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5 **Efficacy of lower limb constraint-induced**  
6 **(CI) therapy for hemiplegia in stroke**  
7 **patients during the maintenance period**

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23 **ABSTRACT**

24 A lower extremity constraint-induced movement therapy protocol developed at the University  
25 of Alabama was used to treat three stroke patients suffering from hemiplegia. Upon  
26 intervention, both walking speed and stability improved, reliance on assistance from an  
27 accompanying individual or support device decreased, and both improvements to standing  
28 position during daily activities and walking activity were seen.

29

30 **KEYWORDS:**

31 Stroke, Rehabilitation, Lower Limb, Constraint-Induced Movement Therapy, Forced Use.

## 32 1. Introduction

33 Stroke is the leading cause of adult mortality in Japan [1] and the primary reason for  
34 healthcare provision [2]. Therefore, stroke rehabilitation has become necessary to reduce  
35 patient disability and improve social/physical function [3]. Many stroke patients experience  
36 hemiplegia and an associated sense of burden towards daily activities [4]. In particular, those  
37 with hemiplegia experience a decrease in lower limb function, poor walking balance, slower  
38 walking speed, increased energy expenditure, and increased risk of falls and fractures [5,6].  
39 Such loss of walking proficiency becomes an impediment to daily activities and social life [7,8],  
40 suggesting that recovery of walking ability is a priority for the majority of patients with  
41 hemiplegia [9,10]. One rehabilitation intervention following a stroke with a large amount of  
42 supporting evidence is constraint-induced movement therapy (CIMT) [11,12]. CIMT was first  
43 developed by Dr. Taub at the University of Alabama as a treatment for the upper limbs of  
44 adult patients with hemiplegia and has since been reported as effective for this aim [13-15].  
45 Functional recovery of paralyzed limbs by CIMT has been reported to be based on brain  
46 plasticity, as reflected in phenomena such as reorganizing neural circuits in the injured brain  
47 [16,17]. Later, a pediatric CIMT protocol was developed as well [18,19], and in 2015, a  
48 protocol for the lower limbs (LE-CIMT) was developed at the University of Alabama. The  
49 LE-CIMT protocol differs slightly from the upper limb and pediatric protocols. One upper  
50 limb hemiplegia CIMT protocol involves “multiple methods for promoting the use of  
51 paralyzed hands” by binding the unaffected hand in a mitten. However, LE-CIMT consists in  
52 applying a load or promoting various exercises for the affected leg rather than binding the  
53 unaffected leg. This is because the patient can walk with both legs prior to starting the  
54 treatment. Ultimately, the intervention increases the use of the affected limb. A few studies  
55 have indicated the effectiveness of LE-CIMT, but most involve binding the unaffected leg by  
56 some apparatus [18-20]. Moreover, an original lower limb CI therapy protocol involving  
57 task-specific instruction that utilizes shaping by a Lower Extremity Motor Activity Log  
58 (LE-MAL) to promote incremental functional improvement has been proposed, and there are  
59 reports on the success of this approach with respect to functional recovery and increase in the  
60 load-bearing ability of the affected leg. Original LE-CIMT includes giving homework to  
61 patients in the form of trying to use the affected leg more while increasing the average  
62 load-bearing capacity of both legs. Therefore, this method is expected to increase the use of  
63 the affected leg through intrinsic motivation and habit formation. This study tests original  
64 LE-CIMT in terms of walking speed, walking endurance, standing position during daily  
65 activities, improvements to walking activity, and the development of habits that increase the  
66 use of the affected leg.

68 **2. Method**

69 Target participants included stroke patients with hemiplegia who attended a clinic at which  
70 the first author worked part-time. Participants were recruited based on the following entry  
71 criteria: ① stroke patients with hemiplegia who experienced the onset of symptoms at least  
72 one year prior; ② ability to walk at least 10 m without the aid of a cane; ③ normal  
73 cognitive function (Mini-Mental State Examination score of 24 or higher); ④ no pain when  
74 performing daily activities that require a walking or standing position; ⑤ no botox injection  
75 or baclofen administration in the past two months; ⑥ presence of an accompanying  
76 individual available during the 2-week program.

77 Of the five individuals recruited, three met the selection criteria. The study was explained to  
78 these selected individuals, and informed consent was obtained before program participation.  
79 Table 1 presents the participants' demographic information.  
80

81 **TABLE 1: Demographic Information of Participants**

| Participant | Age, y, mo | Gender | Involved side | TUG  |
|-------------|------------|--------|---------------|------|
| A           | 52         | M      | L             | 31.5 |
| B           | 50         | M      | L             | 19.7 |
| C           | 62         | F      | R             | 16.6 |

82 F, female; TUG, Timed Up and Go; L, left; M, male; R, right.  
83

84 The LE-CIMT program lasted 2 weeks and the protocol consisted of the following five items:

- 85 ① Motor Activity Log-Lower Extremity (LE-MAL) management
- 86 ② Home Diary (HD)
- 87 ③ Behavioral Contract-LE (LE-BC)
- 88 ④ Home Skill Assignment-LE (HSA-LE)
- 89 ⑤ For training in the walking/standing position, lower limb task practice (TP) and  
90 shaping were followed by self-practice (Task Practice After, TPA) following the end of  
91 the program.

92 A therapist performed the following interventions daily at the clinic on weekdays during the  
93 program period:

- 94 ① Evaluation of LE-MAL
- 95 ② HD Check (check that the LE-BC is being followed)
- 96 ③ 10-item HSA-LE homework instructions
- 97 ④ Training by shaping and TP (attending clinic training along with a family member or  
98 caregiver, receiving practical instruction on assisted training methods from the therapist,  
99 and achieving the ability to perform accompanied at-home training)

100 LE-MAL evaluation considered 14 key activities representative of walking and standing  
101 during daily activities. This score was evaluated on three assistance scale items and other  
102 Functional Performance and Confidence items. The Personal Assistance Scale, among other

103 assistance scales, evaluated how much assistance the accompanying individual provided  
104 during a topic performance on a 10-point scale. The Orthotic Scale evaluates assistive devices  
105 used to perform tasks. A full score of 10 points is assigned if no devices were used. Accordingly,  
106 the score decreases with greater use of the assistive device. The Assistive Device Scale  
107 involves assigning 10 points if no walker or cane is used. Otherwise, the score decreases with  
108 greater use of an assistive device. The assistance scale was scored by taking the average of  
109 the Personal Assistance Scale and Orthotic Scale scores and adding the value to the Personal  
110 Assistance Scale score. The resulting number was divided by 2, and the result was taken as  
111 the evaluation score. Functional performance was subjectively scored with 10 points if the  
112 participant had a sense of normal ability. If the participant felt entirely incapable of  
113 performance, a score of 0 was given. Confidence was evaluated on a 10-point scale and  
114 considered how confident participants were in their ability to walk without falling. In other  
115 words, the LE-MAL score, which primarily involves standing and walking, would be  
116 evaluated by the ability to perform without reliance on an accompanying individual,  
117 equipment, or assistive devices. Participants who felt that they could move normally and  
118 confidently without falling earned more points.

119 HD is a journal that tracks the participants' agreed-upon LE-BC activities and activities  
120 involving the use of the hemiplegic lower limb during walking and other activities. The  
121 therapist checks the HD to determine whether or not LE-BC activities are performed. This  
122 HD serves to heighten the participants' awareness of how they use their hemiplegic lower  
123 limbs.

124 LE-BC was conducted on the first day (Monday) of each week and lasted for the target  
125 duration of that week. LE-BC involved a discussion between the participant and therapist  
126 wherein whether or not the daily walking/standing activities (moving around the house,  
127 going up and down stairs/elevations, housework, hobbies, walking outdoors, etc.) could be  
128 performed independently, with assistance, or not at all. Activities were divided into these  
129 three categories following discussion, and the therapist would read the terms of the written  
130 agreement to the participant. The participant would then sign the document if they were  
131 determined to follow the contract accordingly.

132 HSA-LE instructs the participant to do their homework of using their hemiplegic lower limb  
133 10 times daily. HSA-LE is useful in promoting the use of the hemiplegic lower limb outside  
134 the clinic, which is checked daily following LE-MAL management.

135 The evaluation took place one month before the intervention, the first day of the intervention,  
136 one week following the end of the intervention, and every six months after the intervention  
137 and included a 10-Meter Walk Test (MWT), the Timed Up and Go Test (TUG), and the  
138 evaluation of LE-MAL.

139 The direct intervention was provided during occupational therapy clinic visits in the morning,  
140 lasting 3 hours.

141 **3. Results.**

142 All 3 participants completed the 2-week program and were present for the 6-month follow-up  
 143 evaluation. Evaluation results are summarized in Table 2. TUG was initially of a mean  
 144 duration of 22.5 seconds ( $\pm 7.6$ ) and was reduced to 15.8 seconds ( $\pm 3.3$ ) after intervention for  
 145 an Effect Size improvement of 1.6. LE-MAL was initially a mean sore of 2.7 ( $\pm 0.7$ ) and was  
 146 increased to 4.7 ( $\pm 0.9$ ) for an exceedingly large observed Effect Size of 2.3. 10MWT lasted a  
 147 mean time of 20.6 seconds ( $\pm 6.0$ ) before intervention and improved to 13.0 seconds ( $\pm 2.3$ )  
 148 following intervention for an Effect Size of 1.7.

149  
 150 Table 2: Results 1 month prior to LE-CIMT, pre-intervention, post-intervention, and 6  
 151 months following LE-CIMT intervention

|             | TUG  |      |      |      | LE-MAL |     |      |     | 10MWT(sec) |      |      |      |
|-------------|------|------|------|------|--------|-----|------|-----|------------|------|------|------|
|             | BL   | pre  | post | 6M   | BL     | pre | post | 6M  | BL         | pre  | post | 6M   |
| case A      | 31.5 | 31.1 | 19.2 | 20.9 | 2.2    | 2.1 | 4.5  | 3.9 | 27.6       | 27.3 | 15.5 | 17.3 |
| case B      | 19.7 | 19.5 | 15.7 | 16.8 | 2.8    | 2.6 | 3.9  | 3.5 | 18.4       | 18.7 | 12.7 | 14.8 |
| case C      | 16.6 | 16.8 | 12.6 | 13.5 | 3.3    | 3.4 | 5.6  | 5.1 | 16.1       | 15.8 | 10.9 | 11.7 |
| Effect size | 1.3  |      |      |      | 0.9    |     |      |     | 1.7        |      |      |      |

152 NOTE: TUG; Timed Up & Go Test, Lower Extremity Motor Activity Log; LE-MAL. 10MWT;  
 153 10-Meter Walk Test, Effect size represents the value between pre and post.

154

155 1) Shaping Tasks Used in This Program

156 Case A: Cone step-over, rotational kicking of the target, foot slides, ankle dorsiflexion in  
 157 standing, side-stepping on the treadmill to the right, stepping to the Xs with less involved LE,  
 158 Swiss ball squats, and other activities

159 Case B: 20 m tandem walk, walking and stepping over objects, theraband dorsiflexion, seated  
 160 march, terminal knee extension, mini squat in parallel bars, and other activities

161 Case C: Supine ankle pumps, self-sway, heel lifts in standing, marching in place, walking  
 162 backward on the treadmill, foot slides, ring transfer, and marble transfer with toes

163 2) Home Skill Assignment Homework

164 Case A: Wipe the table, cross at the railroad crossing, walk on the sidewalk, overcome park  
 165 elevation differences, cross-step, cross at the crosswalk, walk down a narrow alley, wipe the  
 166 windows, water the plants, and go shopping at a department store.

167 Case B: Wipe window glass, cook standing up, move laterally in the restroom, walk to a  
 168 friend's house, pass the bicycle parking lot, pass the crosswalk, step back and forth, and shop  
 169 at the supermarket.

170 Case C: Wipe the table, wipe the windows, go up and down the inside stairs, go up three  
 171 elevated areas outside the house, ride the escalator, and cross the 4-way crosswalk.

172 3) Behavioral Contract: Details of the Agreement

173 Activities are classified as "independent activities" to be performed without accompaniment,  
 174 "accompanied tasks" to be performed with another individual, and "prohibited" tasks not to  
 175 be performed. When performing the agreed-upon tasks, an adequate amount of load is to be

176 placed on the paralyzed leg.

177 Case A: Independent, walk three blocks around the house and walk 50 m down the sidewalk;

178 accompanied tasks, go up the elevated areas around the house and wipe the windows;

179 prohibited, walk up/down the stairs at home without using the handrail.

180 Case B: Independent, walk four blocks around the house; accompanied tasks, walk on the

181 sidewalk and use all stairs and elevated areas; prohibited, bathing tasks.

182 Case C: Independent, walk four blocks around the house and walk on the sidewalk;

183 accompanied tasks, surpass elevation changes; prohibited, going up and down stairs.

## 184 **4. Discussion**

185 A LE-CIMT protocol developed at the University of Alabama was used to treat three stroke  
186 patients suffering from hemiplegia. Upon intervention, walking speed and stability improved,  
187 reliance on assistance from an accompanying individual or support device decreased, and  
188 improvements to standing position during daily activities and walking activity were observed.  
189 Previous studies on LE-CIMT have described a training regimen focused on center of mass,  
190 balance, treadmill walking, and other training exercises meant to recover motor function.  
191 However, these studies did not employ shaping with training regimens<sup>20-24</sup>. Marklund and  
192 colleagues evaluated LE-CIMT using TUG in a manner similar to the present study. However,  
193 the effect size was 0.6, whereas, in the present study, it had a larger value of 1.3. The effect  
194 size on standing position and mobility during daily activities, as evaluated by LE-MAL before  
195 and after the intervention, improved to a larger value of 2.3. David and colleagues cited  
196 activity-based therapies (ABTs) as the most effective intervention modality for  
197 neurorehabilitation<sup>25</sup>. Recovery of motor function in patients with hemiplegia returns to  
198 baseline following the conclusion of intervention when a training-focused program is used,  
199 which is why it is essential to introduce lifestyle activities that utilize the affected upper and  
200 lower limbs. Such habit formation promotes the long-term recovery of upper/lower limbs  
201 suffering from hemiplegia. This study involved the implementation of LE-CIMT, a protocol  
202 developed under the principle of long-term recovery. Even six months following the  
203 intervention, LE-MAL, as measured by 10MWT and TUG, was comparatively maintained.  
204 This suggests that interventions based on ABTs can produce long-term, sustained  
205 improvement.

206 **5. Summury**

207 In order to validate the efficacy of LE-CIMT developed at the University of Alabama, we  
208 performed original CIMT in treating three stroke patients suffering from hemiplegia. The  
209 results showed an effect size improvement of 1.6 for TUG mean duration, LE-MAL a very  
210 large effect size improvement of 2.3, and 10MWT an effect size improvement of 1.7.



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215 **COMPETING INTERESTS:**

216 None declared.

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