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EFFECTIVENESS OF COORDINATIVE LOCOMOTOR TRAINING ON BALANCE AND GAIT IN CHEMOTHERAPY INDUCED PERIPHERAL NEUROPATHY PATIENTS

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ABSTRACT

Chemotherapy-induced peripheral neuropathy (CIPN) is the term used to describe the peripheral neuropathy brought on by chemotherapy drugs. CIPN results in numbness, tingling sensation, balance and gait problems. Coordinative locomotor training (CLT) is a non-invasive treatment that combines the PNF patterns with sprinter/skater coordination. The goal of this study was to observe the effectiveness of Coordinative locomotor training on balance and gait in chemotherapy induced peripheral neuropathy patients. For this purpose, a single blinded randomized controlled trial with the sample size of 38 was conducted. After enrollment patients were randomly allocated into two groups. Group A was the interventional group in which participants received Coordinative locomotor training for 30 minutes per session. They were instructed to perform sprinter and skater patterns in three postures that were supine, sitting and half standing. In one session, a total of 3 sets (one set for each posture) with 10 repetitions of each sprinter and skater patterns were performed. While group B was the control group in which participants received conventional physical therapy for 30 minutes. Both interventions were applied three times per week for four weeks. Tinetti performance-oriented mobility assessment (POMA), Timed Up and Go (TUG) test and F8WT were used as outcome measures. Data was recorded at baseline and after applying the interventions for 4 weeks. For the analysis and comparing the recorded data SPSS version 23 was used.

Keywords: neuropathy, chemotherapy induced peripheral neuropathy, coordinative locomotor training, CLT, balance, gait

INTRODUCTION

Cancer is the outcome of uncontrolled cell division and proliferation. Certain cells have the ability to spread to other sections of the body or to the surroundings. We refer to these cells as "malignant," or cancerous. These malignant cells are capable of growing into tumors, penetrate surrounding healthy tissue, and destroy it (1).

Chemotherapy is the use of drugs to treat cancer. These drugs not only destroy the cancer cells but also the normal cells of the body which lead to numerous adverse effects (2). A common side effect of the chemotherapy that has been discussing lately is peripheral neuropathy. This kind of peripheral

neuropathy is known as chemotherapy induced peripheral neuropathy (CIPN). This happens due to the damage of peripheral nerves (3). Loss in both sensory and motor function may arise from injury to these neurons (4). The following medications have been frequently linked to an elevated risk of peripheral neuropathy: thalidomide, taxanes, vinca alkaloids, platinum medicines, and bortezomib (5). CIPN can cause pain, impaired sensory function and reduced proprioception of ankle. These conditions can cause loss of balance, higher risks of fall and walking difficulties at home and in community (6).

Duloxetine is currently the only medication that has been shown to be useful in a phase III randomized, double-blind, placebo-controlled trial to produce clinically significant analgesia against painful CIPN (7). As a result, routine clinical use of duloxetine has been advised as the first option (8). A meta-analysis was conducted in which 12 studies were analyzed in order to assess the effectiveness of non-pharmacologic therapies for the treatment of CIPN. According to these studies, foot baths, massages, and acupuncture significantly reduced CIPN symptoms (9).

There have been different modalities and exercises being used that are may be beneficial to peripheral neuropathy patients. Physical therapy activities emphasizing strength, flexibility, balance, and aerobic capability, according to the Foundation for Peripheral Neuropathy, may be useful to patients with neuropathy (10). Coordinative locomotor training (CLT) is a non-invasive treatment that combines the PNF patterns with sprinter/skater coordination. CLT is a hands-on approach that certified specialists utilize as a tool to improve patient's balance, strength, mobility and to relieve pain. In sprinter and skater patterns the entire body gets engaged with one leg in the closed chain (one foot on the ground or on the wall) (11).

The sprinter pattern mimics the runner's movement. On upper extremity of one side flexion-adduction-external rotation pattern and on lower extremity of the ipsilateral side extension-abduction-internal rotation pattern is performed. While at the opposite upper extremity extension-abduction-internal rotation pattern and on the lower extremity of the ipsilateral side flexion-adduction-external rotation pattern is performed in order to administer the sprinter pattern (12). The skater pattern mimics the skating movement. For upper extremity of one side flexion-abduction-external rotation pattern and the extension-adduction-external rotation pattern in the corresponding lower extremity are performed. For upper extremity of the contralateral side extension-adduction-internal rotation pattern while for the lower limb on the ipsilateral side flexion-abduction-internal rotation pattern is administered to apply skater pattern (12).

Coordinative locomotor training with sprinter and skater in PNF is an effective strategy for improving interlimb coordination while walking. A research indicated significant results of CLT to improve balance and coordination in stroke patients with balance deficits (13). An investigation looked at how a coordinative locomotor training (CLT) program on the balance and gait of stroke patients in order to create efficient treatment training and program techniques to enhance their functional abilities. In summary, this study's findings show how well a CLT program works to help stroke patients with their balance and gait (14). The objective of another research was to determine how supportive locomotor training (CLT) regimens affected cancer patients' lower-limb power, balance, and overall standard of living in cancer individuals. Based on the improvements in leg strength and balance that results show, the CLT regimen is a helpful exercise regimen it can be beneficial cancer patients who are reluctant to move become more physically active (15).

METHODS

This study was single blinded, Randomized Controlled Trial. Sample was collected from Allied hospital and Madinah teaching hospital Faisalabad. Sampling technique was purposive sampling to enroll patients. After enrolling participants were randomly allocated into two groups using lottery method. Total sample size was 38 with 19 participants in each group. Tinetti Performance oriented mobility assessment (POMA) was used as a data collection tool to assess balance while Timed Up and Go Test (TUG) and Figure of 8 Walk Test (F8WT) were used as a data collection tool to assess gait. Group A was the interventional group which received Coordinative locomotor training while

group B was the control group which received conventional physical therapy. Both groups received the treatment for 4 weeks with 3 sessions per week.

ELIGIBILITY CRITERIA

1.1 Inclusion criteria

- Age 35 to 60 years
- Both genders male and female
- Willing to participate in research
- Cancer patients of stage I-III (16)
- Receiving neurotoxic drugs (platinum based, taxanes based or both in combination) (17)
- Have received at least 4 cycles of chemotherapy treatment (18)
- Having numbness and tingling in distal areas
- At medium (19-24) to high (<19) risk of fall according to POMA
- Able to communicate in Punjabi/Urdu/English

1.2 Exclusion Criteria

- Any recent major surgery
- Unhealed lower extremity fracture
- Having diabetic neuropathy before getting chemotherapy drugs (16)
- Other neurological problems including brain cancer (17)
- Cardiovascular diseases (19)
- Bone metastasis (19)
- Lower limb lymphedema (19)
- Musculoskeletal problems (19)
- amputated limb
- with abnormal visual or auditory senses
- uncooperative patients

OUTCOMES

- Balance
- Gait

Data collection tools

Tinetti Performance Oriented Mobility Assessment (POMA)

Balance was assessed using performance-oriented mobility assessment (POMA), also known as Tinetti-test. There are other POMA variants also available, with alterations in the test's name and scoring methodology. The present study concentrates on the 16-item, 28-point version of the POMA. POMA is an objective scale consisting of two subsections balance and gait. Total POMA consists of 16 items where balance part has 9 items and Gait part has 7 items. The patient is asked to perform these items in both sections and each item is scored 0-1 or 2. Total POMA scale scores 28 where a score of less than 19 indicates high risk of fall, 19-24 indicates moderate risk of fall, and 25-28 indicates low risk of fall (20).

Timed Up and Go Test (TUG)

To evaluate the gait on straight path Timed Up and Go test was used. For TUG test patient is sitting on a chair with arms. A 3 meters distance from chair is marked with tape. Instruct the patient that on the word of ‘Go’ stand up from chair, walk upto the mark, turn around, walk back to the chair and walk a 3 meters distance return back to the chair. Patient can use any device for ambulation but will not be assisted by other person. Patient may stop during the test if required (21).

Figure of 8 Walk Test (F8WT)

To measure the patient's walking ability on a curved path Figure of 8 walk test (F8WT) was used. Two markers are set on the floor at 5 feet distance. Patient is asked to stand in the center of those markers then move in either clockwise direction or anti clockwise direction according to his choice around those markers in order to make the figure of 8 and return to his starting position. Time taken and no. of steps taken are recorded to complete this test (22).

MATERIAL USE

1. Material used for POMA

- Hard armless chair
- Stopwatch
- 15 ft walkway

2. Material used for TUG

- One chair with armrest
- Stop watch
- Tape to mark 3 meters

3. Material used for F8WT:

- 2 plastic cones/cups as markers
- Stopwatch
- Tape to measure 5 feet

GROUP A

Patients in this group received Coordinative locomotor training (CLT) in which sprinter and skater patterns were performed in three different positions which were supine, sitting and half standing. In supine position, the patient was either lying on the floor mat or on the couch with one foot supported against the wall. In sitting position patient was sitting on the edge of the couch while in standing position the patient's back was supported against the wall with one foot on the ground. In one session, a total of 3 sets (one set for each posture) with 10 repetitions of each sprinter and skater patterns were performed. First patients were asked to perform 5 repetitions of each sprinter and skater pattern alternatively with right foot supported then repeat the same process with left foot supported in each posture. Patients were asked to hold each sprinter and skater pattern for 10 seconds per repetition with the resting period of 10 seconds between each repetition. For the postural change 5 minutes of resting period was provided between sets (14). Total time taken to complete coordinative locomotor training was 30 minutes per session. This intervention was comprised of total 12 sessions that were applied 3 times per week for 4 weeks (12).

Figure 1. Coordinative Locomotor Training

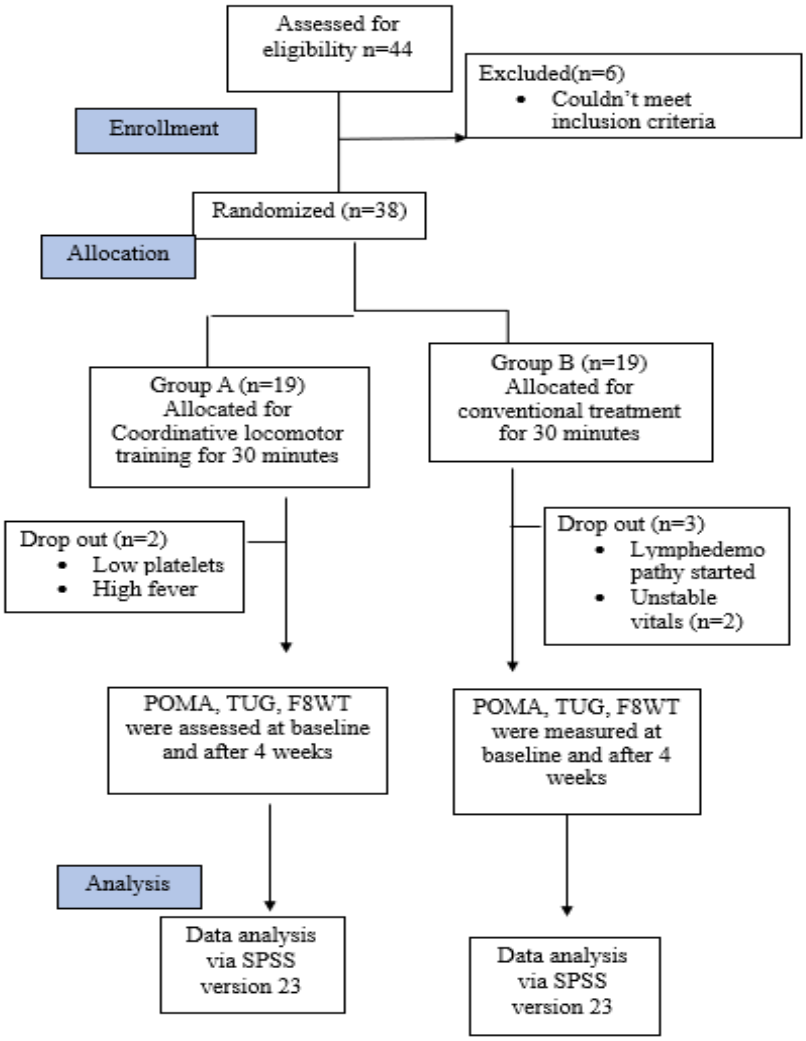
GROUP B

Group B received conventional training in which patients performed following exercises for 30 minutes (14).

1.Reaching out with hands crossed in sitting position
2.Sitting and getting up from chairs of various heights
3.Stepping forward, backward and sideways
4.Toe standing
5.Standing balanced and straight
6.Standing up from chair walk a certain distance and return to sit down
7.Climbing stairs

The intensity of these exercises was adjusted according to the patient's level. These exercises were performed for 3 times per week in 4 weeks (12).

CONSORT CHART



ETHICAL CONSIDERATIONS

A permission letter for data collection was obtained from The University of Faisalabad. Consent was taken from the head of department of physical therapy as well as from the head of oncology department before starting the data collection. Another consent form was signed by the patients or by their caregivers with the assurance that their data will be used for research purpose only. All patients participated in the research voluntarily without being pressurized or forced. Privacy and confidentiality of patients was preserved. Patients were informed about the intent of the research and

regarding the effects of the treatment, they were assured that it will cause no harm to them in any way.

Statistical analysis

For statistical analysis SPSS version 23 was used. Frequency tables, pie charts, bar charts were used for the demographics and descriptive. The Shapiro Wilk Test was conducted of all outcomes at baseline to check normality in data distribution because the sample size was less than 50. All of the p values were less than 0.05 which indicated that the data at baseline was not normally distributed thus non parametric tests were used for both within group and between groups comparison. Wilcoxon Signed Rank t test was used to determine the within group comparison of all outcome measures of both interventional and control groups separately while Mann-Whitney U test was used for a comparison of the differences between groups.

Results

Table 1. Descriptive Statistics of Age in Sample

	N	Minimum	Maximum	Mean± SD
age of the patient	38	36.00	60.00	47.0000±7.35215

Table 1 shows the descriptive statistics of age of all participants. Mean and standard deviation of age of patients was 47.00±7.35

Table 2. Frequency Distribution of Gender in Sample

Gender	Frequency	Percent
Male	5	13.2
Female	33	86.8
Total	38	100.0

The table 2 shows the frequency distribution of gender. Out of 38 patients 5(13.2%) were males and 33(86.8%) were females which indicated that the females' ratio was higher than the males in sample.

Table 3 Frequency Distribution of Cancer Stages in Sample

Stage	Frequency	Percent
Stage 1	3	7.9
Stage 2	20	52.6
Stage 3	15	39.5
Total	38	100.0

Table 3 shows that out of 38 patients, 3(7.9%) patients were in stage 1, 20 (52.6%) were in stage 2 and 15(39.5%) were in stage 3.

Table 4. Frequency Distribution of Chemotherapy Drugs in Sample

Drugs	Frequency	Percent
Platinum based	8	21.1
Taxane based	16	42.1
Combination of Platinum and Taxane	14	36.8
Total	38	100.0

Table 4 indicated that out of 38 patients in sample 8(21.1%) were receiving Platinum based drugs, 16(42.1) were receiving Taxanes based while 14(36.8%) were receiving both Platinum and Taxanes in combination.

As the sample size was less than 50 so the Shapiro wilk test was conducted to evaluate the normality in the data at the baseline of all outcome measures. the p value was less than 0.05 of all the outcome

measures it indicated that the data was not normally distributed. So non parametric tests i.e. Wilcoxon sign rank test and Mann-Whitney U test were performed to analyze the within group and between groups comparison of all outcome measures.

Table 5. Wilcoxon Sign Rank Test for POMA

Groups	POMA	N	Mean ± SD	P value
Group A	before treatment	19	18.4737±1.38918	.000
	after treatment	17	25.2941±.98518	
Group B	before treatment	19	18.0526±1.95714	.000
	after treatment	16	22.4375±1.63172	

Table 5 shows the mean and standard deviation of POMA of both groups. For group A, POMA mean score was 18.47±1.39 at pre-treatment that increased to 25.29±.99 post treatment due to the effect of Coordinative locomotor training. While for group B, POMA mean score was18.05±1.96 at pre-treatment that increased to 22.44±1.63 post treatment due to the effect of control intervention. The p value of Wilcoxon signed rank test for both groups was less than 0.05 which indicated that both treatments improved balance significantly.

Table 6. Wilcoxon Sign Rank Test for TUG

Groups	TUG	N	Mean ± SD	P value
Group A	before treatment	19	13.9226±1.01282	.000
	after treatment	17	9.8494±.57788	
Group B	before treatment	19	13.6874±1.31110	.000
	after treatment	16	10.4419±.83301	

Table 6 shows the mean and standard deviation of TUG score. For group A, TUG mean score was 13.92±1.01 at pre-treatment that decreased to 9.85±.58 post treatment due to the effect of Coordinative locomotor training. While for group B, TUG mean score was 13.69±1.31 at pre-treatment that decreased to 10.44±.83 post treatment due to the effect of control therapy. The p value of Wilcoxon signed rank test for both groups was less than 0.05 which indicated that both treatments improved the patient's gait significantly.

Table 7. Wilcoxon Sign Rank Test for F8WT (time)

Groups	F8WT (time)	N	Mean ± SD	P value
Group A	before treatment	19	13.0826±.99066	.000
	after treatment	17	11.0012±.98927	
Group B	before treatment	19	12.8495±1.32611	.000
	after treatment	16	12.0256±1.26365	

Table 7 shows the mean and standard deviation of time taken for F8WT. For group A, the mean time for F8WT was 13.09±.99 at pre-treatment that decreased to 11.00±.99 post treatment due to the effect of Coordinative locomotor training. While for group B, the mean of time taken for F8WT was 12.85±1.33 at pre-treatment that decreased to 12.03±1.26 post treatment due to effect of Control therapy. The p value of Wilcoxon signed rank test was less than 0.05 which indicated that both treatments had significant effect on time taken for F8WT.

Table 8. Wilcoxon Sign Rank Test for F8WT (steps)

Groups	F8WT (steps)	N	Mean ± SD	P value
Group A	before treatment	19	17.3158±.88523	.000
	after treatment	17	13.0588 ±1.02899	
Group B	before treatment	19	17.1053±1.59495	.000
	after treatment	16	14.5625±1.45917	

Table 8 shows the mean and standard deviation of steps taken for F8WT. For group A, the mean no. of steps for F8WT was 17.32±.89 at pre-treatment that decreased to 13.06±1.03 post treatment due to the effect of Coordinative locomotor training. While for group B, the mean no. of steps taken for F8WT was 17.11±1.59 at pre-treatment that decreased to 14.56±1.46 post treatment due to the effect of control therapy. The p value of Wilcoxon signed rank test was less than 0.05 which indicated that both treatments had significant effect on no. of steps taken for F8WT.

Table 9. Between groups comparison of POMA, TUG, F8WT

	Group	Mean ± SD	P value
Post POMA	Group A	25.2941±.98518	.000
	Group B	22.4375±1.63172	
Post TUG	Group A	9.8494±.57788	0.020
	Group B	10.4419±.83301	
Post F8WT (time)	Group A	11.0012±.98927	.016
	Group B	12.0256±1.26365	
Post F8WT (steps)	Group A	13.0588 ±1.02899	.002
	Group B	14.5625±1.45917	

The p value of Mann Whitney U test for all outcome measures was less than 0.05 which indicated that between both coordinative locomotor training and conventional physical therapy, coordinative locomotor training was more effective in improving balance and gait in chemotherapy induced peripheral neuropathy patients.

DISCUSSION

Chemotherapy induced peripheral neuropathy (CIPN) is one of the adverse effects of chemotherapy drugs. Usually, patients complain pain, tingling, and numbness at their fingers and toes at the beginning that spreads proximally to the arms and legs (23). It has been demonstrated that peripheral neuropathies cause pain, falls, gait deficits, and difficulties carrying out activities of daily living (ADLs) in a variety of populations, such as cancer patients (24), diabetics, and the elderly (25).

Coordinative locomotor training (CLT) is a non-invasive treatment that combines the PNF patterns with sprinter/skater coordination. CLT is a hands-on approach that certified specialists utilize as a tool to improve patient's balance, strength, mobility and to relieve pain. In sprinter and skater patterns the entire body gets engaged with one leg in the closed chain (one foot on the ground or on the wall) (11). This study was conducted to investigate the effectiveness of CLT on balance and gait in CIPN patients.

A previous study used Tinetti performance-oriented mobility assessment scale to assess the balance of chronic stroke patients (26). This current study also used this POMA scale as an outcome measure to assess balance in CIPN patients. A previous study used TUG test to assess the patients' gait (27). This recent study also used this test as an outcome measure to assess gait which was recorded in seconds for covering the 3 meters distance after getting up from a chair. A mean value was recorded after repeating the test three times. F8WT is a test that was used as an outcome measure in this current study to assess the patients' gait on a curved path. Values of time taken and number of steps taken to complete the figure of 8 were recorded. A previous study also supported this idea where F8WT was used to assess the gait in chronic stroke patients (14).

According to a study, out of 1,551 patients chosen from four different cities, 1094 (70.5%) patients were female indicating that the females are more prone to CIPN as compared to males (28). In this current study, majority of patients were also females 33 (86.8%) while the males were 5 (13.2%). In this recent study most of the patients with CIPN were at stage II-III. Out of 38 patients, 3(7.9%) patients were in stage 1, 20 (52.6%) were in stage 2 and 15(39.5%) were in stage 3. A previous study also supports this evidence which indicated that the majority of patients who reported the signs and symptoms of CIPN in breast cancer patients were at the stage of II-III (29). Out of 38 patients in

sample, 8(21.1%) patients were receiving Platinum based drugs, 16(42.1%) patients were receiving Taxanes based while 14(36.8%) patients were receiving both Platinum and Taxanes in combination. Previously a study was conducted by Alex Molassiotis which revealed that the patients receiving taxanes based chemotherapy were more prone to get CIPN as compared to those who were receiving platinum based chemotherapy (30)

The Shapiro Wilk Test was conducted of all outcomes at baseline to check normality in data distribution because the sample size was less than 50. All of these p values were less than 0.05 which indicated that the data of all these outcome measures at baseline was not normally distributed thus non parametric tests were used for both within group and between groups comparison.

A previous RCT based study conducted by Ko Hyo-Eun and Jeon Bo-Seon in 2017 indicated that the Coordinative Locomotor Training showed significant results in improving the balance in chronic stroke patients (14). The current study was in accordance with this previous study in which patients within group of Coordinative Locomotor Training showed significant results before and after intervention as the p value was less than 0.05. The balance in this group improved from baseline to 4 weeks as the POMA mean values improved from 18.47±1.39 to 25.29±.99 respectively. Another previous RCT also supported this current study which was conducted by HG Lee. This previous research observed the effect of coordinative locomotor training on dynamic balance of female students with patellofemoral pain syndrome. It indicated that this technique was effective in significantly improving dynamic balance of this population (31). Previously a single subject design study was conducted by Hwang, Jeong-Keun on cancer patients which indicated that coordinative locomotor training was effective in improving the balance of these patients which also retained in second baseline (15).

Along with balance, this current study indicated that the patients in Coordinative Locomotor Training group also showed greater improvement in the gait as the p values of Wilcoxon signed rank test for TUG and F8WT were less than 0.05. The mean values of TUG from baseline to 4 weeks changed from 13.92±1.01 to 9.85±.58 respectively which indicated that the time taken to cover the distance of 3 meters decreased hence the gait was improved. The results of this current study were in line with the previous study conducted in 2018 by JC Kim and JH Lim on chronic stroke patients which demonstrated that the Coordinative Locomotor Training was helpful in improving the gait of the chronic stroke patients (12). Previously a single subject design study was conducted to know the effect of coordinative locomotor training on gait and postural imbalance. This study concluded that Children's postural imbalance and gait seemed to improve with coordinative locomotor training (32). In current study, the mean values for time taken to complete F8WT changed from 13.08±.99 to 11±.99 of Coordinative Locomotor Training group from baseline to 4 weeks respectively. As the time reduced within group it showed that the patients' gait was significantly improved because the p value of Wilcoxon test was less than 0.05. Similarly, the mean value of number of steps taken to complete the F8WT changed from 17.32±.89 to 13.06±1.03 from baseline to 4 weeks respectively in the Coordinative Locomotor Training group which indicated that the number of steps were reduced eventually with the $p<0.05$. The reduced values of both time taken and number of steps taken indicated that the patients' gait was improved on a curved path. A previous study was in accordance to this current which demonstrated that the Coordinative Locomotor Training was helpful in improving the gait on curved path in chronic stroke patients (14).

In this current study, to determine which intervention was more effective for improving balance and gait as compared to the other one, a comparison of the differences between groups was done using Mann-Whitney U. All p values for Mann-Whitney U test of POMA, TUG and F8WT were less than 0.05 post intervention which indicated that Coordinative Locomotor Training was effective in improving balance and gait as compared to control therapy, hence alternate hypothesis was accepted. A previous study was conducted which compared the results of Coordinative locomotor Training and the same control intervention of this current study in chronic stroke patients. This previous study proved that coordinative locomotor training was more effective in improving balance and gait as compared to the control intervention (14).

The results of this study showed that both CLT and conventional physical therapy had significant effects on balance and gait but between groups comparison showed that the coordinative locomotor training was more effective as compared to the conventional physical therapy
Reliable scales were used to evaluate the patients in this study. Patients in both groups were treated equally without any discrimination from the researchers' side. Previously no study had evaluated the effects of coordinative locomotor training on balance and gait in chemotherapy induced peripheral neuropathy patients.

Limitations
The study was limited to a district level investigation, thus narrowing the target population. This study did not include the brain cancer as the tumor could invade the areas of brain that are responsible for balance control; hence would have interfered with results. Patients with bone metastasis were not included in this study as it causes the bone osteoporosis; hence increases the chances of fracture in such patients. The current study did not prolong for longer period of time, which could have reduced the results of experimental group.

Suggestions
In future more demographic features of patients should be included. It is suggested to increase the sample size of the patients therefore the outcomes can be achieved for the larger population and the research would be more generalized. Both techniques could be used in combination to achieve better results. As the literature availability on Coordinative Locomotor Training is limited so it is highly recommended to the other researchers to consider this approach as a treatment option in different populations for different outcomes as well.

CONCLUSION
It was concluded that both treatments were found effective in improving the balance and gait individually. Significant improvements were seen in both Coordinative Locomotor Training group and Conventional treatment group. However, the inter group comparison showed that the Coordinative Locomotor Training was more effective for all outcomes as compared to the Conventional treatment. These results will add to the knowledge and evidence in promoting the use of Coordinative Locomotor Training in treatment of balance and gait.

Conflict Of Interest
The authors declare no conflict of interest

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