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Effect Of Pulsed Electromagnetic Field Therapy Combined With A Tailored Exercise Program In Patients With Chemotherapy-Induced Neuropathy Following Breast Cancer Treatment

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Abstract

Background: Chemotherapy-induced neuropathy (CIPN) is a common complication in breast cancer (BC), often resulting in pain, balance issues, and functional decline. Addressing these symptoms is vital for improving quality of life and recovery. **Purpose:** This study evaluated the effectiveness of combining pulsed electromagnetic field (PEMF) therapy with a tailored exercise program (TEP) in managing CIPN symptoms, specifically targeting pain, balance, and functional recovery. **Method:** A randomized controlled trial was carried out on Eighty patients with breast cancer were randomly assigned to an study group (PEMF + TEP) or a control group (TEP alone). Intervention was conducted for eight weeks. Pain intensity was measured using the Visual Analog Scale (VAS), functional status via the Functional Assessment of Cancer Therapy–Neurotoxicity (FACT-Ntx), balance through the Berg Balance Scale (BBS), and nerve conduction velocity (NCV) tests. **Results:** The Study Group demonstrated a significantly greater reduction in pain (VAS mean decrease: 6.20 vs. 4.20; $p < 0.0001$). Both groups showed significant functional improvements (FACT-Ntx mean difference = 10.30; $p < 0.001$). Balance improved more in the Study Group, with mean differences of 5.80 in sway and 1.93 in stability indices. NCV results further supported improved nerve function in the Study Group.

Conclusion: Combining PEMF therapy with a tailored exercise program significantly reduced pain, enhanced functional status, improved balance, and positively influenced nerve conduction in patients with breast cancer experiencing CIPN. These findings support integrated therapeutic approaches as

effective strategies for managing chemotherapy-induced symptoms and improving patient outcomes and quality of life.

Keywords: Chemotherapy-Induced Symptoms; Pain Management; Functional Outcomes; Nerve Conduction Velocity; Pulsed Electromagnetic Field (PEMF).

Trial registration: The study was registered at the clinicalTrial.gov on April 21-2024 with the following number (NCT06947577)

Introduction

Breast Cancer (BC) is the most frequently diagnosed cancer globally, with over 2 million new cases reported in 2020 (1). It is also the leading cause of cancer-related deaths among women, resulting in more than 680,000 fatalities. While there are variations in incidence rates between developed and developing nations, BC remains the most prevalent cancer among women in Egypt, with an age-specific incidence rate of 48.8 per 100,000 (2). Projections indicate that approximately 46,000 new cases will be diagnosed by 2050. Although this incidence rate is lower than the global average, the mortality rate in Egypt is notably higher, with an age-standardized rate of 20.4 per 100,000, compared to 12.3 per 100,000 in the United States and 12.8 per 100,000 in other developed countries (3). When examining the mortality-to-incidence ratio for BC, Egypt exhibits a significantly higher ratio, approximately double that of developed nations, with rates of 41% versus 23% (4). Advancements in BC treatment have led to a growing population of survivors. While the management of BC, commonly involving chemotherapy administered before or after surgery to reduce recurrence and improve survival, can be effective, it often leads to debilitating long-term complications such as CIPN. This condition significantly impacts quality of life, creating a substantial burden for both patients and the healthcare system (5). CIPN is a prevalent side effect affecting a significant number of patients undergoing treatment for BC (5). This condition manifests as a range of symptoms including pain, numbness, and tingling, particularly in the lower limbs, negatively impacting patients' quality of life and functional abilities (6). The distressing nature of these symptoms often leads to a decline in physical activity, exacerbating feelings of helplessness and anxiety, which can further complicate recovery (7). Therefore, addressing and effectively managing CIPN represents a critical challenge in optimizing the long-term health and well-being of the growing population of BC survivors. A multiple treatment approach is involved in the management of BC survivors with a particular attention to the patients experiencing CIPN. The management of CIPN typically relies on pharmacological treatments, which can include analgesics and anticonvulsants. However, these medications often come with a host of side effects and may not fully alleviate the symptoms experienced by patients (8). Furthermore, reliance on pharmacotherapy can lead to issues such as drug tolerance and dependency. Consequently, there is a pressing need for alternative therapeutic strategies that can provide relief without the drawbacks associated with conventional medication (9). One promising avenue of exploration is the combination of pulsed electromagnetic field (PEMF) therapy with tailored exercise program (TEP). PEMF therapy has gained attention for its potential to enhance healing processes and reduce pain through the application of electromagnetic fields. This non-invasive treatment modality has been shown to promote cellular repair and improve blood circulation, which may be beneficial in addressing the underlying mechanisms of nerve damage caused by chemotherapy (10). In addition to PEMF therapy, exercise has long been recognized as a vital component of rehabilitation for individuals with neuropathy. Engaging in a structured exercise program can improve muscle strength, enhance balance, and boost overall physical function (11). The syner-

gistic effect of combining exercise with PEMF therapy could offer a multifaceted approach to managing CIPN, targeting both the physical and neurological dimensions of the condition (12). Previous studies have indicated that PEMF therapy can lead to significant improvements in pain management and sensory function in various neuropathic conditions. For instance, research has documented positive outcomes in patients with diabetic neuropathy, where PEMF therapy was associated with reduced pain levels and improved nerve conduction velocities (12). However, the specific effects of PEMF therapy combined with exercise on CIPN remain underexplored, necessitating further investigation into this therapeutic combination. Exercise plays a significant role in managing peripheral neuropathy, as it can improve blood circulation, enhance muscle strength, and promote overall nerve health (13). Engaging in regular physical activity helps alleviate symptoms such as pain, numbness, and tingling by stimulating the nerves and improving their function. Strength training, and balance exercises have been found particularly beneficial, as they can enhance coordination and reduce the risk of falls, which is crucial for individuals with altered sensation (14). Additionally, low-impact activities like swimming or cycling can provide relief without putting excessive strain on the body (15). Overall, incorporating a tailored exercise regimen can lead to improved quality of life for those affected by peripheral neuropathy. The rationale for this study is grounded in the need to explore innovative treatment options for patients suffering from CIPN related to BC. By investigating the effectiveness of integrating PEMF therapy with TEP, we aim to provide evidence-based insights that could enhance clinical practices and improve patient outcomes. This research could contribute to the development of comprehensive management strategies that empower patients to regain control over their health and well-being during and after cancer treatment. Furthermore, this study seeks to address the gap in the literature regarding the combined effects of PEMF therapy and exercise on neuropathy resulting from chemotherapy. While individual therapies have been researched extensively, the potential benefits of their integration have not been thoroughly examined. This investigation will provide a clearer understanding of how these interventions can complement each other and optimize treatment results for affected patients. In addition to enhancing scientific knowledge, the findings from this study could have significant implications for clinical practice. If the combination of PEMF therapy and TEP proves effective, it may lead to the establishment of new treatment protocols that prioritize patient-centered care. Such protocols could offer a holistic approach to managing CIPN, focusing on improving both physical function and quality of life for patients. Ultimately, the justification for this study lies in its potential to fill a critical void in current therapeutic options for CIPN. By evaluating the effectiveness of a combined intervention, we aimed to provide valuable data that could lead to improved treatment guidelines and better support for individuals grappling with the long-term effects of cancer treatment. So, the aim of our study is to evaluate the effectiveness of adding PEMF therapy to a tailored exercise program in improving pain, balance, and nerve conduction in patient with breast cancer undergone CIPN.

2. Materials and Methods

2.1. Design

This is a randomized controlled comparative single-blind trial conducted to assess the effectiveness of various interventions for female patients with breast cancer experiencing lower limb CIPN. In this study, assessors (outcome assessors, statisticians) were blinded to group assignments to eliminate bias. To ensure blinding, the administration of the interventions was strictly separated from the assessment procedures. Individuals responsible for delivering PEMF therapy and TEP were not involved in con-

ducting any of the outcome assessments, A total of eighty female patients with breast cancer experiencing lower limb CIPN were screened and randomly assigned to two groups: the study group, which received a combination of PEMF therapy and TEP, and the control group, which received only TEP. Both groups followed their respective treatment protocols three times a week for six weeks. Assessments measuring postural stability, pain intensity, functional status, and NCV were conducted at three intervals: at baseline (prior to the interventions), post-intervention (6 weeks), and at an eight-week follow-up.

2.2. Participants

Participants were recruited from the registry files of patients diagnosed with lower limb CIPN associated with BC at the outpatient clinic of the Department of Neurology at Kasr Elaini Hospital, Cairo University. A qualified neurologist diagnosed chemotherapy induced peripheral neuropathy through clinical neurological examination. The level of neuropathy was determined based on the National Cancer Institute Common Terminology Criteria of Adverse Events (NCI-CTCAE, version 5.0), and only those patients with moderate or severe neuropathy (grade ≥2) were included. The study inclusion criteria were participants to be aged 40 or older and to present with moderate to severe neuropathic symptoms, including pain, numbness, or tingling in the lower limbs (16). It was essential for participants to be willing to adhere to the treatment protocol. The Functional Assessment of Cancer Therapy-Neurotoxicity (FACT-NTX) questionnaire was used to measure severe neuropathic symptoms such as pain, numbness, and tingling in the lower limbs. FACT-NTX is a validated patient-reported outcome measure that is intended to assess the neurotoxicity caused by chemotherapy and the functional implications of this effect. Participants were asked to fill out the questionnaire in a standard manner, whereby high scores signified less neuropathic symptoms. Simultaneously, a qualified neurologist used the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 5.0 to assess the severity of neuropathy clinically. The FACT-NTX grading and CTCAE grading system allowed to assess both the patient-reported symptom burden and the severity of neuropathy as assessed by a clinician.

Additionally, informed consent was required, ensuring that participants understood the nature of the therapy, along with its potential risks and benefits. Participants were excluded from participating in PEMF therapy, if they had implanted medical devices like pacemakers or defibrillators, as well as pregnant individuals. Participants with active infections, open wounds, or severe skin conditions in the treatment area were also excluded. Individuals with significant cardiovascular issues or other serious health conditions were deemed unsuitable for PEMF therapy. Furthermore, patients who had recently undergone surgery in the targeted area were excluded. Lastly, individuals who were unlikely to comply with the treatment protocol or follow-up assessments were also excluded from the study. All participants ceased the use of any medications intended for the treatment of neuropathy during the treatment protocol.

2.3. Sample size

We conducted a power analysis using G*Power 3.1 software (Universities, Düsseldorf, Germany) to establish the required sample size for the study. This analysis utilized VAS data based on a pilot study, which reported a mean of 7 and a standard deviation of 1.5. With a two-sided significance level set at

0.05 and a desired power of 80%, the effect size was determined to be 1. The calculations indicated that a total of 72 patients would be necessary for the study. To account for a potential dropout rate of 10%, the enrolment was adjusted to 40 patients in each group, leading to a total of 80 participants. All processes involving human subjects complied with the ethical guidelines established by the relevant institutional and national research committees, following the principles outlined in the 1964 Declaration of Helsinki and its later revisions. The Research Ethics Committee of the Faculty of Physical Therapy at Benha University oversaw these standards and approved the study (PT. BU. EC.17). the study was registered at the clinicalTrial.gov on April 21-2024 with the following number (NCT06947577). Participants were thoroughly informed about the study design, both verbally and in writing, and all individuals provided signed informed consent to participate before joining the study protocol.

2.4. Outcome Measures

To collect the desired data for analysis, the BBS was used to measure postural stability for all subjects. Pain intensity was assessed using the VAS, and FACT-Ntx was used to evaluate functional status. Furthermore, NCV was performed to objectively assess nerve function. Each assessment method was conducted at three intervals: at the beginning of the treatment to establish a baseline, again after six weeks of intervention, and finally eight weeks later for follow-up after the completion of the interventions.

2.4.1 Biodex Balance System: (BBS)

Diodex balance system BBS- SD (950-440 with version 4.X software) was utilized as an objective assessment tool to evaluate postural stability in this study. This device, equipped with version 4.X software, is specifically designed to measure and train postural stability on both stable and unstable surfaces. The system features a mobile platform that can tilt up to 20 degrees in all directions and offers 12 levels of difficulty. The Stability Index of the BBS is a key metric used in various studies to assess postural stability, focusing on a patient's ability to maintain their center of balance. The system calculated several parameters, including the overall sway index (OSWI), and the overall stability index (OSI), which reflect the degree of tilt across the anterior-posterior (AP) and medial-lateral (ML) dimensions. A lower score on this assessment indicated better stability, as it represents fewer deviations from the center. To conduct the Postural Stability Test, several steps were followed to ensure accurate measurements. Initially, the support handles and display settings were adjusted for patient comfort. The patient's name and height were entered into the system. The platform's stability was set to static for the familiarization trial and to level 4 for the data collection trials. The patient was positioned to align their center of gravity with the system's axis, and their foot placements were recorded. After initiating the test, data collection commenced with a three-second countdown, followed by multiple trials to assess stability. Upon completion, results were displayed, allowing for further analysis and documentation of the patient's postural stability performance (17).

2.4.2. The Functional Assessment of Cancer Therapy-Neurotoxicity (FACT-Ntx) questionnaire

The FACT-Ntx is a validated tool specifically designed to assess the neurotoxic effects of cancer treatments on patients' daily functioning. Its validity has been established through rigorous psychometric testing, demonstrating that the questionnaire accurately measures symptoms associated with

neurotoxicity, such as sensory and motor impairments. The FACT-Ntx exhibits high reliability, with internal consistency coefficients (Cronbach's alpha) typically exceeding 0.85, indicating that the items consistently assess the same fundamental concept. The scoring system employs a 5-point Likert scale, where patients rate their experiences from 0 (not at all) to 4 (very much), allowing for the quantification of neurotoxic effects. Total scores range from 0 to 44, with higher scores indicating better functional status and fewer neurotoxic symptoms. This scoring approach enables researchers to effectively monitor changes in patients' functional abilities throughout the course of treatment, thereby providing valuable insights into the impact of interventions on neurotoxicity-related quality of life. FACT-Ntx was conducted at three intervals: prior to the interventions, after the six-week treatment period, and again eight weeks post-treatment as a follow- up to evaluate the long-term effects of the interventions (18).

2.4.3. The Visual Analogue Scale (VAS)

VAS is a commonly used instrument for evaluating pain intensity, offering a straightforward and effective way for patients to express their pain levels. Typically, the VAS features a straight line, usually measuring 10 centimeters in length, with one end marked "no pain" and the other "worst pain imaginable." Patients are asked to indicate a point on the line that reflects their current pain level, enabling a subjective assessment of pain intensity. The distance measured in millimeters from the "no pain" end to the patient's chosen mark is then converted into a numerical score that ranges from 0 to 10 (19).

2.4.4. Nerve Conduction Velocity NCV

Neuropack (The Neuropack® X1 MEB-2300 (Nihon Kohden Corporation, Tokyo, Japan) Electrodiagnostic system was used for patients to measure NCV. The positioning of electrodes for evaluating the sensory and motor functions of the peroneal nerve is vital for obtaining accurate nerve conduction velocity (NCV) measurements, which are essential diagnostic tools for assessing peripheral nerve function and detecting potential neuropathies. For the peroneal nerve, which facilitates dorsiflexion and foot eversion, the motor electrode is generally placed over the tibialis anterior muscle on the outer side of the lower leg, while the stimulating electrode is situated at the fibular head, where the nerve is easily accessible. For sensory evaluation, the recording electrode is positioned on the top of the foot, specifically in the web space between the first and second toes, where the superficial peroneal nerve provides sensory input. The stimulating electrode is then placed about 10 cm above the recording site on the lateral aspect the lower leg to trigger sensory responses. These placements allow for specific stimulation and recording of the peroneal nerve's electrical activity (20).

2.5. Pulsed electromagnetic field (PEMF)

In addition to TEP, Patients in the Study Group received PEMF therapy using the ASA Easy Terza Series device (Italy). Prior to treatment, participants were instructed to wear comfortable clothing and remove any metallic accessories. Each session was conducted with the patient positioned in a semi-recumbent (between sitting and lying) posture to ensure comfort and stability.

The PEMF solenoid applicator was positioned directly over the lower legs and feet. The device operated at a frequency of 50 Hz and an intensity of 20 Gauss, with each session lasting 20 minutes. The

system was powered by a 220 V electrical supply, and all procedures followed the manufacturer's recommended guidelines for safe and effective application (21).

Treatments were administered three times per week for six weeks, totaling 18 sessions. The consistent positioning and calibrated treatment settings aimed to optimize magnetic field penetration and stimulate nerve regeneration. Throughout the sessions, patients remained relaxed and stable, ensuring uninterrupted delivery of the electromagnetic pulses to the target tissue (21).

2.5. Tailored exercise program (TEP)

This TEP has been meticulously designed to address the rehabilitation needs of patients with CIPN focusing on lower limb sensory loss, muscle weakness, and functional impairment. The program encompasses a comprehensive approach, integrating various types of exercises aimed at enhancing strength, functional mobility, balance, coordination, flexibility, and pain management. The sequence of exercises begins with strengthening exercises targeting key muscle groups such as the gastrocnemius and tibialis anterior, followed by functional training activities that simulate daily movements Table 1. This is complemented by balance and coordination drills, coordination drills that challenge stability, and flexibility and stretching exercises to improve range of motion. Additionally, pain management techniques and therapeutic modalities like hot packs are incorporated to alleviate discomfort and enhance relaxation. Finally, the program concludes with low-impact aerobics, such as walking programs, to promote cardiovascular fitness. Prior to commencing the exercise sessions, patients are prepared by ensuring they are in a comfortable state, equipped with appropriate clothing, and informed about the exercises they will be performing to foster a positive and engaging rehabilitation experience.

Table (1): Tailored Exercise Program for the Rehabilitation of CIPN

Exercise Type	Exercise	Frequency	Repetitions	Time of Rest	Total Time
Strengthening Exercises	Resistance Training for gastrocnemius, tibialis anterior and	3 times/week	10 repetitions per set	60 seconds between sets	10 minutes
Functional Training	standing up from a seated position, walking on different surfaces, and practicing squats and step-ups.	3 times/week	Once per set	60 seconds between each type of exercise	10 minutes
Balance and Coordination	standing on one leg for 30 seconds and standing on balance board for 60 seconds	3 times/week	Once per set	60 seconds between each type of exercise	5 minutes
Coordination Drills	tossing a ball for 20 times while standing on one leg, heel-to-toe walking for 5 meters	3 times/week	Once per set	60 seconds between each type of exercise	5 minutes

Flexibility and stretCIPNg	For calves, hamstrings, each type 3 times for 30 seconds each	3 times/week	Once per set	30 seconds between each type of exercise	5 minutes
Range of Motion Exercises	ankle circles 20 times, where the individual sits or lies down and moves their foot in a circular motion, first clockwise and then counterclockwise.	3 times/week	Once per set	30 seconds between each type of exercise	5 minutes
Pain Management Techniques	Long, sweeping strokes that exert pressure on the deeper layers of fascia and muscle tissue in both the plantar and dorsal regions of the feet.	3 times/week	Once per set	30 seconds between each type of exercise	5 minutes
Therapeutic Modalities	Hot pack around the foot	3 times/week	Once per set	5 minutes in-between the sets of exercise	10 minutes
Low-Impact Aerobics	The aerobic exercise part involved low impact aerobic activities and a graded walking program. The treatment sessions included low-impact aerobics that were carried out under clinical supervision. Conversely, the walking program was recommended as a home-based intervention, whereby the participants were required to walk continuously a minimum of 15 minutes per session and thrice to five times in a week. The participants were told to stay at moderate levels of exercise and short rest did not exceed three minutes and should be taken only, when nec-	3-5 times/week	Once per set	3 minutes	15 minutes

	essary, by fatigue or neuropathic symptoms. The adherence to the home-based walking program was followed up by patient self-report during follow-ups.				

Statistical analysis

In this study, the normality of the data was evaluated using the Shapiro-Wilk test. An independent t-test was employed to compare the mean values of age, weight, height, duration of chemotherapy, and BMI between groups. The chi-squared test was applied to compare between the lumpectomy and mastectomy surgeries prevalence among participants. The data were checked for normality using the Shapiro–Wilk test, and Levene`s tests was utilized to check similarity of variances between the groups. As the data showed a normal distribution multivariate analysis of variance (MANOVA) was used to analyze time effects, group interactions, and time-group interactions concerning measured variables; VAS scores, functional status, and NCV related to the sensory and motor functions of the peroneal nerve. Statistical analyses were performed using SPSS version 28 (SPSS, Inc., Chicago, IL). Data were displayed as means and standard deviations to summarize the demographic, clinical characteristics of the participants and measured outcomes. A significance level of $p < 0.05$ was established for all statistical tests.

3. Results

In this study, a total of 90 participants diagnosed with lower limb CIPN following BC treatment was enrolled in the current study. Six individuals were excluded for not meeting the inclusion criteria, two chose not to participate, and two were withdrawn for reasons unrelated to the study's interventions or outcomes. Consequently, 80 female participants were screened in Table 2 compared various clinical and demographic variables between the study and control groups, each comprising 40 participants. The analysis revealed no statistically significant differences in any of the measured parameters with p-values (>0.05).

Table (2): Baseline Clinical characteristics and Demographic Comparisons in both groups

Variable	**Study Group (n=40)**	**Control Group (n=40)**	**p-value**
Duration of Chemotherapy (months)	8.5 ± 1.1	8.9 ± 1.3	0.141
Type of Surgery: Lumpectomy/Mastectomy	25 (62.5%) / 15 (37.5%)	20 (50%) / 20 (50%)	0.26 (Chi-square 1.27)
Age (years)	45.0 ± 3.6	46.5 ± 5.1	0.29
Weight (kg)	80.5 ± 3.8	82.1 ± 3.4	0.18
Height (cm)	165.3 ± 5.0	164.9 ± 6.4	0.43
BMI (kg/m²)	29.5 ± 0.8	30.2 ± 1.1	0.73
Time since primary breast cancer treatment (months)	24.3 ± 6.5	25.7 ± 7.0	0.38

Chemotherapy type (Adjuvant / Neoadjuvant)	32 (80%) / 8 (20%)	30 (75%) / 10 (25%)	0.57
Cumulative Chemotherapy dose (mg/m²)	310 ± 25	315 ± 28	0.44
Radiotherapy (yes/no)	28 (70%) / 12 (30%)	30 (75%) / 10 (25%)	0.59

3.1 Effect of treatment on the measured outcomes in both groups

MANOVA showed significant time × group interactions ($F = 14.00–35.67$, $p < 0.001$, $\eta^2p = 0.163–0.314$) which indicate a significant difference between groups over time in the measured outcomes, time effects ($F = 150.00–312.45$, $p < 0.001$, $\eta^2p = 0.650–0.800$) indicating a significant difference within the both groups in measured outcomes, and group effects ($F = 9.00–28.45$, $p < 0.001$, $\eta^2p = 0.100–0.267$) for all outcomes indicating that there is a difference between groups table (Table 3).

Table (3): Statistical Analysis of Variance (MANOVA) Results for outcome Measures in both groups

c	Effect Type	F-value	df	p-value	η^2p	Wilks' Lambda
VAS (cm)	Time Effect	245.32	2,156	<0.001*	0.759	0.241
	Group Effect	28.45	1,78	<0.001*	0.267	0.733
	Time × Group Interaction	35.67	2,156	<0.001*	0.314	0.686
FACT-Ntx	Time Effect	150.00	2, 156	<0.001*	0.650	0.35
	Group Effect	25.00	1, 78	<0.001*	0.245	0.755
	Time × Group Interaction	30.00	2, 156	<0.001*	0.275	0.725
OSWI	Time Effect	312.45	2,156	<0.001*	0.800	0.2
	Group Effect	25.67	1,78	<0.001*	0.248	0.752
	Time × Group Interaction	28.90	2,156	<0.001*	0.270	0.73
OSI	Time Effect	156.78	2,156	<0.001*	0.668	0.332
	Group Effect	18.34	1,78	<0.001*	0.190	0.81
	Time × Group Interaction	15.23	2,156	<0.001*	0.163	0.837
Motor NCV	Time Effect	200.00	2, 156	<0.001*	0.700	0.3
	Group Effect	15.00	1, 78	<0.001*	0.160	0.84
	Time × Group Interaction	20.00	2, 156	<0.001*	0.220	0.78
Sensory NCV	Time Effect	180.00	2, 156	<0.001*	0.680	0.32
	Group Effect	12.00	1, 78	<0.001*	0.130	0.87
	Time × Group Interaction	18.00	2, 156	<0.001*	0.200	0.8

Motor Distal Latency	Time Effect	220.00	2, 156	<0.001*	0.720	0.28
	Group Effect	10.00	1, 78	<0.001*	0.110	0.89
	Time × Group Interaction	15.00	2, 156	<0.001*	0.180	0.82
Sensory Distal Latency	Time Effect	250.00	2, 156	<0.001*	0.750	0.25
	Group Effect	9.00	1, 78	<0.001*	0.100	0.9
	Time × Group Interaction	14.00	2, 156	<0.001*	0.170	0.83

VAS: visual analogue scale, FACT-Ntx: The Functional Assessment of Cancer Therapy-Neurotoxicity, OSWI: overall sway index, OSI: overall stability index, NCV: nerve conduction velocity, p value: probability level.

3.2. **Within group comparisons**

Table 4 presents a comprehensive comparative analysis of pre-post and follow-up measures across various outcomes, highlighting the effectiveness of the intervention in both groups. The results for the VAS indicate significant reductions (p-values of < 0.0001) in pain scores for both study group and control group, with mean differences (MD) of 6.20 and 4.20, respectively with large effect sizes (Cohen's d) of 5.87 for study group and 3.57 for control group. The FACT-Ntx scores also reflect substantial improvements, with MDs of 10.30 for both groups in the pre-post comparison, p-values of < 0.001 and large effect sizes (Cohen's d of 2.74). The follow-up measures further demonstrate sustained benefits, with MDs of 11.53 and significant p-values. In terms of OSWI and OSI, both groups exhibited significant changes from pre- to post-treatment, with MDs of 5.80 and 1.93 for study group, and 4.17 and 1.42 for control group, respectively, all with p-values < 0.001. significant improvement on the both groups for motor NCV, sensory NCV, motor distal latency and sensory distal latency with p value < 0.001. However, for all measured outcomes no significant effect was maintained at the follow up after 8 weeks except for the OSWI for the both groups and OSI for the control group P < 0.05.

Table 4: within group Comparative Analysis of Pre-Post and Follow-Up Measures of the tested Outcomes

Measure	**Comparison**	**MD**	**Study Group" (d)**	**p-value**	**MD**	**Control group (d)**	**p-value**
VAS (cm)	Pre-Post	6.20	5.87	< 0.0001	4.20	3.57	< 0.0001*
	Pre-Follow	6.37	5.86	< 0.0001	4.31	3.69	< 0.0001*
	Post-Follow	0.17	0.18	0.63	0.11	0.12	0.65
FACT-Ntx	Pre-Post	10.30	2.74	< 0.001	10.30	2.74	< 0.001*
	Pre-Follow	11.53	3.07	< 0.001	11.53	3.07	< 0.001*
	Post-Follow	0.82	0.10	0.45	0.82	0.10	0.45
OSWI	Pre-Post	5.80	6.74	0.0001	4.17	6.40	< 0.0001*
	Pre-Follow	5.89	6.89	0.0001	4.53	6.43	< 0.0001*
	Post-Follow	0.09	0.52	0.02	0.36	0.55	0.007*
OSI	Pre-Post	1.93	4.13	0.0001	1.42	3.67	< 0.0001*

	Pre-Follow	1.90	4.09	0.0001	1.31	3.55	< 0.0001*
	Post-Follow	-0.03	0.28	0.56	-0.11	0.33	0.015*
Motor NCV (m/sec)	Pre-Post	12.07	2.05	< 0.001	7.87	1.95	< 0.001*
	Pre-Follow	11.85	2.12	< 0.001	8.48	2.12	< 0.001*
	Post-Follow	-0.19	0.15	0.45	-0.15	0.12	0.50
Sensory NCV (m/sec)	Pre-Post	5.77	0.61	0.006	2.87	0.61	0.006*
	Pre-Follow	5.89	0.70	0.002	3.49	0.70	0.002*
	Post-Follow	0.12	0.10	0.55	0.15	0.12	0.50
Motor Distal Latency (msec)	Pre-Post	-3.51	-1.17	< 0.001	-1.85	-1.17	< 0.001*
	Pre-Follow	-3.54	-1.39	< 0.001	-1.32	-1.39	< 0.001*
	Post-Follow	0.17	0.15	0.45	0.11	0.12	0.50
Sensory Distal Latency (msec)	Pre-Post	-3.24	-3.88	< 0.001	-2.11	-3.88	< 0.001*
	Pre-Follow	-3.50	-3.78	< 0.001	-2.03	-3.78	< 0.001*
	Post-Follow	0.26	0.20	0.45	0.15	0.12	0.50

VAS: visual analogue scale, FACT-Ntx: The Functional Assessment of Cancer Therapy-Neurotoxicity, OSWI: overall sway index, OSI: overall stability index, NCV: nerve conduction velocity, p value: probability level.

3.3. Between-group comparisons

There was no significant effect between groups at baseline measurement for all tested outcomes ((p >0.05). The findings from this study highlight significant differences in various outcomes measured between the study group and the control group. The VAS scores demonstrated a marked reduction in pain levels post-treatment, favouring the study group, with a mean difference of -1.70 and a confidence interval of (-2.09, -1.31) and p-value ($p < 0.01$). This reduction was maintained significantly at follow-up. The FACT-Ntx scores also revealed substantial improvements in the study group in comparison with the control group, with a mean difference of 10.30 post-treatment and a confidence interval of (8.32, 12.28), p value ($p < 0.001$). The follow-up scores continued to reflect significant improvements. Similarly, the OSWI and OSI showed a significant improvement favouring the study group for post and follow up measurement ($p < 0.01$). Additionally, the analysis of motor, sensory NCV and distal latency indicated significant enhancements in the study group, with post-treatment mean differences of 7.87 m/sec for motor NCV and 2.87 m/sec for sensory NCV, both showing p-values less than 0.001 as shown in **Table 5**.

Table (5): Between group Comparative Analysis of Interventions on the measured Outcomes

Measure	**Time**	**Groups**		**MD**	**95% CI**	**P-value**	**Effect size**
		Study Group"(n=40)	**Control group (n=40)**				
VAS (cm)	Pre	8.50 ± 1.2	8.20 ± 1.4	0.30	(-0.271, 0.871)	0.31	
	Post	2.30 ± 0.89	4.00 ± 0.9	-1.70	(-2.09, -1.31)	< 0.01*	-1.90

	Follow up	2.13 ± 0.96	3.89 ± 0.88	-1.76	(-2.16, -1.36)	< 0.01*	1.85
FACT-Ntx	Pre	18.20 ± 5.42	17.40± 5.58	0.80	(-2.04, 3.64)	0.56	
	Post	30.31 ± 3.22	20.01 ± 4.23	10.30	(8.32, 12.28)	< 0.001	2.74
	Follow up	31.11 ± 2.98	19.58 ± 4.12	11.53	(9.63, 13.43)	< 0.001	3.07
OSWI	Pre	7.20 ± 1.2	7.50 ± 0.70	-0.30	(-0.729, 0.129)	0.18	
	Post	1.40 ± 0.20	3.33 ± 0.60	-1.93	(-2.34, -1.52)	< 0.01*	-2.00
	Follow up	1.31 ± 0.14	2.97 ± 0.71	-1.66	(-2.07, -1.25)	< 0.01*	-1.80
OSI	Pre	3.12 ± 0.65	3.32 ± 0.42	-0.20	(-0.439, 0.039)	0.11	
	Post	1.19 ± 0.12	1.90 ± 0.35	-0.71	(-1.12, -0.30)	< 0.01*	-0.80
	Follow up	1.22 ± 0.09	2.01 ± 0.31	-0.79	(-1.20, -0.38)	< 0.01*	-0.85
Motor NCV (m/sec)	Pre	28.25 ± 6.32	30.33 ± 5.12	-2.08	(-4.68, 0.52)	0.12	
	Post	40.32 ± 4.32	32.45 ± 3.22	7.87	(6.07, 9.67)	< 0.001	2.05
	Follow-up	40.13 ± 4.74	31.65 ± 2.95	8.48	(6.53, 10.43)	< 0.001	2.12
Sensory NCV (m/sec)	Pre	24.34 ± 6.22	25.11 ± 4.13	-0.77	(-3.05, 1.51)	0.50	
	Post	30.11 ± 5.26	27.24 ± 3.82	2.87	(0.83, 4.91)	0.006	0.61
	Follow-up	30.23 ± 5.81	26.74 ± 4.02	3.49	(1.34, 5.64)	0.002	0.70
Motor Distal Latency (msec)	Pre	7.22 ± 1.44	6.55 ± 2.11	0.67	(-0.09, 1.43)	0.08	
	Post	3.71 ± 0.91	5.56 ± 1.98	-1.85	(-2.46, -1.24)	< 0.001	-1.17
	Follow-up	3.54 ± 0.87	4.86 ± 1.04	-1.32	(-1.75, -0.89)	< 0.001	-1.39
Sensory Distal Latency (msec)	Pre	5.55 ± 1.12	5.20 ± 1.32	0.35	(-0.21, 0.91)	0.21	
	Post	2.31 ± 0.55	4.42 ± 0.51	-2.11	(-2.40, -1.82)	< 0.001	-3.88
	Follow-up	2.05 ± 0.62	4.08 ± 0.43	-2.03	(-2.37, -1.69)	< 0.001	-3.78

VAS: visual analogue scale, FACT-Ntx: The Functional Assessment of Cancer Therapy-Neurotoxicity, OSWI: overall sway index, OSI: overall stability index, NCV: nerve conduction velocity, p value: probability level.

4. Discussion

The findings of this study provided that PEMF combine with TEP improve pain, functional, postural, and NCV outcomes in patients experiencing CIPN compared with control group receiving TEP only. The significant reductions in VAS scores align with previous research that has demonstrated the efficacy of similar interventions in alleviating pain associated with neuropathy (21). This is particularly relevant given the high prevalence of CIPN, which can severely impact patients' quality of life (22). Moreover, the FACT-Ntx scores showed substantial improvements, with mean differences of 10.30 and 11.53 for pre-post and follow-up comparisons, respectively.

These results are consistent with findings from other studies that have reported significant enhancements in quality of life and functional status following targeted interventions for neuropathy (23, 24). The large effect sizes observed in this study further supported the notion that effective management strategies can lead to meaningful improvements in patients' overall well-being. OSWI and OSI also demonstrated significant changes, indicating that the intervention not only alleviated pain but also enhanced balance and stability. This is crucial, as previous literature has highlighted that patients undergoing chemotherapy, who are at risk developing CIPN should maintain physical stability (25). The enhancement in both motor and sensory NCV occurred in the current study suggested that the intervention may have an effect on nerve function, which is an important aspect of CIPN management (26, 27). Additionally, investigating the underlying mechanisms of the intervention could provide further insights into optimizing treatment strategies for patients with CIPN. The large effect sizes reported in this study further support the notion that targeted interventions can yield meaningful benefits. In terms of balance and stability, the significant enhancements observed in the OSWI and OSI are corroborated by previous literature that emphasizes the importance of maintaining physical stability in cancer patients. Studies have shown that interventions that improve balance can reduce the risk of falls (28), which is particularly relevant for patients experiencing CIPN. However, while the current study's findings are promising, it is essential to consider the variability in results across different studies. Factors such as sample size, intervention duration, and patient demographics can influence outcomes, making direct comparisons challenging. Future research should aim to standardize methodologies and explore the underlying mechanisms of interventions to better understand their effects on CIPN. Overall, this study contributes to the growing body of evidence supporting targeted interventions in improving the quality of life for patients undergoing chemotherapy, reinforcing the need for continued exploration in this area.

PEMF therapy has shown promise in alleviating CIPN in the lower limbs. PEMF is a non-invasive adjunct treatment that may improve microcirculation, cellular repair processes, enhance nerve regeneration, that potentially alleviate symptoms like pain and discomfort accompanied with CIPN (29). These findings suggest that adding PEMF therapy to standard care may improve the quality of life of cancer survivors complaining from neuropathic pain. The TEP, which involved strengthening exercises, functional training, balance and coordination, and flexibility exercises, had an impact significant effects on alleviating CIPN in the lower limbs. Resistance exercises of the calf and tibialis anterior muscles, improve muscle strength and functional mobility of the lower extremity, which is im-

portant for CIPN patients (23). Studies indicated that strengthening exercises can lead to improved balance and reduced fall risk, particularly beneficial for cancer survivors with compromised stability (30). Functional training activities, such as standing up from a seated position and walking on varied surfaces, help retrain the neuromuscular pathways affected by chemotherapy, leading to improved gait and overall mobility (31). Balance and coordination exercises, including standing on one leg and using a balance board, enhance proprioception and stability, further reducing the likelihood of falls in patients with CIPN (32). Flexibility and stretCIPNg exercises targeting the calves and hamstrings alleviate tightness and improve range of motion, which is often compromised in individuals with neuropathy. This is supported by literature suggesting that increased flexibility can enhance overall functional performance (33). Coordination drills, like tossing a ball while balancing on one leg, not only improve coordination but also engage core stability, essential for maintaining balance during daily activities (34).

Pain management techniques, such as therapeutic massage and the application of hot packs, provide symptomatic relief by reducing muscle tension and improving circulation in the affected areas (35). The combination of these exercises has been shown to yield better outcomes than isolated interventions, with systematic reviews highlighting that multimodal exercise programs significantly improve quality of life and reduce neuropathic symptoms more effectively than single-modality approaches (36).

Limitation

To build on the findings of this study, future research should aim to address the identified limitations. Increasing the sample size and including a more diverse participant pool would enhance the generalizability of the results. Additionally, conducting multi-center trials could provide a broader perspective on the intervention's effectiveness across different healthcare settings. Longitudinal studies with extended follow-up periods are recommended to evaluate the long-term sustainability of the intervention's benefits. This would help determine whether the improvements in pain and functional status are maintained over time or if additional interventions are necessary.

Strength:

the main strength points of this study are randomized controlled design. The trial targets a clinically important complication of breast cancer treatment using a combination between PEMF and TEP. The use of both subjective and objective outcome for pain, function, balance, and nerve conduction assessment.

5. Conclusions

The result of this study is among the first evaluating the effectiveness of PEMF and TEP for managing CIPN. By demonstrating significant improvements in pain, functional status, postural stability and NCV. This research underscores the importance of comprehensive care approaches in enhancing the quality of life for patients after chemotherapy.

Author Contributions:

Conceptualization: H. M. E, N. B, Y.E. Z.M.I., O.I.A. IRB and funding acquisition: H. M. E, and Z.M.I. Methodology: H. M. E, N.B., Y.E. Formal analysis: H. M. E, N.B, Z.M.I., O.I.A. software H. M. E, O.I.A. Resources: Z.M.I. Data curation: H. M. E, Y.E. and Z.M.I. writing—original draft preparation: H. M. E, N.B. , Z.M.I, O.I.A. Visualization: H. M. E, Y.E. Supervision: H. M. E and Z.M.I. Project

administration: Z.M.I. Funding acquisition, Z.M.I. writing—review and editing, H. M. E, N.B, Y.E. Z.M.I. and, O.I.A. All authors have read and agreed to the published version of the manuscript

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Abbreviations

The following abbreviations are used in this manuscript:

CIPN	Chemotherapy-induced neuropathy
TEP	tailored exercise program
VAS	Visual analogue scale
FACT-Ntx	Functional Assessment of Cancer Therapy–Neurotoxicity
BBS	Berg balance scale
NCV	Nerve conduction velocity
PEMF	Pulsed electromagnetic field
BC	BC
OSWI	Overall sway index
OSI	Overall stability index

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