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Verification of the Effectiveness of Lower Extremity Constraint-Induced Movement Therapy Performed on Patients with Post-Stroke Hemiplegia in Maintenance Phase under Spasticity Treatment on Musculus Triceps Surae

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1. INTRODUCTION

Stroke is a cerebrovascular disease accompanied by ischemic or hemorrhagic injury in brain tissue [1]. Many patients who have experienced stroke exhibit hemiplegic symptoms [2], having difficulties in performing activities of daily life (ADL) [3]. These patients often experience degradation in walking balance capability, walking speed, and other relevant abilities required in ADL because of the motility disturbance resulting from hemiplegia [4,5]. Walking ability degradation in patients with hemiplegia makes some movements required in ADL or social activities challenging for them [6,7]. In this sense, improving patients' walking ability is the issue with the highest priority in rehabilitation support [8]. Patients with hemiplegia often exhibit a tendency to habituate themselves not to use paralytic-side extremities, a symptom also known as learned non-use, reported to induce additional degradation in motor functions [9-11]. Constraint-induced Movement Therapy (CIMT) was developed, based on behavioral neurology research findings, with the aim of overcoming learned non-use and improving motor functions [12,13]. CIMT was initially developed by Dr. Taub of the University of Alabama for the treatment of upper extremities of adult patients with hemiplegia, and several studies reported its efficacy [14-16]. Studies of CIMT for the lower extremities of patients with post-stroke hemiplegia have been conducted since the 2000s, though their protocols differ. Many of these studies focus on the intensive training of paralytic-side lower extremities by putting weight on the patient's leg joint, such as fixing extremities of non-paralytic-side using splints [17-23]. The protocol of the CIMT for lower extremity (LE-CIMT) was developed at the University of

Alabama in 2015. This particular protocol contains a repetitive, concentrated, and task-oriented practice program aimed to enhance the trainee's motivation from behavioral psychology perspectives, including those similar to the protocol for the CIMT for upper extremities, such as Motor Activity Log (MAL), Behavioral Contract (BC), and Shaping. In addition, the practice program was modified to the one applicable for the training of walking or activities performed in standing posture. The contents of MAL for the lower extremity are organized to manage supporting the trainee to conduct activities in standing posture and walking without the help of personal assistance or orthotic/assistive devices, called lower extremity motor activity log (LE-MAL). Regarding the contents of BC for lower extremities (LE-BC), the relevant activities are divided into three categories, and the concerned parties are supposed to sign the contract in terms of activities performed alone, conducted with a helper's assistance, and prohibited to perform. The second and third authors of this paper previously reported that their approach, which included the LE-CIMT program following the abovementioned protocols, was successful in improving motor functions in participants' paralytic-side lower extremities, which resulted in reducing the requirement of staffing and assistance in handling rehabilitation apparatus [24]. The restriction in the motion range of dorsiflexion often poses problems in the LE-CIMT program; thus, the program implementation can be challenging for patients with hemiplegia who have dorsiflexion motion range restriction at the knot of the ankle joint. Many studies reported that motion range restriction in the ankle joint of patients with hemiplegia inhibits normal gait [25-27]. Therefore, LE-CIMT should be implemented while improving the particular motion range restriction. As a study reported that improving motion range restriction in the ankle joint of patients with hemiplegia contributed to improving their walking speed and balance [28], LE-CIMT using a spasm-reducing device (Piston Device for Foot: PDF) was conducted on six patients with post-stroke hemiplegia in this study. Notably, the study aimed to conduct LE-CIMT using PDF to verify its efficacy.

2. METHOD

The program recruit notice was sent to 162 patients with hemiplegia who belong to stroke patient associations in Japan, and those who satisfied the following criteria were selected.

1. Those with hemiplegia and more than 12 months had passed since the stroke.
2. Those who are able to walk 10m and longer using a walking stick without someone's assistance.
3. Those with less than +5 degree restriction in the passive range of motion in ankle joint dorsiflexion on the paralytic side.
4. Those with accompanying persons during the two-week program period.

The following exclusion criteria were also set.

1. Those without Botox injection or baclofen administration in the past two months.
2. Those who are currently employed and unable to spare free time during the day.
3. Those who are confirmed with degradation in cognitive functions (scored less than 24 in the Mini-Mental State Examination).

Among ten applicants, six had satisfied the selection criteria and received an explanation regarding the purpose of this study in detail, and their written consent was obtained before program participation. Table 1 shows the

participants' attributes. The study was conducted by following the protocol approved by the Research Ethics Committee of Shonan University of Medical Sciences (Approval Number: 21035).

The LE-CIMT program was conducted for two weeks, and the protocol consisted of the following four items.

1) Motor Activity Log-Lower Extremity (LE-MAL) management

2) Home Diary (HD)

3) Behavioral Contract-LE (LE-BC)

4) Home Skill Assignment-LE (HSA-LE)

A therapist performed the following interventions daily at the clinic on weekdays during the program period.

1) Evaluation of LE-MAL

2) HD Check (check that the LE-BC is being followed)

3) 10-item HSA-LE homework instructions

4) Training by shaping and TP

5) 10-minute spasm-reduction treatment using PDF at the arrival to the clinic and every hour after the arrival (see Fig. 1 [29]).

The participants received direct intervention by therapists at the clinic for three hours every weekday morning. They returned home in the afternoon to perform the assignment regarding activities in standing posture and walking repeatedly, according to BC. The degree of assistance they received in 14 activities in MAL was asked in advance, and the participants were instructed to perform these activities without assistance, as much as possible, consciously.

3. RESULTS

All six participants completed the two-week program and participated in the follow-up evaluations conducted in one week and six months after the program. The participants all complied with BC and performed assignments. The evaluation results are shown in Table 2 and Fig. 2. All comparative results regarding the 10-meter walking test (10MWT), Timed up and Go test (TUG), and LE-MAL indicated differences of less than 1% significance between pre-and post-intervention and pre-intervention and six-month follow-up.

4. DISCUSSION

In this study, six patients with post-stroke hemiplegia received spasm-reduction treatment using PDF four times a day on the paralytic-side musculus triceps surae in addition to the original protocols of LE-MICT to examine the efficacy of modified LE-MICT. The results indicated significant improvement in all tests of 10MWT, TUG, and LE-MAL between pre-and post-intervention and pre-intervention and follow-up.

The minimal detectable change in 10MWT at a comfortable walking speed was 2.83 seconds [30], indicating a clinically significant improvement. In addition, the minimal detectable change in TUG was 2.1 seconds, also indicating a clinically significant improvement [31]. These results demonstrated that the program intervention improved recipients' walking speed and balance, thereby reducing their dependency on helpers or assistive devices.

Moreover, it is significant that the intervention effect endured for six months after the treatment. CIMT was originally developed to overcome learned non-use in paralytic-side extremities by habituating the recipients to use them positively in their daily lives; the program conducted in this study achieved the initial goal of CIMT. The spasm-reduction treatment introduced in this study on paralytic-side musculus triceps surae probably contributed to improving the range of motion in ankle joint dorsiflexion, which could result in improving various movements closer to normal operation. We believe that the approach employed in this study on musculus triceps surae improved the participants' performance in actions in standing posture and walking ability. During gait, the dorsiflexion of the ankle joint is known to rotate the tibia forward against the ankle and the body to move forward [32, 33]. However, the restriction in the dorsiflexion motion range in the ankle joint causes irregular pelvis movement [34] and reduces the gait distance [35], thereby degrading the forward propulsion [36]. The outcome of LE-CIMT in this study was favorable, probably because the program overcame these problems in the process. The LE-CIMT intervention introducing spasm-reduction treatment using PDF in this study suggested its potential for long-term and sustainable improvement. However, this study has a limitation regarding the sample size, which was insufficient. Further investigation should also be necessary for efficacy evaluation regarding each treatment component by employing a treatment package of multiple therapies, such as adding spasm-reduction therapy to CIMT.

5. CONCLUSION

The LE-CIMT program introducing spasm-reduction therapy using PDF on paralytic-side musculus triceps surae, in addition to the original protocols of LE-CIMT, was conducted on six patients with post-stroke hemiplegia in their maintenance phase, who exhibited the dorsiflexion motion range restriction in the ankle joint. The results indicated significant improvements in all tests of 10MWT, TUG, and LE-MAL between pre-and post-intervention and pre-intervention and follow-up.

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Fig. 1. How to use Piston Device for Foot?

Quickly flexing and extending the joints reduces spasticity. Previous research has shown that an effective speed is 5 times per second or more [29].

Table 1. Demographic Information of Participants

Participant	Age, y	Gender	Involved side	TUG
A	63	M	L	12.1
B	58	M	L	11.6
C	54	M	R	13.2
D	48	F	L	10.7
E	42	F	R	14.0
F	32	F	R	13.8

Table 2. Results one month prior to LE-CIMT, preintervention, postintervention, and six months following LE-CIMT intervention

Item	Period	A	B	C	D	E	F
10MWT (sec)	BL	14.2	15.6	12.6	14.8	16.2	13.8
	Pre	14.4	15.7	12.4	14.6	16.0	13.5
	Post	10.1	11.8	9.2	9.8	12.1	9.4
	3M	12.2	12.3	10.1	10.4	12.8	10.3
TUG	BL	12.1	11.6	13.2	10.7	14	13.8
	Pre	11.9	11.7	12.9	10.8	14.2	13.5
	Post	8.8	7.9	7.1	6.7	11.3	9.4
	3M	9.1	8.2	8.0	7.4	11.2	10.2
LE-MAL	BL	6.6	6.7	7.2	6.8	8.8	8.3
	Pre	6.6	6.7	7.2	6.8	8.8	8.3
	Post	8.7	9.4	9.5	9.8	9.6	9.5
	3M	8.5	9.2	9.4	9.8	9.7	9.8

Note: 10MWT, 10-Meter Walk Test; TUG, Timed Up and Go Test; LE-MAL, Lower Extremity Motor Activity Log.

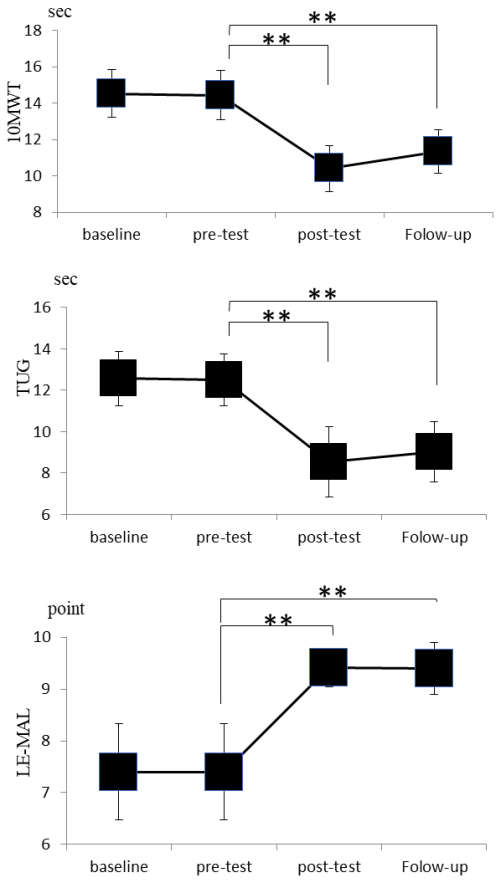

Fig. 2. Significant differences were observed in the 10MWT, TUG test, and LE-MAL before and after the intervention, and between the pre-test and Follow-up.

** represents a significant difference with a significance level of less than 1%