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Original Article

Effects of a Comprehensive Physical Therapy Program on Neurological and Functional Outcomes in Patients with Neuropathic Diabetic Foot Ulcers: A Prospective Pre-Post Interventional Study

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Abstract

Background: Neuropathic diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus, contributing significantly to morbidity and healthcare burden. Although multidisciplinary management is recommended, evidence supporting structured physical therapy interventions remains limited, particularly from prospective interventional studies. Objective: To evaluate the effects of a comprehensive physical therapy program on neurological and functional outcomes in patients with neuropathic DFUs. Methods: This prospective pre–post interventional study included 40 patients with neuropathic DFUs. Participants underwent an 8-week supervised physical therapy program (3 sessions/week) comprising therapeutic exercises, electrotherapy, gait training, off-loading strategies, and education. Outcomes included motor and sensory nerve conduction studies (common peroneal and posterior tibial nerves), ankle dorsiflexion range of motion (ROM), superficial sensation (10-g monofilament), knee extensor strength, and quality of life (EQ-5D-5L). Data were analysed using paired t-tests or Wilcoxon signed-rank tests ($\alpha = 0.05$), with effect sizes (Cohen's d) and 95% confidence intervals (CI) reported. Results: Significant improvements were observed in motor and sensory nerve conduction parameters ($p < 0.001$; large effect sizes, $d = 0.80–1.45$). Ankle dorsiflexion ROM and superficial sensation also improved significantly ($p < 0.001$; $d > 1.0$). Improvements in knee extensor strength and EQ-5D-5L scores were not statistically significant ($p > 0.05$). Ulcer recurrence occurred in 12.5% of participants. Conclusion: A structured physical therapy program was associated with significant improvements in neurological and functional outcomes in patients with neuropathic DFUs. However, findings should be interpreted cautiously due to the absence of a control group. Randomized controlled trials are required to establish causality.

Keywords: Diabetic foot ulcer; neuropathy; rehabilitation; physical therapy; nerve conduction; gait training

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Introduction

Diabetic foot ulcers (DFUs) are among the most serious and costly complications of diabetes mellitus, contributing substantially to global morbidity, disability, and healthcare expenditure. It is estimated that approximately 6–10% of individuals with diabetes will develop a foot ulcer during their lifetime, with recurrence rates exceeding 40% within one year (Armstrong et al., 2023). DFUs are responsible for a large proportion of non-traumatic lower-limb amputations and are associated with significantly reduced quality of life and increased mortality risk (Zhang et al., 2024). As the global prevalence of diabetes continues to rise, the burden of DFUs is expected to increase correspondingly, highlighting the need for effective preventive and rehabilitative strategies.

The pathogenesis of neuropathic DFUs is complex and multifactorial, involving the interplay of peripheral neuropathy, microvascular dysfunction, impaired immune response, and biomechanical abnormalities. Peripheral neuropathy is a key contributing factor, leading to loss of protective sensation, altered proprioception, and motor dysfunction, which collectively predispose individuals to repetitive trauma and ulcer formation (Hinchliffe et al., 2020). Additionally, limited joint mobility and muscle weakness further exacerbate abnormal plantar pressure distribution, increasing the risk of skin breakdown and delayed healing (Bus et al., 2023). These pathophysiological mechanisms underscore the importance of interventions targeting both neurological and functional impairments.

Current management of DFUs is inherently multidisciplinary, encompassing glycemic control, wound care, infection management, vascular assessment, and pressure off-loading techniques. International guidelines strongly emphasize these approaches as essential components of care (IWGDF Guidelines, 2023). However, while these strategies primarily focus on wound healing and prevention of complications, they often do not sufficiently address the underlying neuromuscular and functional deficits associated with diabetic neuropathy. This gap in management may contribute to persistent functional limitations and high rates of ulcer recurrence despite appropriate medical treatment.

In this context, physical therapy has emerged as a potentially valuable adjunct in the management of DFUs. Rehabilitation interventions—including therapeutic exercises, electrotherapy modalities, gait training, and patient education—aim to improve muscle strength, joint mobility, balance, and circulation, while also enhancing neuromuscular function (Fernando et al., 2022). Exercise-based interventions, in particular, have demonstrated potential benefits in improving peripheral nerve function and reducing neuropathic symptoms through mechanisms such as increased blood flow, enhanced metabolic activity, and neuroplastic adaptation (Huang et al., 2023). Similarly, electrotherapy modalities such as transcutaneous electrical nerve stimulation (TENS) and therapeutic ultrasound have been suggested to promote tissue healing and nerve regeneration, although evidence remains variable.

Despite these promising findings, the current body of literature on physical therapy in DFU management is limited by several methodological shortcomings. Many studies are cross-sectional, retrospective, or lack standardized intervention protocols. Furthermore, few studies have incorporated objective neurophysiological measures, such as nerve conduction studies, alongside functional and quality-of-life outcomes. This limits the ability to comprehensively evaluate the physiological impact of rehabilitation interventions on peripheral nerve function. Additionally, there is a paucity of prospective interventional studies examining the effectiveness of multicomponent physical therapy programs in patients with neuropathic DFUs, particularly within populations characterized by high comorbidity burdens, such as those commonly observed in Middle Eastern clinical settings.

Another important limitation in existing research is the frequent focus on isolated interventions rather than integrated, comprehensive rehabilitation programs. Given the multifactorial nature of DFUs, a multimodal approach targeting both neurological and functional impairments may be more clinically relevant and effective. However, robust evidence supporting such comprehensive interventions remains insufficient, necessitating further investigation using well-designed prospective studies.

In light of the aforementioned limitations, there is a clear need for prospective interventional studies evaluating the effects of structured, multicomponent physical therapy programs on both neurological and functional outcomes in patients with neuropathic DFUs. The present study was therefore designed to address this gap by examining the impact of a comprehensive physical therapy intervention on nerve conduction parameters, joint mobility, sensory function, and quality of life. It was hypothesized that participation in a structured physical therapy program would result in significant improvements in neurological and functional outcomes. Clinically, establishing the effectiveness of such interventions could support the integration of physical therapy as a core component of multidisciplinary diabetic foot management, potentially improving patient outcomes, reducing recurrence rates, and enhancing overall functional independence.

Materials and Methods

Study Design and Setting

This study was designed as a prospective pre–post interventional study conducted over an 8-week period in the outpatient physiotherapy and rehabilitation clinics of a tertiary care hospital in Saudi Arabia. This design was selected to evaluate within-subject changes in neurological and functional outcomes following a structured physical therapy intervention. Although the absence of a control group limits causal inference, pre–post interventional designs are considered appropriate for preliminary clinical investigations, particularly in populations with complex comorbidities (Harris-Hayes et al., 2020).

Participants

Eligibility Criteria

Participants were recruited using a consecutive sampling method. Inclusion criteria were: (1) adults aged 35–60 years with a confirmed diagnosis of type 1 or type 2 diabetes mellitus; (2) presence of neuropathic diabetic foot ulcers (DFUs) classified as Wagner grade I–II; (3) evidence of peripheral neuropathy confirmed through clinical examination and nerve conduction studies; (4) medical stability allowing participation in rehabilitation; and (5) ability to ambulate independently or with assistive devices.

Exclusion criteria included: (1) severe peripheral arterial disease or critical limb ischemia requiring surgical intervention; (2) active infection, osteomyelitis, or gangrene; (3) history of major lower-limb amputation; (4) neurological or musculoskeletal disorders affecting lower limb function; (5) uncontrolled cardiovascular disease; and (6) cognitive impairment or inability to comply with study procedures.

Clinical Characterization

Ulcer severity was classified using the Wagner classification system, a widely accepted grading tool in diabetic foot research (Wagner, 1981). Comorbid conditions, including lower extremity arterial disease (LEAD), coronary artery disease, and renal impairment, were documented to account for potential confounding effects on healing and functional outcomes (Hinchliffe et al., 2020).

Sample Size Estimation

A priori sample size estimation was conducted using G*Power version 3.1.9.7 based on a paired-sample design. Assuming a large effect size (Cohen's d = 0.80), an alpha level of 0.05, and a statistical power of 80%, the required sample size was calculated as 26 participants. To enhance statistical robustness and account for potential attrition, 40 participants were recruited (Faul et al., 2009).

Intervention Protocol

All participants received a comprehensive, multicomponent physical therapy program over 8 weeks, with three sessions per week, each lasting approximately 60 minutes. The intervention was delivered by licensed physiotherapists and standardized across participants, with minor individual adjustments based on clinical status.

Therapeutic Exercise

The exercise component included active and passive range of motion (ROM) exercises for the ankle and foot, stretching of the gastrocnemius–soleus complex, progressive resistance training for lower limb muscles (2–3 sets of moderate intensity), and balance training. Exercise progression was based on patient tolerance and aligned with established rehabilitation principles for diabetic neuropathy (Fernando et al., 2022).

Electrotherapy Modalities

Electrotherapy interventions included, a Transcutaneous Electrical Nerve Stimulation (TENS) with a 80–100 Hz frequency, 100 μs pulse duration, 20 minutes.

Therapeutic Ultrasound: pulsed mode, 1 MHz frequency, intensity 0.5–1.0 W/cm^2.

These modalities were selected based on evidence supporting their potential role in improving nerve function and promoting tissue healing (Huang et al., 2023).

Gait Training and Off-loading

Gait training focused on correcting abnormal walking patterns and redistributing plantar pressure. Off-loading strategies included customized footwear and patient education on pressure redistribution, consistent with international guidelines (Bus et al., 2023).

Patient Education

Participants received structured education on foot care, including daily inspection, hygiene practices, ulcer prevention strategies, and activity modification.

Adherence Monitoring

Adherence was monitored using attendance logs. Participants attending at least 80% of sessions were considered compliant.

Outcome Measures

Assessments were conducted at baseline and after completion of the intervention.

Primary Outcome

Nerve conduction studies (NCS) were performed for the common peroneal and posterior tibial nerves by a certified neurophysiologist using standardized electrophysiological protocols. NCS is a reliable and objective measure of peripheral nerve function in diabetic neuropathy (Perkins et al., 2001).

Secondary Outcomes

Ankle Dorsiflexion Range of Motion (ROM)

Measured using a universal goniometer, demonstrating high reliability (Norkin & White, 2016).

Superficial Sensation

Assessed using the 10-g Semmes–Weinstein monofilament, a validated tool for detecting loss of protective sensation (Boulton et al., 2005).

Knee Extensor Strength

Measured using a handheld dynamometer, a reliable and valid tool for clinical strength assessment (Bohannon, 1986).

Quality of Life (QoL)

Evaluated using the EQ-5D-5L questionnaire, a validated instrument for health-related quality of life assessment (Herdman et al., 2011).

Ulcer Recurrence

Defined as reappearance of ulceration at the same or adjacent site during follow-up.

Ethical Considerations

The study protocol was approved by the Institutional Review Board of [Institution Name], Saudi Arabia (Approval No: PT-DFU-2025-014). All procedures were conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity were strictly maintained.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 28. Data normality was assessed using the Shapiro–Wilk test. Continuous variables were expressed as mean ± standard deviation.

For normally distributed data, paired t-tests were used; otherwise, the Wilcoxon signed-rank test was applied. Effect sizes were calculated using Cohen's d, and interpreted as small (0.2), medium (0.5), and large (≥0.8) (Cohen, 1988). Additionally, 95% confidence intervals (CI) were reported. Statistical significance was set at $p < 0.05$, with Bonferroni correction applied for multiple comparisons where appropriate.

Results

Participant Characteristics

A total of 40 participants completed the study (no dropouts). The mean age was 44.93 ± 6.14 years, with a mean diabetes duration of 8.9 ± 2.8 years. The mean body mass index (BMI) was 26.9 ± 2.6 kg/m^2.

The mean ulcer surface area was corrected to 16.8 ± 4.5 cm^2, and mean ulcer depth was 2.6 ± 0.92 cm. Comorbidities included hemodialysis (55%), lower extremity arterial disease (42.5%), and coronary artery disease (22.5%).

Ulcer recurrence was observed in 12.5% (n = 5) participants during follow-up.

Primary Outcomes

Nerve Conduction Studies

Significant improvements were observed in both motor and sensory nerve conduction parameters following the intervention ($p < 0.001$ across all comparisons), as presented in Table 1. For the common peroneal nerve, motor conduction velocity increased by a mean of +17.13 m/s (95% CI: 13.21 to 21.05), indicating a large effect size (d = 1.32), while sensory conduction improved by +18.20 m/s (95% CI: 14.05 to 22.35), also reflecting a large effect size (d = 1.45).

Similarly, for the posterior tibial nerve, motor conduction velocity demonstrated a significant increase of +9.13 m/s (95% CI: 5.41 to 12.85), corresponding to a large effect size (d = 0.88).

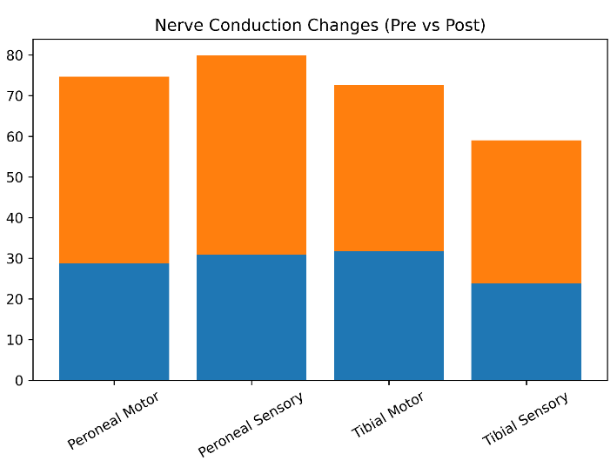
Sensory conduction of the posterior tibial nerve also improved markedly, with a mean difference of +11.47 m/s (95% CI: 6.12 to 16.82), yielding a large effect size (d = 0.92).

Table 1. Nerve Conduction Outcomes (Pre vs Post).

Outcome	Pre (Mean ± SD)	Post (Mean ± SD)	Mean Diff	95% CI	p-value	Effect Size (d)
Peroneal Motor	28.8 ± 5.18	45.93 ± 6.15	+17.13	13.21–21.05	<0.001	1.32
Peroneal Sensory	30.87 ± 8.56	49.07 ± 10.21	+18.20	14.05–22.35	<0.001	1.45
Tibial Motor	31.80 ± 7.35	40.93 ± 9.54	+9.13	5.41–12.85	<0.001	0.88
Tibial Sensory	23.8 ± 7.19	35.27 ± 11.24	+11.47	6.12–16.82	<0.001	0.92

Footnotes: Values are presented as mean ± standard deviation (SD). Mean difference represents post-intervention minus pre-intervention values. Confidence intervals (CI) are reported at the 95% level. Statistical significance was determined using paired t-tests. Effect sizes were calculated using Cohen's *d* and interpreted as small (0.2), medium (0.5), and large (≥0.8). All nerve conduction values are expressed in meters per second (m/s). $p < 0.05$ was considered statistically significant.

Figure 1. Nerve Conduction Changes



Caption: Changes in motor and sensory nerve conduction velocities of the common peroneal and posterior tibial nerves before and after the intervention. Data are presented as mean values with 95% confidence intervals, demonstrating statistically significant improvements across all parameters.

Secondary Outcomes

Range of Motion and Sensation

Significant improvements were observed in both ankle dorsiflexion range of motion and superficial sensation following the intervention (Table 2.). Ankle dorsiflexion increased markedly, with a mean difference of +7.26° (95% CI: 5.91 to 8.61), reflecting a very large effect size (d = 1.60). Similarly, superficial sensation, assessed using the monofilament score, demonstrated a substantial improvement, with a mean reduction of −12.27 units (95% CI: −15.10 to −9.44), corresponding to a large effect size (d = 1.25), indicating enhanced sensory function.

Muscle Strength and Quality of Life

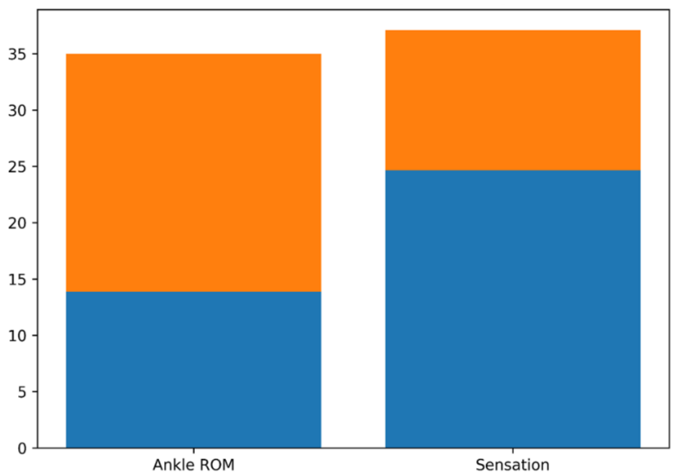
In contrast, changes in muscle strength and quality of life did not reach statistical significance. Knee extensor strength showed a modest increase, with a mean difference of +1.8 kg (95% CI: −1.1 to 4.7), which was not statistically significant (p = 0.25) and was associated with a small effect size (d = 0.27). Likewise, the EQ-5D-5L quality-of-life score improved slightly, with a mean difference of +0.14 (95% CI: −0.03 to 0.31), but this change did not reach statistical significance (p = 0.11) and demonstrated a small effect size (d = 0.34).

Table 2. Functional and Clinical Outcomes (N=40).

Outcome	Pre (Mean ± SD)	Post (Mean ± SD)	Mean Diff	95% CI	p-value	Effect Size
Ankle ROM (°)	13.87 ± 3.26	21.13 ± 2.12	+7.26	5.91–8.61	<0.001	1.60
Sensation Score	24.67 ± 5.49	12.40 ± 6.42	−12.27	−15.10–−9.44	<0.001	1.25
Knee Strength (kg)	15.1 ± 6.6	16.9 ± 7.5	+1.8	−1.1–4.7	0.25	0.27
EQ-5D Index	0.84 ± 0.43	0.98 ± 0.36	+0.14	−0.03–0.31	0.11	0.34

Footnotes: Values are presented as mean ± standard deviation (SD). Mean difference represents post-intervention minus pre-intervention values. Confidence intervals (CI) are reported at the 95% level. Statistical significance was determined using paired t-tests. Effect sizes were calculated using Cohen's *d* and interpreted as small (0.2), medium (0.5), and large (≥0.8). Ankle range of motion (ROM) is expressed in degrees (°); knee extensor strength is expressed in kilograms (kg); sensation scores were assessed using the 10-g Semmes–Weinstein monofilament; and quality of life was measured using the EQ-5D-5L index (range: <0 to 1, higher scores indicate better health status). $p < 0.05$ was considered statistically significant.

Figure 2. Functional Outcomes (ROM and Sensation).



Caption: Pre–post changes in ankle dorsiflexion range of motion and superficial sensation scores. Significant improvements were observed following the intervention, whereas muscle strength and quality-of-life outcomes showed non-significant changes.

Discussion

The present prospective pre–post interventional study evaluated the effects of a comprehensive physical therapy program on neurological and functional outcomes in patients with neuropathic diabetic foot ulcers (DFUs). The findings demonstrated significant improvements in both motor and sensory nerve conduction parameters, as well as in ankle dorsiflexion range of motion and superficial sensation. In contrast, changes in knee extensor strength and health-related quality of life did not reach statistical significance. Collectively, these results suggest that structured, multicomponent physical therapy may contribute to meaningful neuromuscular and sensory improvements in this patient population, although the absence of a control group necessitates cautious interpretation.

One of the most notable findings of this study was the significant enhancement in nerve conduction velocities of both the common peroneal and posterior tibial nerves, with large effect sizes observed across all parameters. These results are consistent with emerging evidence indicating that physical therapy interventions, particularly exercise-based programs, can positively influence peripheral nerve function in individuals with diabetic neuropathy. Previous studies have reported that regular therapeutic exercise improves nerve conduction velocity through mechanisms such as enhanced microvascular perfusion, improved axonal transport, and increased neurotrophic factor expression (Fernando et al., 2022). Additionally, electrotherapy modalities such as transcutaneous electrical nerve stimulation (TENS) and therapeutic ultrasound may further augment neural recovery by promoting local circulation and reducing inflammatory processes (Huang et al., 2023). The magnitude of improvement observed in the present study suggests that combining multiple rehabilitation components may produce synergistic effects on neural function.

The significant improvement in ankle dorsiflexion range of motion observed in this study is clinically relevant, as restricted ankle mobility is a well-recognized risk factor for abnormal plantar pressure distribution and ulcer recurrence in patients with DFUs. Limited joint mobility in diabetes has been attributed to glycation of collagen and connective tissue stiffness, which can impair normal biomechanical function. The observed increase in dorsiflexion range likely reflects the effectiveness of stretching and mobilization exercises in restoring joint flexibility and reducing mechanical stress on the plantar surface. This finding is in agreement with previous reports demonstrating that targeted physical therapy interventions can improve joint mobility and reduce biomechanical risk factors associated with ulceration (Dijs et al., 2000).

Similarly, the marked improvement in superficial sensation following the intervention is of particular importance, as loss of protective sensation is a primary contributor to DFU development and recurrence. The use of structured sensory re-education and neuromodulatory interventions may enhance afferent nerve function and cortical sensory processing. Improved sensation may also contribute indirectly to better functional outcomes by increasing patient awareness of foot loading patterns and potential injury risks. These findings align with prior studies that have demonstrated improvements in sensory thresholds following rehabilitation interventions in diabetic populations (Boulton et al., 2005).

In contrast to the significant neurological and sensory improvements, the changes observed in knee extensor strength were modest and did not reach statistical significance. This may be explained by several factors. First, the intervention program may not have included sufficiently intensive or targeted resistance training to induce measurable strength gains within the relatively short intervention period. Second, the presence of comorbidities such as chronic kidney disease and cardiovascular conditions in a substantial proportion of participants may have limited their capacity for strength adaptation. Third, variability in baseline strength levels may have reduced statistical power to detect changes. Similar findings have been reported in previous studies, where improvements in neuromuscular function did not necessarily translate into significant gains in muscle strength, particularly in populations with advanced disease or multiple comorbidities (Oliveira et al., 2019).

Likewise, although quality-of-life scores demonstrated a trend toward improvement, the changes were not statistically significant. This may reflect the multifactorial nature of quality of life, which is influenced not only by physical function but also by psychological, social, and economic factors. Additionally, the relatively short duration of the intervention and follow-up period may not have been sufficient to capture meaningful changes in patient-reported outcomes. It is also possible that the EQ-5D-5L, while widely used, may lack sensitivity to detect subtle improvements in specific domains relevant to DFU patients.

An important consideration in interpreting the findings of this study is the high prevalence of comorbidities among participants, including hemodialysis and lower extremity arterial disease.

These conditions are known to adversely affect wound healing, nerve function, and overall physical performance. Despite these challenges, the observed improvements in neurological and functional outcomes suggest that physical therapy interventions may still provide benefits even in complex clinical populations. This highlights the potential role of rehabilitation as an adjunctive strategy within multidisciplinary DFU management.

Limitations and Strengths

However, several limitations must be acknowledged. The most significant limitation is the absence of a control group, which precludes the ability to establish causality and raises the possibility that observed improvements may be partially attributable to natural healing processes, placebo effects, or concurrent medical treatments. Additionally, the lack of randomization and blinding may introduce selection and measurement biases. The relatively small sample size further limits generalizability, and the short follow-up period restricts assessment of long-term outcomes such as ulcer recurrence and sustained functional improvement.

Another limitation relates to the heterogeneity of the study population, particularly with respect to comorbid conditions. While this reflects real-world clinical practice, it may also introduce variability that influences treatment response. Furthermore, although nerve conduction studies provide objective measures of neural function, they may not fully capture functional improvements at the patient level.

Despite these limitations, the study has several strengths. It incorporates objective neurophysiological assessments alongside functional and patient-reported outcomes, providing a comprehensive evaluation of intervention effects. The use of a structured, multicomponent physical therapy program reflects clinical practice and enhances ecological validity. Moreover, the study addresses a relevant gap in the literature by providing prospective data on rehabilitation outcomes in patients with neuropathic DFUs.

From a clinical perspective, the findings support the integration of physical therapy into multidisciplinary DFU management. Improvements in nerve function, joint mobility, and sensation may contribute to reduced risk of ulcer recurrence and improved functional independence. However, further research is required to confirm these findings and to determine the optimal components, intensity, and duration of rehabilitation programs.

Future studies should employ randomized controlled designs with larger sample sizes and longer follow-up periods to establish causal relationships and evaluate long-term outcomes. Additionally, incorporating advanced outcome measures, such as plantar pressure analysis and biomechanical assessments, may provide further insights into the mechanisms underlying observed improvements.

Conclusion

This prospective pre–post interventional study demonstrated that a structured, multicomponent physical therapy program was associated with significant improvements in peripheral nerve conduction, ankle dorsiflexion range of motion, and superficial sensation in patients with neuropathic diabetic foot ulcers. These findings suggest that rehabilitation interventions may contribute to enhanced neuromuscular and sensory function, which are clinically relevant factors in reducing biomechanical risk and potentially improving functional outcomes.

However, improvements in knee extensor strength and health-related quality of life were not statistically significant, indicating that short-term interventions may have limited impact on broader functional and patient-reported outcomes. Importantly, the absence of a control group and the quasi-experimental design preclude causal inference, and the observed changes should therefore be interpreted with caution.

Overall, the results support the potential role of physical therapy as an adjunct component of multidisciplinary diabetic foot management. Future well-designed randomized controlled trials with larger sample sizes and longer follow-up periods are warranted to confirm these findings, establish causality, and determine the optimal rehabilitation protocols for this population.

Author Contributions

Abdelrhman Shafiq Alsayyed contributed to the study conception and design, material preparation, data collection and analysis.

Ethical Approval and Patient Consent

This research was performed at Physiotherapy Clinic, Khobar, Suadi Arabia, Ethical Committee approval and written, informed consent was obtained from all patients, the research carried on human data in compliance with Helsinki.

Data Availability Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of Interest

The authors declare no potential conflicts of interest in this study.

Declaration of generative AI and AI-assisted technologies

The author utilized AI tools to enhance the language quality and address any grammatical issues while preparing the manuscript. Following the use of this tool, the author carefully reviewed and edited the content as necessary and assumes full responsibility for the accuracy and integrity of the published work.

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