### **ORIGINAL ARTICLE**

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# EFFECTS OF MODIFIED CONSTRAINT-INDUCED MOVEMENT THERAPY FOR LOWER LIMB ON MOTOR FUNCTION IN STROKE PATIENTS: A RANDOMIZED CONTROLLED STUDY

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# ABSTRACT

*Background:* Few studies have examined the effectiveness of modified constraint-induced movement therapy (mCIMT) for the paretic lower limb following stroke. This study aimed to investigate the effects of mCIMT on motor function of the lower limb in stroke patients.

*Methods:* A randomized, controlled study of 30 participants, who were randomized to 2 groups, was conducted. The study group received mCIMT, and the control group received neurodevelopmental therapy (NDT) for two weeks. All were evaluated for motor function through the Functional Ambulation Classification (FAC), Berg Balance Scale (BBS), 10-Meter Walk Test, gait parameters (cadence and step length ratio) and postural symmetry ratio at pretreatment and post-treatment, like two times.

*Results:* The improvements in BBS score, postural symmetry ratio, step length ratio, cadence and walking velocity had greater in the study group than the control group (P < 0.05). The improvement of FAC score was more pronounced in the study group (P = 0.005).

*Conclusion:* mCIMT for paretic lower limb had superior effect against the NDT to enhance the motor function (gait parameters, balance, ambulation, and symmetry) in patients with stroke. mCIMT may be used as a new alternative treatment for lower limb rehabilitation.

*Keywords:* Modified constraint-induced movement therapy, gait, balance, stroke, lower limb, neurodevelopmental therapy.

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#### **INTRODUCTION**

Stroke is one of the main causes of disability and mortality in the adult population in the developed World [1]. The loss of motor control, abnormal movement pattern, tone disorders, coordination difficulties, and sensory dysfunction of the lower extremities which arise post-stroke period reduces motor function [2, 3]. In spite of this, the patients experience to walk from the early period, but their walking pattern is slow, inefficient, unstable and incoordination. Consequently, Taub et al. (1999) reported that "learned misuse" develops for the lower limb function in stroke patients [4, 5].

Constraint-induced movement therapy (CIMT) or modified constraint-induced movement therapy (mCIMT) refers to a specific treatment for a motor disability that combines constraint of the movements in the nonparetic limb, intensive practice, and shaping of the behavior to improve the amount of use of the paretic limb during daily life activities [6]. The developed treatment for the paretic upper limb improves the use of the paretic limb functionally by overcoming the "learned disuse" that develops following stroke [7, 8]. Ro et al. (2006) have been shown the positive effects of CIMT on motor function of the upper limb and motor network in the brain after stroke [9]. Similarly, in recent years, mCIMT is also applied for the paretic lower limb to overcome "learned misuse" and increase the quality of motor function [10, 11]. Due to the bipedal ort h of lower limb activities, it is difficult to apply the constraint of movements in the nonparetic lower limb which is one of the main components of the CIMT. Therefore, the studies are controversial in the constraint. While some authors suggested that nonparetic limb restriction was the least important point for lower limb CIMT, with intensive practice and functional activities being noteworthy [12-14], the others used one partial restriction method in different way, such as the whole leg orthosis, the below-knee prosthesis, the addition of a shoe insert [15-17]. However, to our knowledge, the combination of the two different partial restriction method has not been used to increase the constraint of the nonparetic lower limb in the previous studies of mCIMT. Thus, this study targeted to examine whether mCIMT which applied the all main components of mCIMT without compromising from the original protocol was effective in improving the motor functioning of the lower limb in patients with stroke. We hypothesized that mCIMT program would lead to specific improvements in balance, gait and symmetry outcomes compared with the neurodevelopmental therapy (NDT).

#### **METHODS**

#### Study design and participants

This study was planned as a prospective, assessor-blind, randomized controlled study. The Hacettepe University Non-interventional Clinical Research Ethics Boards approved the study protocol of this study (approval no: GO 14/22-15). Between February 2014 and February 2015, 153 patients were screened for study eligibility, 33 patients of them were enrolled in the study as participants and 30 par-

Participants were included in this study if they had been diagnosed a single cerebrovascular accident in the cerebral hemisphere, as determined by computed tomography or magnetic resonance imaging; were > 18 age of years; were between 3 and 12 months post onset; exhibited mild to moderate disability according to lower extremity recovery stages (Brunnstrom recovery stages III-V); could participate an intensive rehabilitation programme that permitted by the physiatrist.

Patients were excluded if they had a recurring stroke, had medical comorbidities (e.g., unstable blood pressure, cardiac pacemaker), had an unstable medical condition (e.g., severe acute myocardial infarction), had cognitive impairment, additional neurological problems and orthopedic problems that are preventing participation to an intensive rehabilitation program. Thirty-three subjects were initially recruited ort he studies and randomly divided into two groups, a control group (n=15) and a study group (n=18). Two participants were excluded because of severe knee pain and having unstable blood pressure and one subject in the study group withdrew voluntarily from the study. Thirty participants completed the treatment.

The sample size for each group was determined to be 11 participants, based on another study whose design was similar to that of our study [18]. The Power Analysis and Sample Size software package (PASS 14) were used. The confidence level for statistical significance was set at 5% with power equal to 80%. An average effect size of 0.59 for the outcome measures was sustained. Although the calculated sample size for each group was 11 participants, at least 15 participants were included in each group due to dropout problem during the study.

#### Randomization

After the inclusion criteria were fulfilled and the participants signed the written informed consent form, the randomization was conducted using the block randomization procedure by a physiotherapist who was not involved in this study. The randomization was stratified based on age ( $\leq 60$  or > 60 years), gender (male or female), the hemiplegic side (left or right) and type of stroke (ischemic or hemorrhagic) because of balanced distribution of the participants according to important parameters which have known prognostic effects [19].

#### **Outcome measure**

All participants were evaluated by a physiotherapist who was blinded to their grouping. The participants were evaluated at pretreatment and posttreatment. Walking velocity was measured with "10-meter walk test" over 16 m, timed over the middle 10 m when the participant walked normally without a cane or with a cane at his/her comfortable walking speed. To eliminate acceleration and deceleration periods, patients started and ended their tests 3 m before and after the walkway. The time along this walkway was recorded in seconds with a stopwatch. The velocity was calculated in m/s [20]. This test has demonstrated excellent test-retest reliability (ICC = 0.95-0.99) [21], interrater reliability (ICC = 0.998) [22], and intrarater reliability (ICC=0.87 to 0.88) [23].

Cadence was measured by counting the step number in one minute and was recorded in steps/min [24].

Balance performance was assessed by the Berg Balance Scale (BBS). The BBS, a 14-item scale designed to measure balance in a clinical setting with a maximum score of 56 [25]. Each item is scored from 0 (cannot perform) to 4 (the best performance). In this scale, a score of 0–20 indicates that the subject has poor balance, a score of 21–40 means acceptable balance ability, and a score of 41–56 means advanced ability. The scale is considered to be a valid and reliable measurement of the balance control ability [26]. The ambulation was quantified by using the Functional Ambulation Classification (FAC), which has excellent test-retest reliability and interrater reliability [23]. The patients can be rated through the observation of the physiotherapist between 0 (cannot walk) and 5 (can walk independently anywhere) categories [27].

Step length asymmetry was determined by a step length ratio (SLR) which was defined paretic step length divided by non-paretic step length [28]. Step length was measured using the simple footprint method [29]. The footprint method is easy, inexpensive [30, 31] and the method is highly reliable both interrater and intrarater (ICC=0.92-1.00) [32]. The patient was seated on an armrest chair and was dusted both feet with the powder. Following, the patient walked at their self-selected walking speed over the dark floor. Measurement of the middle line 3 meters of the walkway was taken only to consider the normal pattern of gait and avoid the impact of the acceleration and deceleration. The feet prints were marked by a pen and a ruler between the heel and toe points. Step length was calculated as a linear distance on the midline between two successive contralateral center of the heel [33].

Postural symmetry ratio was calculated using the following equation (1) [34]:

$$\lim_{x \to 0} \frac{\text{weight on the nonparetic lower limb}}{\text{total body weight}} - 0.5 \lim_{x \to 0} |x \ 100\%^{(1)}$$

Load on the nonparetic lower limb was measured with two digital weighing scale (Scale-Sinbo, SBS-4421) while patients normally stood with one foot on each scale platform and arms hanging loosely by their sides [35]. During the assessment, the display screen of the scale was closed to avoid receiving feedback from the screen when the patient supposed to be standing with each leg equally loaded [36]. Then, the subject was positioned on the platform of the scale, and the entire body weight was recorded. The measurements were repeated three times. A percentage of 0 demonstrated equal weight bearing and best postural control in standing position, while a higher percentage demonstrated asymmetry and poor postural control [34].

### Intervention

Each program for two groups was executed by a physiotherapist, who was the first author and had eight years working experience in the neurologic rehabilitation field. mCIMT was conducted for the paretic lower limb in the study group for two weeks, per week five day and each session 120 minutes. CIMT included three main components: the intensive practice of the functional activities, limited use of the nonparetic lower limb and transferring the gains from the training session to the patient's real environment with "transfer package" [7]. The intensive practice was applied to the selection of the appropriate functional activities by the "shaping" principles by the feedback, coaching, modeling, and encouragement of the physiotherapist. The functional activities described in Table 1. Each of the functional activities was performed intensively by the paretic lower limb, unilaterally, over 20 minutes, repetitively. After each 20-minute activity period, a rest period of 5 minutes was given to the patients. The constraint of the nonparetic lower limb was known to be difficult because of the bilateral characteristics of lower limb function. Therefore, the constraint was fulfilled by a combination of 2 different methods; 1) immobilization of the knee of the nonparetic limb with a whole-leg orthosis and 2) use of a shoe insert on the nonparetic lower limb (Figure 1) [15, 36, 37]. This method may be increased the restriction of the nonparetic lower limb. The shoe insert had a 1 cm lift and 5° lateral wedge, and the whole-leg orthosis constrained the knee flexion at the fullest extension position. Training on the use of the orthosis and shoe insert was provided for patients and their relatives. The restriction was used during treatment sessions, including on the treadmill, and for 90% of the participants' waking hours. When the patient took off the orthosis, the range of motion exercises of the knee was asked to perform to prevent the contracture. The used functional activities during therapy session were set to home as a home program with transfer package, and the participants were strongly encouraged to incorporate the use of their paretic lower limb into their daily activities. The exercises in the training were personalized and adjusted during treatment to fulfill the specific needs of each as determined by the degree of impairment and endurance level. The session was immediately interrupted if the blood pressure and heart rate of participants were uncontrolled or the patient felt chest discomfort.

NDT program was applied for two weeks, per week five day and each session lasted 120 minutes in the control group. The program consisted several exercises that based on motor-learning principles (specificity, progressive overload, and variation). Functional exercises were chosen according to the participants' abilities and needings. NDT required continuous observation, evaluation, progression and modification of the program dealing with participants' progression. Exercises in NDT program were performed in different positions (supine, prone, sitting and standing) including weight-bearing exercises, balance activities and walking (Table 1).

Therapy	Aim	Exercises
NDT Supine position	<ul> <li>To maintain range of motion and length of muscle.</li> <li>To improve the strength of the trunk extensors, paretic hip and knee extensors</li> <li>To develop the weight bearing on paretic lower limb</li> </ul>	<ul> <li>Manuel static stretching of the hamstrings</li> <li>Rotation of the trunk</li> <li>Bridging</li> <li>Flexion and extension of the knee and hip</li> <li>Lowering the paretic lower limb from the bed with hip extension and knee flexion</li> <li>Pushing the wall with both limbs</li> </ul>
Prone position	<ul> <li>To improve muscle and joint conditions</li> <li>To break up synergistic movements pattern</li> </ul>	<ul> <li>Mobilization of the ankle joint and functional stretching of gastro-soleus.</li> <li>Extention of the hip with knee flexion</li> </ul>
Sitting position	<ul> <li>To develop the weight bearing on paretic lower limb</li> <li>To improve knee control</li> <li>To terminate the synergistic movements and start the selective movement</li> </ul>	<ul> <li>Weight bearing on the affected side</li> <li>Reaching with trunk rotation</li> <li>Standing from sitting position with weight bearing on the affected side</li> <li>Knee controlling in high sitting position with weight bearing</li> <li>Exercises of hip flexion and knee extension</li> <li>Dorsi flexion of the ankle</li> </ul>
Standing position	<ul> <li>To facilitate the walking</li> <li>To improve balance</li> <li>To improve the independence in activities of daily living.</li> <li>To facilitate the participation of the social life</li> </ul>	<ul> <li>Weight bearing to different directions</li> <li>Stepping to different directions</li> <li>Squatting</li> <li>Knee flexion and extension in a narrow range of motion</li> <li>Climbing stairs</li> <li>Rising on toe</li> <li>Standing on one leg</li> <li>Balance activities</li> </ul>
CIMT	<ul> <li>To facilitate the functional activities</li> <li>To increase the weight bearing on the paretic lower limb</li> <li>To improve balance</li> <li>To increase the sensorial input from the paretic lower limb</li> </ul>	<ul> <li>Sit to stand transfer by using a appropriate chair</li> <li>İndoor overground walking training (forward, backward, sidewards)</li> <li>Weight bearing activities to different directions</li> <li>Climbing up and down stairs and ramp</li> <li>Balance activities on the paretic lower limb</li> <li>Knee controling on a step</li> <li>Stepping over obstacles</li> <li>Working with a bicycle ergometer</li> <li>Walking training on the treadmill</li> </ul>

 Table 1: Details of the exercises in NDT and CIMT.

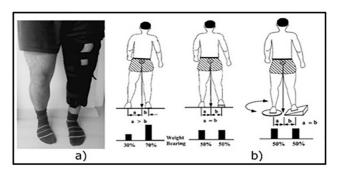


Figure 1: Constraint method of the nonparetic lower limb:

(a) Whole leg orthosis, (b) addition of a shoe insert in the shoe of the nonparetic lower limb. The shoe insert relatively changed the weight-bearing symmetry from the nonparetic lower limb to the paretic lower limb [15,37].

# Statistical Analysis

All statistical analyses were performed with SPSS 20.0 (IBM Corp, Chicago, IL, US). The variables were investigated using the Kolmogorov-Smirnov test to determine whether or not they were normally distributed. Descriptive analyses were performed and presented using means and standard deviations for results of the balance, gait parameters and symmetry; medians and interquartile range ort he FAC score. The paired t-test was used to compare the changes in the groups within the times. The improvements in the outcome measures were quantified by subtracting the pretreatment scores from the posttreatment scores. Then, Student's t-test was used to compare the differences in these changes between groups. Chi-square analysis was used to compare proportions. Values of p<0.05 were deemed statistically significantly different.

#### RESULTS

Figure 2 demonstrates the flow of the participants' enrollment throughout the study. A total of 30 participants included 16 females and 14 males with a mean age of 56.4  $\pm$ 13.45 and average time poststroke of 6.7  $\pm$  2.94 months. Participants were randomly assigned into the study (n = 15) or control group (n = 15). The clinical characteristics of the participants are summarised in Table 2. There were no significant differences between the groups at baseline, including demographic data and motor recovery of the lower extremity of Brunnstrom stages.

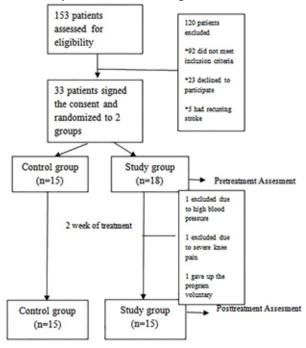


Figure 2: Study design and sample flowchart.
Table 2: Participant Characteristics.

	Study group	Control group	p <sup>a</sup>	p <sup>b</sup>
No. of subjects, n	15	15	1	1
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Age in years <sup>c</sup>	$55.13 \pm 14.70$	$57.67 \pm 12.20$	.61	
Poststroke months <sup>c</sup>	$6.80 \pm 2.70$	$6.63 \pm 3.18$	.88	
BMI in kg/m <sup>2c</sup>	$26.26 \pm 3.49$	29.71 ±7.56	.12	
Gender, n (%)				
Male	8 (53.3)	6 (40)		.46
Female	7 (46.7)	9 (60)		
Affected side, n (%)				
Left	10 (66.7)	10 (66.7)		1.0
Right	5 (33.3)	5 (33.3)		
Type of stroke, n (%)				
Ischemia	11 (73.3)	12 (80)		.66
Hemorrhage	4 (26.7)	3 (20)		
Brunnstrom reco-				
very stage, n (%)				
III	12 (80)	11 (73.3)		.66
IV	3 (20)	4 (26.7)		
V	-	-		

<sup>a</sup>Student's t test.

<sup>b</sup>Chi Square test.

<sup>c</sup>Values are given as mean ± standart deviation.

Each therapy methods significantly improved the Berg balance score, walking velocity, cadence and ratio of step length and postural symmetry. When the participants were generally at level 2 and three at pretreatment according to FAC, they developed functionally and progressed to level 4 and 5. Although the median score of FAC level remained at 3 in the control group and changed from 3 to 4 in the study group, the both improvement were meaningful (P < 0.001). Table 3 shows the effects of these therapies.

**Table 3:** Effects of a Modified Constraint Induced Movement Therapy and a Neurodevelopmental Therapy on Berg Balance Scale, Functional Ambulation Scale, Walking Velocity, Cadance, Step Length Ratio and Postural

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	Study group (n=15) p Control group (n=15)			р		
BBS <sup>a</sup>	Pretreat- ment 32.67± 9.64 (15-44)	Posttreat- ment 43.47 ± 7.60 (24-52)	<0.001	Pretreat- ment 34.13 ± 9.12 (11-45)	Posttreat- ment 39.80± 8.89 (20-53)	<0.001
FAC <sup>b</sup>	3 (2-4)	4 (2-5)	<0.001	3 (2-4)	3 (2-5)	<0.001
Walking velocity (m/s) <sup>a</sup>	$\begin{array}{c} 0.33 \pm 0.13 \\ (0.09 \text{-} 0.51) \end{array}$	0.44 ± 0.18 (0.11-0.69)	<0.001	0.34 ± 0.13 (0.13-0.56)	0.38 ± 0.15 (0.15-0.71)	<0.001
Cadence (step/min) <sup>a</sup>	64.33 ± 15.14 (36-91)	76.40 ± 16.83 (40-104)	<0.001	64.33 ± 12.48 (36-76)	69.87 ± 12.62 (40-82)	<0.001
Step length ratio <sup>a</sup>	1.50 ± 0.56 (0.93-2.56)	1.13 ± 0.29 0.72-1.73)	0.001	1.15 ± 0.45 (0.73-2.65)	1.07 ± 0.24 (0.72-1.66)	0.040
Postural symmetry ratio <sup>a</sup>	16.58 ± 5.07 (6.52-27.96)	7.15 ± 4.00 (1.36-15.35)	<0.001	13.60 ± 7.46 (2.77-33.37)	$\begin{array}{c} 10.28 \pm 6.40 \\ (0.34 \text{-} 26.39) \end{array}$	<0.001

Symmetry Ratio in Patients With Stroke.

Abbreviations: BBS, berg balance scale; FAC, functional ambulation classification.

<sup>a</sup>Values are given as mean ± standard deviation (minimum- maximum).

<sup>b</sup>Values are given as median (minimum- maximum). Bold values: p<0.05.

The comparison of the improvements on the motor function score among two groups are shown in Table 4. All motor function domains were found significantly greater improvement in the study group when compared with the control group. Motor function significantly improved the following scores: balance (net change of control group vs study group, respectively: 5.7 vs 10.8; P = 0.002), ambulation (0.40 vs 0.93; P = 0.005), walking velocity (0.04 vs 0.11; P = 0.010), cadance (5.5 vs 12.1; P < 0.001), step length ratio (-0.1 vs -0.4; P = 0.035) and postural symmetry ratio (3.3 vs 9.4; P < 0.001).

**Table 4:** Comparison of therapy effects on berg balance scale, functional ambulation scale, walking velocity, cadance, step length ratio and postural symmetry ratio between groups.<sup>a</sup>

		0 1			
Changes in motor func-	Study group (n=15)	Control group	95% confidence interval		p <sup>b</sup>
tion	(11-13)	(n=15)	Lower	Upper	
BBS	$10.80 \pm 4.54$	5.67 ± 3.39	2.14	8.13	0.002
FAC	$0.93 \pm 0.46$	$0.40 \pm 0.51$	0.17	0.89	0.005
Walking velo- city (m/s) Cadence	0.11 ± 0.08	0.04 ± 0.04	-0.02	0.12	0.010
(step/min)	12.07 ± 5.52	5.53 ± 3.23	3.15	9.91	< 0.001
Step length ratio Postural sym-	-0.37 ± 0.43	-0.08 ± 0.26	-0.55	-0.02	0.035
metry ratio	-9.43 ± 3.66	-3.32 ± 1.60	-8.27	-3.95	<0.001

**Abbreviations:** BBS, berg balance scale; FAC, functional ambulation classification; NDT: neurodevelopmental therapy; CIMT: constraint induced movement therapy; BMI:

#### body mass index.

<sup>a</sup>Values are given as mean ± standard deviation. <sup>b</sup> Student's t Test. Bold values: p<0.05.

# DISCUSSION

In this study, we investigated the effectiveness of the mCIMT versus NDT on the motor function of the paretic lower limb during stroke rehabilitation. These results suggest that mCIMT can be an efficacious rehabilitation method for patients with stroke. mCIMT increased the walking velocity, cadence, score of the BBS, and improved step length symmetry and postural symmetry significantly better when compared with NDT.

For the lower limb, the studies differ regarding the intensive practice period, the presence of the constraint, method of the constraint and duration of the constraint, because of these differences and any consensus on the CIMT protocol of paretic lower limb, the comparison of the studies are difficult [17]. Although Regnaux et al. (2002) and Bonnyaud et al. (2013) have used the same protocol for one session, 20 minutes, they have found different results [38, 39]. Corresponding with these studies, their constraint method or duration of their treatment can be considered to be inadequate. Hase et al. (2011) have used a below-knee prosthesis as the constraint method and applied CIMT techniques during three weeks, a 3-5 session in a day and each session lasted 5 minutes. They have shown that the stance phase of the paretic limb improved, but gait parameters did not change [16]. Wang et al. (2012) studied the comparison between the Bobath therapy and CIMT without the constraint of the non-paretic limb [40]. As a result of this study, they suggested that the walking velocity and the balance ability increased.

It is known that the loss of load perception in the paretic limb likely impacts the control of walking in stroke survivors [41], the present study has been applied two different constraint method together to increase this perception. One of this constraint method have been used by Rodriguez et al. (2002) found that the symmetrical weight bearing increased walking speed and step length [37]. Kallio et al. (2014) applied the other constraint method which is also used in this study., Numata et al., (2008) Marklund and Klassbo,(2006) and according to them the motor function, balance, walking and weight bearing ability improved significantly [17, 42, 36]. Similarly, with these studies, the present study showed also significant improvements in the walking velocity, cadence, balance ability, postural symmetry, step length symmetry and functional ambulation. It is known that the minimal clinically important difference in the walking velocity is 0.06 m/s [43]. Thus, the improvement observed in the study group suggest functional improvements in the walking velocity. Also, Perry et al. (1995) reported that ambulation ability had been correlated with walking velocity and they categorized the ambulation three subgroups [44]. According to this classification, while the participants in the study groups were more likely to be

household ambulators at pretreatment and progressed to limited community ambulators at the end of the treatment, the participants in the control group remained at the same household ambulators level. Because the walking velocity changed from 0.28 m/s to 0.44 m/s in the study group and from 0.28 m/s to 0.38 m/s in the control group. Similarly, with these results, the change of FAC level suggested the functional improvement and decreased the requirement of the assistance of the another people. As a result of functional improvements in FAC, while the study group progressed from level 3 to level 4, the control group was still at level 3. Moreover, Nakamura et al. (1988) demonstrated that the walking velocity was improved by increasing the cadence and step length [45]. The results of this study have also suggested Nakamura et al. because in the study group have meaningful changes in the walking velocity, cadence and nonparetic step length.

Berg balance scale was sensitive to change and had excellent test-retest reliability in stroke population [46]. The minimal clinical detectable change was found 4.66, and 6.9 in the different studies [46, 47]. The results of the present study also suggested that the change of the balance ability in both groups will be reflected the function. Nevertheless, the control group remained in the acceptable balance level. Also, while the BBS score in the study group increased from acceptable to good balance level, Berg et al. (1992) reported that this improvement (from 22 to 43.5) requires the using of walking assistance device in daily life to avoid the falling [48].

The gait after stroke is described by asymmetry and decreased weight bearing on the paretic limb [49]. The spasticity, muscle weakness, co-contraction and decreased the voluntary contribution of the central nervous system have not adequately explained the asymmetry [50]. The loading of the limb and the step length are thought to play a protecting role the gait symmetry [51]. The step length ratio is used to calculate the gait symmetry, and it is reported in the stroke population between 0.92 and 1.13 [51, 52]. If the ratio is 0, it is known that the paretic and nonparetic step length are equal. The present study observed that the step length ratio changed in favor of symmetry in both groups. The improvement of the ratio was significantly better in the mCIMT group, due to the increased the weight bearing on the paretic limb and lenghted the nonparetic step length.

Another original issue that is addressed in this study, postural asymmetry. The postural symmetry is one of the important determinants to achieve the goals of ambulation [37]. The increased percentage of the weight bearing on the paretic lower limb will develop the postural symmetry greatly and consequently the gait symmetry in the study group. We know that the loading of the paretic lower limb during CIMT organizes the extensor activity by sending feedback from Ib afferents to the central nervous system instance phase [53]. In particular, the increased limb loading in the late stance phase enhances the sensorial inputs which is received from plantar flexors via the Ib afferents and than allows the knee flexion by inhibiting the Quadriceps activity [54]. This mechanism also may lead to relatively declining the compensatory strategies in gait (e.g., stiff knee gait). We showed that mCIMT is effective to increase the weight bearing on a paretic limb that is one of the major problems to avoid the sufficient gait pattern. We are thinking of the developing of the gait symmetry constitutively by limb loading. Therefore, the primary goal of the rehabilitation to develop the gait symmetry should be to increase the weight bearing following a stroke.

The main strengths of this study are the randomized controlled study, and the comprehensive assessment of outcomes related to motor function (objective measures of gait, balance, symmetry, and ambulation level). Moreover, the present therapy was transferred into the patient's daily life outside of training session. The transferring the gains from the training session reinforced the motor learning. Lastly, two different constraint method was used firstly in the current study to increase the weight bearing on an affected lower limb and the representation area of the paretic limb. However, this study also has some limitations. First, despite the sample size calculation, the sample size was relatively small. Demonstration of these results is required with a larger sampling. Second, the results can only be generalized to patients who met the inclusion criteria. Third, the effect of the therapy is not clear whether arise from the constraint method. Therefore, further study would evaluate the efficacy of using different constraint settings in patients with stroke. Fourth, the physiotherapist was not blind to the application of the treatment program, but the assessor physiotherapist was blind to groups. We think that this factor may strengthen the study. In the present study, two different constraint method is used firstly, and their effect on the brain structure has not been reported. Therefore, further studies are needed to investigate whether this method causes the changes in brain structure.

#### CONCLUSION

mCIMT for lower limb greater improved the balance, gait performance, ambulation level and symmetry in patients with mild to moderate stroke when compared with NDT. The therapy program should practice for many patients with different stages of stroke (acute, subacute, chronic). Further studies of these effects in a long-term follow-up are needed to determine the effectiveness period.

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# **Declaration of Conflicting Interests**

The authors have no conflict of interest to declare of this article.

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