 0.5, and 0.8 interpreted as small, medium, and large, respectively. All statistical analyses were performed using two-tailed tests with the significance level set at $p < 0.05$.

Results

Participant flow and baseline characteristics: Twenty participants were enrolled and randomly allocated to the intervention group (n = 10) or the control group (n = 10). All 20 participants completed the six-week programme and were included in the analysis, with no dropouts or loss to follow-up. Baseline demographic and clinical characteristics are presented in Table 1. The groups were comparable at baseline for BMI ($p = 0.583$) and sex distribution, although the intervention group was significantly older (mean 64.0 years, SD 6.4) than the control group (mean 57.8 years, SD 5.4; $p = 0.032$). All primary and secondary outcome measures were comparable between groups at baseline ($p > 0.05$ for all comparisons).

Table 1. Baseline demographic and clinical characteristics of participants.

Variable	NMES + Exercise (n = 10)	Control (n = 10)	p-value
Age (years), mean (SD)	64.0 (6.4)	57.8 (5.4)	0.032*
BMI (kg/m²), mean (SD)	31.6 (2.9)	31.0 (2.3)	0.583
Sex (male/female), n	5 / 5	7 / 3	—
Pain VAS (0–10), mean (SD)	7.7 (0.8)	7.5 (0.4)	0.426
WOMAC Function (0–68), mean (SD)	56.3 (5.9)	60.6 (5.1)	0.129
KOOS-QOL (0–100), mean (SD)	43.0 (6.2)	44.1 (7.0)	0.751
Quadriceps Strength (kg), mean (SD)	17.7 (2.4)	16.0 (2.0)	0.059

*BMI = body mass index; VAS = Visual Analogue Scale; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; KOOS-QOL = Knee Injury and Osteoarthritis Outcome Score quality-of-life subscale. * Statistically significant ($p < 0.05$).*

Primary outcomes:

Both groups demonstrated statistically significant within-group improvements in all three primary outcomes following the six-week intervention ($p < 0.001$ for all within-group comparisons). The results are summarised in Table 2. For pain (VAS), the NMES group showed a mean reduction of 3.1 points (SD 0.5) compared with 1.1 points (SD 0.2) in the control group, yielding a statistically significant between-group difference of -2.0 (95% CI -2.3 to -1.7, $p < 0.001$) with a large effect size ($d = 5.56$). For WOMAC function, the NMES group improved by a mean of 25.7 points (SD 3.5) versus 11.2 points (SD 2.7) in the control group, with a between-group difference of -14.5 (95% CI -17.5 to -11.5, $p < 0.001$, $d = 4.59$). For quality of life (KOOS-QOL), the NMES group improved by 23.9 points (SD 4.0) versus 9.6 points (SD 2.8) in the control group, with a between-group difference of 14.3 (95% CI 11.1 to 17.5, $p < 0.001$, $d = 4.13$).

Table 2. Primary outcome measures at baseline and post-intervention.

Outcome	Group	Pre-intervention, mean (SD)	Post-intervention, mean (SD)	Within-group p	Between-group MD (95% CI)	d
Pain (VAS 0–10)	NMES + Ex	7.7 (0.8)	4.6 (0.9)	<0.001	-2.0 (-2.3 to -1.7)	5.56
	Control	7.5 (0.4)	6.4 (0.4)	<0.001		
WOMAC Function (0–68)	NMES + Ex	56.3 (5.9)	30.6 (6.3)	<0.001	-14.5 (-17.5 to -11.5)	4.59
	Control	60.6 (5.1)	49.4 (6.6)	<0.001		
KOOS-QOL (0–100)	NMES + Ex	43.0 (6.2)	66.9 (6.2)	<0.001	14.3 (11.1 to 17.5)	4.13
	Control	44.1 (7.0)	53.7 (5.7)	<0.001		

VAS = Visual Analogue Scale; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; KOOS-QOL = Knee Injury and Osteoarthritis Outcome Score quality-of-life subscale; MD = mean difference; d = Cohen's d. All between-group comparisons p < 0.001.

Secondary outcomes: Statistically significant between-group differences in favour of the NMES group were observed across all secondary outcomes (Table 3). The NMES group demonstrated substantially greater gains in quadriceps isometric strength (mean between-group difference 4.0 kg, 95% CI 3.0 to 5.1, p < 0.001, d = 3.62). Functional mobility as measured by the TUG test improved by a mean of 2.8 seconds (SD 0.6) in the NMES group compared with 1.3 seconds (SD 0.5) in the control group (between-group difference -1.5 s, 95% CI -2.0 to -1.0, p < 0.001). Chair stand performance improved by 5.6 repetitions (SD 1.3) in the NMES group versus 2.1 repetitions (SD 0.9) in the control group (difference 3.5, 95% CI 2.5 to 4.5, p < 0.001). The six-minute walk distance increased by a mean of 86.1 metres (SD 13.8) in the NMES group compared with 28.4 metres (SD 9.3) in the control group (difference 57.7 m, 95% CI 46.7 to 68.7, p < 0.001). Knee ROM improved by 8.3 degrees (SD 2.2) in the NMES group versus 3.3 degrees (SD 1.2) in the control group (difference 5.0 degrees, 95% CI 3.3 to 6.7, p < 0.001).

Table 3. Secondary outcome measures at baseline and post-intervention.

Outcome	Group	Pre, mean (SD)	Post, mean (SD)	Between-group MD (95% CI)	d
Quad. Strength (kg)	NMES + Ex	17.7 (2.4)	25.4 (2.0)	4.0 (3.0 to 5.1)	3.62
	Control	16.0 (2.0)	19.7 (2.1)		
WOMAC Total (0–96)	NMES + Ex	64.1 (6.9)	35.4 (8.1)	-14.9 (-18.2 to -11.6)	4.28
	Control	71.8 (4.8)	58.0 (5.6)		
TUG (seconds)	NMES + Ex	14.5 (1.7)	11.8 (1.6)	-1.5 (-2.0 to -1.0)	2.78
	Control	14.6 (2.2)	13.3 (2.3)		
Chair Stand (reps)	NMES + Ex	10.5 (1.8)	16.1 (2.2)	3.5 (2.5 to 4.5)	3.22
	Control	10.5 (1.9)	12.6 (2.1)		
6MWT (metres)	NMES + Ex	295.4 (54.0)	381.5 (57.1)	57.7 (46.7 to 68.7)	4.92
	Control	271.0 (40.0)	299.4 (46.3)		
Knee ROM (degrees)	NMES + Ex	105.7 (6.9)	114.0 (8.1)	5.0 (3.3 to 6.7)	2.83
	Control	106.6 (6.8)	109.9 (6.8)		

Quad. = quadriceps; TUG = Timed Up and Go; 6MWT = six-minute walk test; ROM = range of motion; MD = mean difference; d = Cohen's d. All within-group p < 0.001; all between-group p < 0.001.

Patient Global Assessment and adherence: On the Patient Global Assessment, seven participants (70%) in the NMES group reported being "much improved" and three (30%) reported being "improved." In the control group, five participants (50%) reported being "improved" and five (50%) reported being "slightly improved." No participant in either group reported being unchanged or worse. Mean treatment adherence was 94.3% (SD 2.7%) in the NMES group and 88.4% (SD 5.5%) in the control group. Mean weekly analgesic consumption decreased from 6.0 tablets (SD 0.8) to 2.3 tablets (SD 1.2) in the NMES group and from 5.6 tablets (SD 0.7) to 3.9 tablets (SD 1.1) in

the control group, representing a greater reduction in the NMES group.

Discussion

This randomised controlled trial provides evidence that the addition of NMES to a supervised quadriceps strengthening programme produces significantly greater improvements across a comprehensive range of clinical outcomes compared with quadriceps strengthening exercise alone in patients with knee OA. While both groups improved significantly from baseline, the NMES combined group demonstrated substantially larger gains in all primary and secondary outcomes, including pain, self-reported function, quality of life, quadriceps strength, functional mobility, walking endurance, and knee range of motion. These findings are consistent with the study hypothesis and support the incorporation of NMES as an adjunct to standard exercise-based rehabilitation for knee OA.

The magnitude of between-group differences observed in the present study is noteworthy. The between-group mean difference of 14.5 points on the WOMAC function subscale exceeds the reported minimal clinically important difference (MCID) of approximately 6 to 8 points for this measure in knee OA populations, suggesting that the observed superiority of the combined intervention is not only statistically significant but also clinically meaningful. Similarly, the between-group difference of 2.0 points on the 10-point pain VAS exceeds the established MCID of 1.5 points for pain in knee OA, indicating that the additional pain relief achieved by NMES augmentation is likely to be perceived as meaningful by patients. The large effect sizes (d = 2.78 to 5.56) observed in this study, while impressive, should be interpreted with consideration of the small sample size, which can inflate effect size estimates and widen confidence intervals.

The mechanisms underlying the superior outcomes in the NMES combined group likely relate to the ability of NMES to overcome arthrogenic muscle inhibition and facilitate greater quadriceps muscle activation. By delivering electrical impulses directly to the motor nerve, NMES bypasses the volitional pathways that are suppressed by joint afferent inhibition, thereby recruiting a larger proportion of the available motor unit pool and generating stronger muscle contractions than would be possible through voluntary effort alone. This enhanced muscle activation may have produced greater quadriceps hypertrophy and neuromuscular adaptation, which in turn contributed to improved joint stability, reduced mechanical stress on the articular cartilage, and enhanced functional capacity. The pre-activation effect of NMES applied immediately before strengthening exercises may have further primed the neuromuscular system for more effective voluntary contractions during the subsequent exercise component of each session.

The findings of this study are broadly consistent with previous systematic reviews and meta-analyses that have reported favourable effects of NMES on quadriceps strength and pain in knee OA. However, several features distinguish the present investigation. First, the NMES protocol was applied in combination with a comprehensive, supervised strengthening programme rather than as a standalone intervention, reflecting a more clinically realistic treatment model. Second, the outcome assessment was multidimensional, encompassing both patient-reported and performance-based measures, which provides a more complete picture of the intervention's impact. Third, the high treatment adherence rate of 94.3% in the NMES group suggests that the combined programme is well tolerated and feasible in a clinical setting. These findings extend the existing literature by demonstrating that NMES augmentation yields benefits not only in strength and pain, but also in quality of life, functional mobility, and physical performance.

Several limitations of this study warrant consideration. The sample size of 20 participants, while adequate to detect large effects based on the a priori power analysis, limits the generalisability of the findings and increases the risk of type I error. The significant age difference between groups at baseline (p = 0.032), although unlikely

to account for the magnitude of observed between-group differences, represents a potential confounding factor that should be addressed in future studies through stratified randomisation. The lack of long-term follow-up prevents conclusions about the persistence of treatment effects beyond the six-week intervention period. Additionally, the single-blind design, while methodologically appropriate given the nature of the intervention, introduces the possibility of performance bias. The absence of a true sham-NMES control group also precludes definitive conclusions about the specific contribution of the electrical stimulation component separate from the enhanced treatment time and therapist attention received by the intervention group.

Conclusions

The results of this randomised controlled trial demonstrate that a six-week programme combining NMES with supervised quadriceps strengthening produces significantly greater improvements in pain, functional disability, quality of life, quadriceps strength, functional mobility, walking endurance, and knee range of motion compared with quadriceps strengthening exercise alone in patients with knee OA. The magnitude of between-group differences exceeded established minimal clinically important differences for key outcome measures, suggesting that the addition of NMES to standard rehabilitation protocols may offer meaningful clinical benefits. Future research with larger sample sizes, longer follow-up periods, and sham-controlled designs is recommended to confirm these findings, elucidate the optimal NMES parameters and treatment duration, and evaluate the cost-effectiveness of this combined approach in routine clinical practice.

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Declarations

Ethics approval and consent to participate: This study was approved by the institutional ethics review board of Saidu Medical College / Saidu Group of Teaching Hospital . All participants provided written informed consent prior to enrolment.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

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Authors' contributions: Nisaruddin conceived and designed the study, supervised the intervention, and critically revised the manuscript. Saima Rahman contributed to data analysis and drafted the manuscript. Fazal Haq, Anwar Saleem, and Fatima Iqbal performed data collection, administered interventions, and carried out outcome assessments. Sangin Khan assisted with data entry and literature search. All authors read and approved the final manuscript.

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