

Effects of vibration therapy with routine physical therapy on pain, balance, and functional disability in diabetic neuropathy patients: a randomised controlled trial

Sajawal Bashir¹, Ayesha Jamil², Sarwat Ali³

Abstract

Objective: To evaluate the impact of integrating vibration therapy with standard physical therapy on pain levels, balance, functional impairment, and overall patient satisfaction among individuals with diabetic neuropathy.

Method: The single-blind, randomised controlled trial was conducted from September 2022 to February 2023 at the Physiotherapy Department of Omar Hospital, Lahore, Pakistan, and comprised patients of either gender aged 40-75 years having diabetic peripheral neuropathy. The participants were randomised using computer-generated numbers into group A receiving routine physical therapy only, and group B receiving vibration therapy with routine physical therapy. Each intervention lasted 30 minutes and six sessions were given over 2 weeks. Assessment was done at baseline, and at end of 1st and 2nd week for pain, balance, functional disability and satisfaction level using standard tools. Data was analysed using SPSS 21.

Results: Of the 72 patients with mean age 59.2 ± 9.47 years and mean duration of diabetes 14.23 ± 6.4 years, 40 (56%) were males and 32 (44%) were females. Each group had 36 (50%) subjects. At the baseline, there were no significant differences between the groups ($p > 0.05$). Intergroup comparison for pain, functional disability were significantly better in group A compared to group B ($p < 0.05$), but balance and patient satisfaction were not significantly different post-intervention ($p > 0.05$). Intragroup improvements post-intervention were significantly better compared to baseline values ($p < 0.05$).

Conclusion: Vibration therapy was found to be better than routine physical therapy in terms of addressing pain and functional disability.

RCT registration: The study was registered at ClinicalTrials.gov (Trial #: NCT05580705 Date of Approval: October 14, 2022). Link: <https://clinicaltrials.gov/study/NCT05580705>.

Key Words: Balance, Diabetic neuropathy, Functional disability, Pain, Physical therapy, Satisfaction, Vibration therapy.

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Introduction

Diabetic peripheral neuropathy (DPN) is characterised by nerve dysfunction owing to microvascular injury by persistent hyperglycaemia in patients with type 2 diabetes mellitus (T2DM). The damage to the primary afferent nociceptors makes central neurons more reactive, and this leads to agonising pain along with numbness in the hands and feet.¹ Individuals suffering with DPN are prone to experiencing physical and psychological problems that hinder their ability to engage in routine everyday activities.² Distal symmetrical neuropathy is the most prevalent form of peripheral neuropathy, presenting with severe sensory loss and

shooting pain, burning and tingling in the lower extremities, especially the toes and feet, affecting balance and stability.³ DPN is associated with other complications, such as poor kidney function and vision abnormalities, further exacerbating physical and psychological limitations.⁴ In Pakistan, the prevalence of DPN ranges widely, reflecting a substantial burden on the healthcare system and highlighting the need for effective management strategies.⁵ Local literature provides insights into the prevalence and impact of diabetes and its complications in Pakistan. For instance, studies indicate a high prevalence of diabetes and associated complications in the region, with significant impacts on quality of life (QOL) and healthcare utilisation.⁶ In Pakistan, barriers to effective diabetes management include limited access to healthcare resources, socioeconomic factors, and a lack of awareness about the benefits of physical activity. Studies have shown that these barriers contribute to suboptimal management of diabetic complications, including DPN.⁷ Furthermore,

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^{1,2}Department of Physical Therapy, University of Lahore, Lahore, ³Department of Physical Therapy, Bajwa Hospital, Lahore, Pakistan.

Correspondence: Sarwat Ali. **Email:** sarwat1997@gmail.com

ORCID ID: 0000-0002-4789-8343

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local research highlights the need for affordable and accessible treatments that can be easily integrated into patients' routines.

In order to manage the deleterious effects of diabetic distal neuropathy, multimodal therapy is advised, although safe and effective adjuvant therapies need further identification⁸. Physical therapy, including electrical stimulation and exercises, has minimal side effects, and almost no pharmacological interactions.⁹ Such non-invasive techniques in treating problems associated with DPN have been beneficial in terms of managing neuropathic pain and improving QOL.¹⁰ Vibration therapy (VT) is a non-invasive, and non-pharmaceutical therapeutic option whose short- and long-term effectiveness has been proven in preliminary case reports¹¹, with few contraindications.

VT enhances the ability of the nervous system to detect and respond to mechanical stimuli, facilitating movement and improving overall function. Most studies have investigated the correlation between whole-body vibration and neuromuscular performance, including its potential to improve strength, power, and flexibility.¹² To the best of our knowledge, there is no published evidence regarding the impact of foot-sole VT on DPN patients. The current study was planned to fill the gap in literature by determining whether foot-applied VT impacts pain, balance, function and patient satisfaction in DPN patients.

Patients and Methods

The single-blind, randomised controlled trial (RCT) was conducted from September 2022 to February 2023 at the Physiotherapy Department of Omar Hospital, Lahore, Pakistan. After approval from the ethics review committee of the University of Lahore, Lahore, the RCT was registered with clinicaltrials.gov (NCT05580705), and was conducted as per the Consolidated Standards of Reporting Trials (CONSORT) guidelines.¹³ The sample size was calculated on the basis of literature¹¹ with 95% confidence interval (CI) and 80% power using G*Power 3 software.¹⁴ The sample was inflated to account for a To account for a potential 20% dropout rate.

The sample was raised using non-probability purposive sampling technique from among those visiting the outpatient department (OPD). Those included were DPN patients of either gender aged 40-75 years with diabetes onset exceeding 6 years¹⁵ who were managing diabetes with oral medication, had glycated haemoglobin (HbA1c) level <8.5%¹⁶, and a confirmed DPN diagnosis by a registered medical practitioner.¹⁷ All potential participants were required to stand on both feet.¹⁸

Individuals with systemic conditions, such as advanced cardiovascular, renal or hepatic diseases¹⁹, as well as those with open wounds/ulcers on the ankles and feet¹⁸ were excluded, and so were those with neurological disorders affecting balance, such as vertebral artery syndrome, multiple sclerosis, Parkinson's disease, Alzheimer's disease, stroke and cerebral ataxia.¹⁶ Musculoskeletal issues, like leg length discrepancy, ankle sprain and severe osteoarthritis of the knee and hip joints, were also grounds for exclusion.²⁰ Those who had undergone VT before the intervention were also excluded²¹, as were those taking antihypertensive drugs with blood pressure exceeding 160/95mmHg.²²

After taking written informed consent, the participants were randomised into 2 equal groups using computer-generated numbers by an independent researcher not involved in the data-collection or analysis process. Allocation concealment was ensured by using sealed, opaque envelopes that were prepared by the independent researcher who opened them sequentially to assign the subjects to their respective groups. Group A was given routine physical therapy, while group B was given VT additionally.

Routine physical therapy included range of motion (ROM) exercises of the knee, ankle, foot and toes, followed by strengthening exercises using a Thera band. There were 10 repetitions of each exercise. VT was provided using a Manipol brand vibrator (Model: MA-116, Rating: 220-240 V/25 W/50-60 Hz; manufactured in China) with a 360° off-centered axis and a frequency of 2500 Hz per minute. Vibration was applied on the sole of both feet for around 5min. Total time duration of each session was 30 minutes, and 6 sessions were given over two weeks on an alternate days. Pain intensity, balance, functional status and patient satisfaction towards the treatment were the outcome measures recorded through Numeric Pain Rating Scale (NPRS)²³, Berg Balance Scale (BBS)²⁴, Revised Neuropathy Disability Score (R-NDS)²⁵, and Patient Satisfaction Questionnaire-18 (PSQ-18)²⁶, respectively, at the baseline, and at end of 1st and 2nd weeks of intervention. The assessor was blinded to the treatment group.

Data was analysed using SPSS 21. Quantitative variables were expressed as mean \pm standard deviation, while qualitative variables were expressed as frequencies and percentages. Data normality was assessed using the Kolmogorov-Smirnov test. Non-parametric tests were employed, with median and interquartile range (IQR), were used for non-normally distributed data. Intergroup differences were assessed using the Mann-Whitney test, and intragroup differences were examined with Friedman test. $P < 0.05$ was taken as significant.

RCT registration: The study was registered at ClinicalTrials.gov (Trial #: NCT05580705 Date of Approval: October 14, 2022). Link: <https://clinicaltrials.gov/study/NCT05580705>.

Results

Of the 120 individuals approached, the final sample comprised 72(60%) patients; 40(56%) males and 32(44%) females. The overall mean age was 59.2 ± 9.47 years and mean duration of diabetes was 14.23 ± 6.4 years. Each group had 36(50%) subjects.

At the baseline, there were no significant differences between the groups ($p > 0.05$) except for pain ($p < 0.05$). Pain and disability were significantly different between the groups at the end of 1st week ($p < 0.05$), while pain alone was significantly different at the end of the 2nd week ($p < 0.05$). No significant differences at any stage were observed in terms of balance and patient satisfaction between the groups (Table 1).

Intragroup improvements post-intervention were significantly better for all outcome measures compared to the baseline values (Table 2).

Table-1: Intergroup comparison of pain intensity, neuropathy disability, balance, and patient satisfaction levels

Ranks	Group of patients	N	Mean Rank	Sum of Ranks	p-value
Pain Intensity at Baseline	Group A (RPT)	36	31.88	1147.50	.046
	Group B (VT)	36	41.13	1480.50	
Pain Intensity at 1st week	Group A (RPT)	36	41.47	1493.00	.033
	Group B (VT)	36	31.53	1135.00	
Pain Intensity at 2nd week	Group A (RPT)	36	50.83	1830.00	< 0.001
	Group B (VT)	36	22.17	798.00	
Revised NDS at Baseline	Group A (RPT)	36	34.00	1224.00	.246
	Group B (VT)	36	39.00	1404.00	
Revised NDS at 1st week	Group A (RPT)	36	32.32	1163.50	.050
	Group B (VT)	36	40.68	1464.50	
Revised NDS at 2nd week	Group A (RPT)	36	35.53	1279.00	.631
	Group B (VT)	36	37.47	1349.00	
BBS at Baseline	Group A (RPT)	36	39.04	1405.50	.301
	Group B (VT)	36	33.96	1222.50	
BBS at 1st week	Group A (RPT)	36	35.75	1287.00	.761
	Group B (VT)	36	37.25	1341.00	
BBS at 2nd week	Group A (RPT)	36	35.15	1265.50	.584
	Group B (VT)	36	37.85	1362.50	
(PSQ-18) at Baseline	Group A (RPT)	36	35.44	1276.00	.668
	Group B (VT)	36	37.56	1352.00	
(PSQ-18) at 1st week	Group A (RPT)	36	34.92	1257.00	.513
	Group B (VT)	36	38.08	1371.00	
(PSQ-18) at 2nd week	Group A (RPT)	36	33.32	1199.50	.193
	Group B (VT)	36	39.68	1428.50	

RPT: Routine physical therapy, VT: Vibration therapy, NDS: Neuropathy disability score, BBS: Berg balance scale, PSQ-18: Patient satisfaction questionnaire-short form.

Table-2: Intragroup comparison of pain intensity, neuropathy disability, balance, and patient satisfaction levels.

Ranks	Mean Rank	Mean Rank	Standard Deviation	p-value	
Group A (RPT)	Pain Intensity at Baseline	2.75	6.27	0.97	< 0.001
	Pain Intensity at 1st week	1.97	5.47	1.02	
	Pain Intensity at 2nd week	1.28	4.72	0.97	
Group B (VT)	Pain Intensity at Baseline	3.00	6.75	0.97	< 0.001
	Pain Intensity at 1st week	1.99	5.02	0.81	
	Pain Intensity at 2nd week	1.01	2.94	0.92	
Group A (RPT)	Revised NDS at Baseline	1.16	1.74	2.13	0.015
	Revised NDS at 1st week	0.58	0.99	1.78	
	Revised NDS at 2nd week	1.05	1.75	2.10	
Group B (VT)	Revised NDS at Baseline	1.72	2.09	2.17	0.004
	Revised NDS at 1st week	1.61	2.07	2.08	
	Revised NDS at 2nd week	1.16	1.74	1.75	
Group A (RPT)	BBS at Baseline	1.16	1.74	1.75	< 0.001
	BBS at 1st week	0.58	0.99	2.01	
	BBS at 2nd week	1.05	1.75	2.24	
Group B (VT)	BBS at Baseline	1.72	2.09	1.39	< 0.001
	BBS at 1st week	1.61	2.07	2.03	
	BBS at 2nd week	1.16	1.74	2.58	
Group A (RPT)	(PSQ-18) at Baseline	83.05	5.26	1.86	0.039
	(PSQ-18) at 1st week	84.77	5.36	2.13	
	(PSQ-18) at 2nd week	84.05	5.24	2.01	
Group B (VT)	(PSQ-18) at Baseline	83.63	4.71	1.78	0.008
	(PSQ-18) at 1st week	85.58	4.69	2.13	
	(PSQ-18) at 2nd week	85.69	4.45	2.10	

RPT: Routine physical therapy, VT: Vibration therapy, NDS: Neuropathy disability score, BBS: Berg balance scale, PSQ-18: Patient satisfaction questionnaire-short form.

Discussion

The current findings, which are consistent with those of Caputo et al., suggested VT may have an instantaneous effect on reducing the pain of patients with painful DPN.²⁷ Some studies have reported that VT enhances blood flow and increases skin temperature. These immediate effects may explain the observed reduction in pain intensity and enhanced sensation in the foot-sole among DPN patients. Conversely, VT may have had an immediate impact on the dynamic balance of DPN patients.

Mahbub et al. found no enhancement in balance indices among elderly and healthy individuals.²⁸ This discrepancy could be linked to the utilisation of a lower vibration level in the earlier research. Alternatively, it is plausible that the earlier study²¹ involved older participants who were healthy and physically active, displaying superior balance and mobility.

VT can promptly enhance the sensation in the soles of both feet for DPN individuals, as evidenced in the current findings. The device's passive vibration and tactile stimulation help improve balance by stimulating the

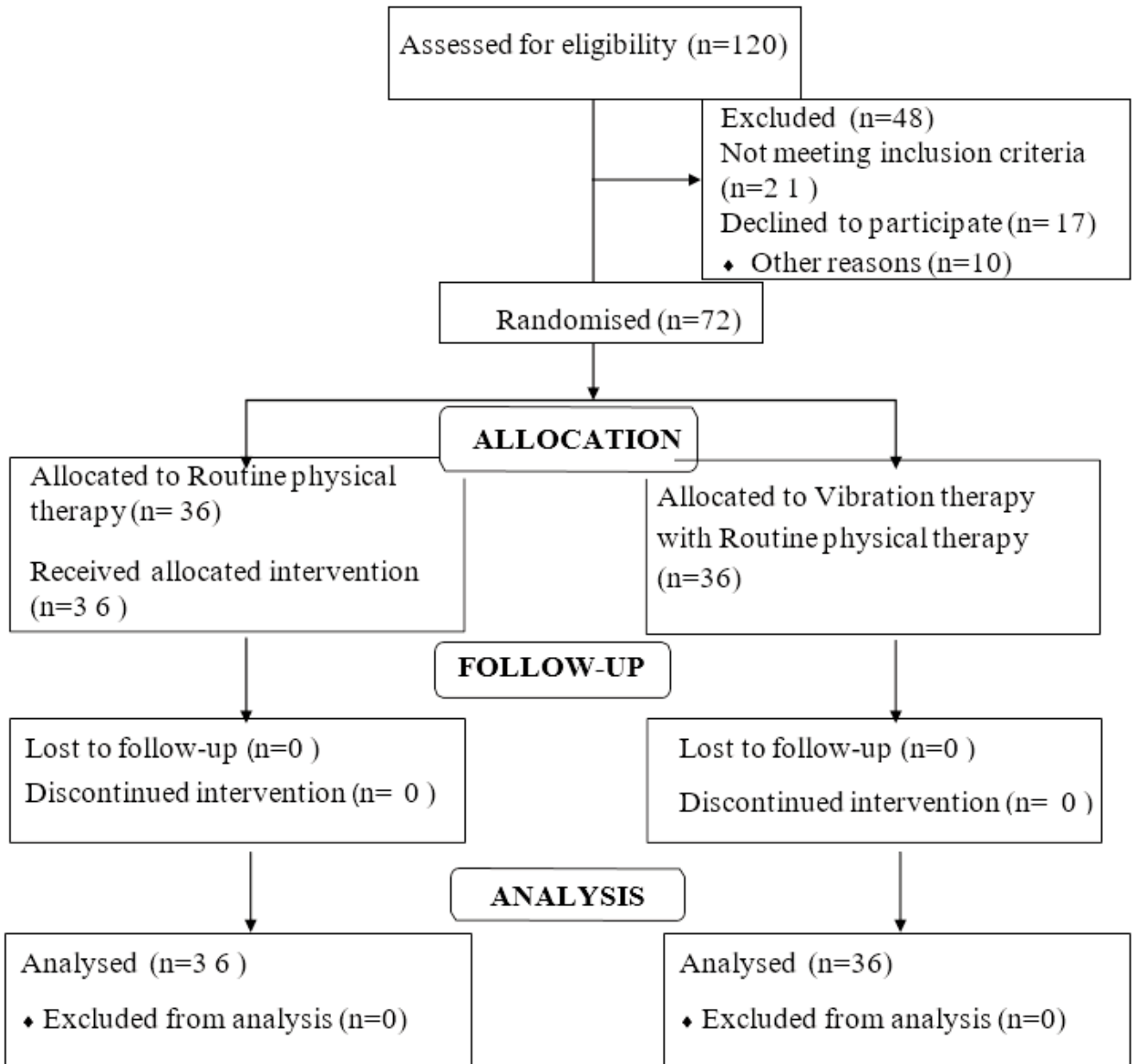


Figure: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

nervous system in the foot's sole.²⁹ Naghdi et al. observed a similar significant enhancement in stroke patients.³⁰ In contrast, some studies^{31,32} did not align with the current findings, and, notably, both these investigations involved young and healthy participants. A potential explanation for the variance in results is the fact that individuals without neuropathy typically have sufficient blood flow to their skin, which differs from those grappling with neuropathic conditions. Similar to the current study, Sohrabzadeh et al. in 2021 also discovered that VT effectively alleviates pain, enhances sole-foot sensation,

and improves dynamic balance.¹⁶

The current findings suggest that VT may positively impact both general and neuropathic pain. Consistent with earlier pilot studies, this also showed a significant decrease in pain scores.^{33,34}

The present investigation also revealed that, compared to the control group, experimental patients experienced improvements in static and dynamic balance due to VT. The sensory stimulation induced by vibration activates tactile receptors in the soles, and mechanoreceptors in

the epidermis and joints, providing essential information for restoring balance after VT.³⁵ As has been established, pain was the most debilitating symptom in this group³⁶, and VT helped alleviate it, contributing to better mental and emotional health.

As a result of the interplay of physiological and psychological factors, patients with painful DPN (PDPN) are more likely to participate in social activities. Patients PDPN benefit from VT in several ways, including improved health and fitness, and enhanced physical performance. Patients with PDPN who participated in VT reported improvement in their neuropathic pain, neuropathy disability score, balance, and overall satisfaction.

VT is a more tolerable and effective therapy for enhancing functional ability in individuals with advanced neuropathy who cannot participate in conventional exercise regimens. The method has no side-effects and is simple for relieving neuropathic pain.

The current results showed that VT was superior to the more traditional forms of treatment. Any patient experiencing trouble with resistive exercise may benefit since it requires less time and has more options. This research demonstrates that VT has the potential to fill a void left by currently available drugs by providing pain relief to those with severe DPN without interfering with their ability to exercise. Current pharmaceutical therapy satisfaction ratings are poor, at 27%. Thus, there is a need for treatments like these, and more investigation is required.¹¹

The current RCT has some limitations. First, the sample size not large enough to warrant generalisability of the findings. Additionally, the study's duration of 2 weeks made it challenging to evaluate long-term effects or the sustainability of the observed benefits. Besides, the use of purposive sampling technique may have introduced selection bias. Finally, the single-blind design was another source of potential bias, especially in the assessment of outcomes, which could have affected the accuracy of the findings.

Future studies should consider larger and more diverse sample sizes, longer follow-up periods, double-blind designs, and a combination of subjective and objective measurement tools to ensure more reliable and generalisable outcomes.

Conclusion

VT was found to be better than routine physical therapy in terms of addressing pain and functional disability, but not with respect to balance and patient satisfaction.

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Conflict of Interest: None.

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Authors Contribution:

SB: Literature search, study design and concept, data collection and interpretation, final approval.

AJ: Literature search, final approval,

SA: Literature search, study design and concept, data collection and

interpretation, drafting.

All authors agreement to be accountable for all aspects of the study.