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Exploring Effects of Modified Trampoline Training v/s Proprioceptive Training on Balance in Cancer Patients with Chemotherapy-Induced Peripheral Neuropathy: Randomized Controlled Trial

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Abstract

Context: Chemotherapy Treatment-Induced Peripheral Neuropathy (CIPN), is a significant side effect of anti-neoplastic treatment faced by cancer patients. CIPN results in sensory-motor deficiencies, altered proprioceptive signals, and poor posture control, increasing the risk of fall. Modified trampoline training is a recent rehabilitation method that can stimulate proprioception. However, its effects in cancer patients with CIN remain unexplored. The study's objective was to examine and compare the effects of Modified Trampoline Training (MTT) and Conventional Proprioception Training (CPT) on balance in cancer patients with CIPN. **Study Designs and Settings:** This randomized controlled trial was conducted in the tertiary care center, Miraj. Methods: The study included male and female patients aged between 41-60 years, suffering from colorectal cancer who are receiving or have received chemotherapy and were experiencing the symptoms of CIPN. A total of 26 patients were divided into two equal groups. Group A received MTT and Group B received CPT for 3 days/week for 4 weeks. The outcome measure was balance which was assessed using the Berg Balance Scale (BBS) and Timed Up-and-Go test (TUG). Statistical analysis: The data was analyzed using paired and independent t-tests for within and between groups respectively. **Results:** Within-group analysis showed statistically significant improvement in all the outcomes for both groups ($p<0.01$). Between groups, the analysis revealed that the MTT group showed better improvement for BSS ($p<0.0$) and TUG ($p = 0.01$) than the control group. **Conclusion:** The study concluded that MTT is more effective than CPT in improving balance in cancer patients with CIPN.

Keywords: Cancer, Chemotherapy, Proprioception, Peripheral Neuropathy, Trampoline Training

1. Introduction

Cancer is a strong impacting public health problem commonly characterized by unidentifiable and uncontrollable malignant growth of cells[1]. The incidence rate of cancer in India is estimated to be 94 cases per 100,000 people, out of which 77% of patients are registered at oncological clinics and have the following types of cancers. Gastro Intestine Tract Cancer (28.3%); Hematological Cancer (24.4%); Lung malignant Cancer (12.6%); Colorectal Cancer (96%)[2].

Chemotherapy is the commonest treatment given for the treatment of cancer that has a deteriorating effect on the various systems of the body, the nervous system being one of the very common systems getting affected. 'Anti-neoplastic chemotherapy' involves intervention

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that targets the tumor cells and aims to eradicate those cells. They act on cell division and cell cycle leading to interruption and proliferation of cells. This causes toxicity to peripheral nerves which varies depending on the drug used for the treatment, cumulative doses of chemotherapeutic agent used, time of infusion, and number of chemotherapy sessions[3,4]. Neurotoxic chemotherapy activates mitochondrial and vascular dysfunction, causes oxidative stress on dorsal root ganglion, microtubule, mechanoreceptors, and axon, and induces sensory and motor neuropathy. This peripheral neuropathy is referred to as Chemotherapy Induced Peripheral Neuropathy (CIPN)[4,5]. CIPN weakens the reception, transmission, and response to stimuli, consequently impairing one's tactile sensory perception. Sensory nerve damage may result in pain, sensitivity, numbness, tingling or prickling, burning, and problems with positional awareness whereas motor nerve damage may result in weakness, muscle atrophy, muscle twitching or fasciculation, and paralysis[5,6]. These symptoms lead to abnormal gait, problems like ataxia, and loss of balance[7].

For each symptom reported, patients are assessed on the Numerical Rating Scale (NRS), a 0-10 numerical scale[8]. Patients having numbness and tingling with a score of 3 or greater on NRS for 10 or more days are considered to have significant CIPN[9]. The severity of CIPN can also be known on the basis of the W.H.O. grading scale for CIPN[10].

Exercise prescription guidelines for cancer patients have been given by various organizations including the American Cancer Society and American College of Sports Medicine. Exercise plays a vital role in reducing the symptoms related to peripheral neuropathy and therefore an important focus of rehabilitation for cancer patients with CIPN is the development of interventions to promote proprioception and balance[11]. To improve foot mobility, proprioception, and balance, the literature review reveals the use of various physiotherapy exercises such as closed kinematic chain exercises[12], walking on uneven surfaces, wobble board training, thera disc exercises, and mini-trampoline training[13].

Modified Trampoline Training (MTT) is the recent rehabilitation method that can stimulate proprioception and enhance a person's ability to improve both static balance and dynamic balance[14]. Trampoline training includes prescribing different exercises on an unstable surface that results in co-contraction of the muscles that ultimately, trains the brain to recognize the segment position of the bodily movement and train the proprioceptive pathways more effectively[15,16]. Therefore the objective of the study was to assess the effectiveness of modified trampoline training and to compare it with Conventional Proprioceptive Training (CPT) in terms of balance in cancer patients with CIPN.

2. Materials and Methods

2.1 Study Design, Setting, and Ethical Consideration

The study procedures followed during the study were in accordance with the Helsinki Declaration. The present study was an assessor-blinded randomized controlled trial conducted in the tertiary care center, in Miraj, India. The study duration was 6 months. Ethical clearance for the study was obtained by the Institutional Ethical Review Committee. All participants gave written informed consent prior to the commencement of the study. All the COVID-19 precautions were taken according to the Indian Council of Medical Research guidelines. For better reporting of the trial, CONSORT- 2010 statement guidelines were referred.

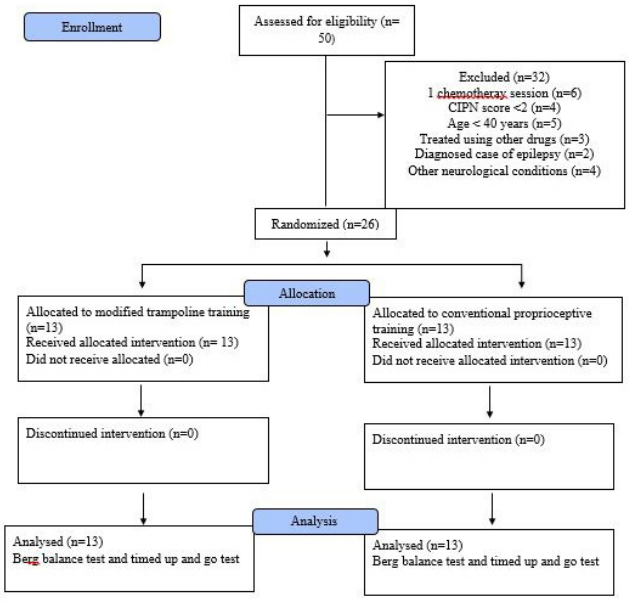

Figure 1. Consort flow diagram.

2.1.1 Study Participants

The target population of the study were patients having colorectal cancer who were on oxaliplatin as a drug for chemotherapy. The sample size of the study was 26 which

was calculated based on the population standard and the desired significance level (p = 0.05). A total of 50 patients having colorectal cancer were screened for inclusion and exclusion criteria, out of which 26 patients were selected using a random number table. Allocation into two groups was done using a concealed envelope (Figure 1).

The inclusion criteria for the study were; male and female colorectal cancer patients aged between 41-60 years and have undergone at least 3 chemotherapy sessions; treated using platinum-based drug, Oxaliplatin-high single dose or multiple doses; having CIPN grade 2-4 according to WHO scale;[10] CIPN symptoms with NRS score ≥ 3 for 10 days or more;[9] Berg Balance Score between 21-40; MMT grade of at least 3+ and who were willing to participate. Patients with neurological disorders other than CIPN, like Brain Tumor stroke, multiple sclerosis, Parkinson's disease, epilepsy,dementia; patients with vision problems and auditory sense disorder, severe cardio-respiratory problems including symptoms of dyspnea, chest pain, peripheral vascular disease, osteoporosis, recent fracture and who were unable to understand or follow commands were excluded.

2.1.2 Procedure

Medical information regarding the cancer treatment was obtained from medical records from the study setting. Demographic data, type, and stage of cancer, chemotherapy session, chemotherapy agent used, CIPN grade with the help of W.H.O scale, CIPN severity with the help of Numerical Rating Scale (NRS), MMT grade on the basis of Manual Muscle Testing was taken.

2.1.3 Outcome Measures

Balance testing using Berg Balance Scale and Timed up and Go test. The outcome measures were taken at 2 timeframes; at baseline and after 4 weeks of intervention.

1. Berg Balance Scale: It is used to measure balance function by assessing the performance of function tasks. It includes 14 functional tasks which are rated between 0 to 4, based on their performance. The higher the score, the better is the balance[17].
2. Timed up and go test: It is used to assess a person's mobility that requires both static and dynamic balance. Patients are initially seated and are instructed to stand, walk 3 meters, turn around, walk back, and take back the initial seating position. Balance is interpreted by the time taken to complete this task. Less time taken indicates more stability[18].

2.1.4 Intervention

Intervention is described according to the TIDieR checklist. The exercises were performed in the physiotherapy department at Cancer Hospital, Miraj. Twenty-six patients were divided randomly into two equal groups using the envelop method. Group A received modified trampoline training and Group B (control group) received conventional proprioceptive training for 3 times a week for 4 weeks. The total duration of one treatment session was 30 minutes. Exercises were given by a certified physiotherapist after completion of the BPTh program with the objective of improving balance.

Group A: Modified trampoline training[14].

The exercises prescribed were taken from the study done by Hahn *et al*[14]. The session was divided into warm-up (5 min), training (15 min), and cool down (5 min) Warm-up and cool down included an active range of motion and stretching exercises for the lower limb.

Training session- It consisted of exercises in standing, weight shifts, exercises in walking, and performing tasks. (Figure 2)

Figure 2. Intervention- exercise protocol for both the groups.

The details of the intervention are described in Table 1.

Group B: Conventional Proprioceptive Training[15].

Conventional training exercises were taken from the study done by Kaur *et al*[15]. The session was divided into warm-up (5 min), training (15 min), and cool-down (5 min)

2.1.5 *Statistical Analysis*

Data was analyzed using SPSS Version 16.0 software. The Shapiro-Wilk test was used to check the normality of data. Inferential statistical analysis was done using the paired 't' test for within-group and independent 't' test for between-group analysis, with the level of significance (p-value) set at 0.05.

3. Results

All 26 participants completed all the sessions and were analyzed. There were no incidences of injuries/falls during the course of the intervention. The basic characteristics of all the patients in terms of their mean age, gender, type of cancer, and total number of chemotherapy sessions received are presented in Table 2.

Table 1. Intervention- exercise protocol for both the groups

Group A: Modified trampoline training Exercises performed on trampoline		
Standing	• With feet in a walking stance • With feet together • One supporting leg	**Dosage** 30-sec hold 3 reps Rest interval: According to patient convenience
Weight Shifting	• Front, back, right, and left in 2 positions 1st position: With feet together 2nd position: In walking stance • Lifting the heel	
Walking	Alternative Steps to the front and back of the opposite leg in place	
Performing Task	• Tossing a balloon between the patient and the therapist • Throwing small ball between the patient • Picking up objects on the Trampoline.	
Group B: Conventional proprioceptive training Exercises performed on the Floor and Mat		
On the floor (Stable surface)	• Standing with a narrow base of support • Single-leg stance • Forward lunges • Mini squats	**Dosage** 30-sec hold 3 reps Rest interval: According to patient convenience
On Mat (Unstable surface)	• Standing with a narrow base of support • Single-leg stance • Forward lunges • Mini squats	

Table 2. Characteristic features of patients in both groups

		Group A	Group B	Chemotherapy Sessions (in Number)	Group A (Total no of Patients)	Group B (Total no of Patients)
AGE (avg. in years)		56.92	55.76	3	2	5
Gender	**Male**	9	8	4	2	2
	Female	4	5	5	2	2
Type of Cancer	**Colon**	9	6	6	4	2
	Rectal	4	7	7	2	2
				8	1	0

Table 3. Within group analysis of outcome measure

Outcome	Mean ± SD	T-Value	#P-Value
Group A: Modified trampoline training			
PRE BBS	38.38 ± 2.66	22.94	0.0001
POST BBS	42.46 ± 2.56		
PRE-TUG	19.76 ± 2.77	18.5	0.0001
POST-TUG	16.92 ± 2.69		
Group B: Conventional proprioceptive training			
PRE BBS	40.84 ± 1.40	14.65	0.0001
POST BBS	49.23 ± 2.45		
PRE-TUG	19.69 ± 2.86	22.44	0.0001
POST-TUG	13.92 ± 2.90		

SD: Standard deviation; BBS: Berg balance scale; TUG: Timed up and go test;#p value using paired t test

Table 4. Between-group analysis of outcome measure

Outcome	Group	Mean ± SD	T-Value	P- Value
Post BBS	Group A	49.23 ± 2.45	6.886	0.0001
	Group B	42.46 ± 2.56		
Post TUG	Group A	13.92 ± 2.90	2.733	0.0116
	Group B	16.92 ± 2.69		

SD: Standard deviation; BBS: Berg balance scale; TUG: Timed up and go test;#p value using independent t test

3.1 Within-Group Analysis

Within-group analysis for both the groups showed statistically significant values for both the BBS and TUG tests, indicating that there was an improvement in balance in cancer patients having CIPN after both interventions (Table 3).

3.2 Between-Group Analysis

Between-group analysis shows statistical significance for BBS ($p<0.01$) and TUG ($p = 0.01$) indicating that Group A that is the MTT intervention group showed better improvement in outcome measure than the control group, CPE. (Table 4)

4. Discussion

The present study was conducted with the objective of assessing and comparing the effects of MTT and CPT in cancer patients with CIPM on balance.

The results of the study concluded that modified trampoline training was an effective rehabilitation protocol that improved static and dynamic balance in patients with cancer patients with CIPM. The result of this study was in accordance with the previous literature. Hahn J, *et al.,* observed improvement in muscle endurance, sensory-motor control, and dynamic balance in stroke patients who underwent modified trampoline training[14]. A study done on collegiate females also provides evidence that an unstable surface elicited greater dynamic balance improvement compared to a stable surface[15]. Recent rehabilitation bibliography balance exercises when performed on unstable surfaces improve proprioception, train the brain to recognize the segment position of the body's movement, and train the proprioceptive pathways more effectively[15,16].

For the improvement of balance, proprioceptive training is important as it helps with the planning of movement[16]. Proprioception directed by sensory receptors (mechanoreceptors and proprioceptors) which are situated in skin, joints, and muscle spindles allows the identification of limb position and movement via neural signal. Change in muscle length and joint position helps in forming a continuous loop of feed-forward and feedback inputs between sensory receptors and the nervous system which results in improvement in proprioception[19]. Previous study by Irshad Ahmad *et al,* a significant effect of sensorimotor and gait training on proprioception, nerve function, and electromyographic activity of lower limb muscles in patients with diabetic neuropathy was

seen[20]. In the present study, conventional proprioceptive exercises were performed on even and uneven surfaces Holding a position resulted in increased stimulation of mechanoreceptors present in muscle spindles, Golgi tendon organ, and joint capsule responsible for enhancing proprioception inputs from the foot ankle, and trunk and preventing loss of balance in colorectal cancer patients with CIPN.

When MTT and CPT were compared, it was found that MTT yielded better improvements in balance as compared to CPT. During Modified Trampoline Training the patients were challenged to continuously respond to changes in gravity by performing different tasks on a trampoline as this provides alteration in complex sensory and motor stimuli that provided deep proprioception sense[14]. The superiority of MTT over CPT could be attributed to deep proprioception sense on trampoline training in addition to the above-mentioned mechanism for improving proprioception. Therefore, study concluded that modified trampoline training is more effective.

5. Conclusion

Conventional Proprioceptive Training to improve balance in cancer patients with chemotherapy-induced peripheral neuropathy. The study had few limitations. Reporting of outcome measures at multiple timelines and long-term effects of the training were not assessed.

5.1 Clinical Implications

Modified Trampoline Training is been commonly used in Sports rehabilitation and neurorehabilitation, but this study concludes that it can be used for Oncology rehabilitation which is safe and effective.

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