

Constraint-induced movement therapy for lower extremity use in activities of daily living in people with chronic hemiparesis: multiple case study

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Lower extremity constraint-induced movement therapy (LE-CIMT) is an intensive intervention protocol recently reported to improve lower extremity use in individuals with chronic hemiparesis. To test if the LE-CIMT that uses essential CIMT components, including the transfer package and intensive task-oriented training, is a feasible and potentially effective intervention to improve the lower extremity real-world use and functional ability in a group of individuals with chronic hemiparesis. A quasi-experimental pre- and post-test design study with 12 individuals with chronic stroke and impaired ambulation skills engaged in a 10-weekday LE-CIMT. Intervention feasibility was assessed, examining the training adherence, acceptability, and safety. The lower extremity motor activity log (LE-MAL), lower extremity motor function test (LE-MFT), timed up and go (TUG) and spatiotemporal gait parameters were used as clinical outcomes. Clinical data were collected at baseline, 3-day post-CIMT protocol and 30-day follow-up assessment. At baseline, LE-MAL and LE-MFT outcomes were tested over 2-week apart to ensure a stable measurement and determine the smallest real difference (SRD) in the study sample. The LE-CIMT

showed excellent adherence, acceptability and safety. Ten out of 12 participants showed improvements over SRD in LE-MAL composite score (1.2 point) and eight participants in LE-MFT adjusted scores (0.8 point) in post-CIMT and 30-day follow-ups. LE-CIMT is a feasible intervention that has the potential to promote improvements in real-world use and functional ability of the paretic lower extremity in individuals with chronic stroke. *International Journal of Rehabilitation Research* 45: 215–222 Copyright © 2022 Wolters Kluwer Health, Inc. All rights reserved.

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Introduction

The lower extremity constraint-induced movement therapy (LE-CIMT) is an intensive intervention recently well-reported based on the modification of the original CIMT for upper extremity [1]. Considering that most activities performed with the lower extremity are essentially bilateral, the upper extremity restraint device is not applied in the LE-CIMT. At the same time, the intensive task-oriented training based on shaping principles and the transfer packages are still essential components of the CIMT intervention. Then, the recently reported LE-CIMT differs from other intensive training protocols [2–7] by the application of the shaping method for delivering the motor training, and for the administration of the behavioral transfer package for improving the lower extremity use in the real-life situation; that is the real-world lower extremity use. Shaping is a strategy that combines both approaching a target movement in small steps and incrementally increasing the complexity of a task as the participant's performance improves. Shaping activities in the LE-CIMT protocol also include the involvement of the less-affected lower extremity. The

transfer package assures continued use of the function being treated during unsupervised periods of LE-CIMT. The participant is actively involved in this through procedures involving self-monitoring and problem-solving with the therapist [1,8].

The application of the LE-CIMT in a single case of an individual with chronic hemiparesis [9] showed promising results. Therefore, more research into the intervention feasibility in a group of individuals from this population is required to strengthen the applicability of the LE-CIMT and justify a randomized clinical trial. Additionally, previous studies that applied intensive lower extremity training such as LE-CIMT do not use all the essential components of the intervention. This represents a misunderstanding that promotes discrepancies in the intervention results among lower extremity intensive interventions without the standardized elements as suggested in the description of the intervention protocol [1].

This study evaluates the adherence, acceptability, safety, changes in the lower extremity real-world use

and function, and gait parameters after applying the LE-CIMT protocol in individuals with chronic hemiparesis after stroke.

Methods

Participants

A convenience sample of 12 individuals (eight men), age, in average, 55 (± 16) years old, were included if (1) had a diagnosis of one, first-ever stroke; (2) had a chronic stroke (>6 mo); (3) scored ≤ 5.0 on lower extremity motor activity log (LE-MAL) [10]; (4) were able to walk at least 8 meters, three times/day with or without an assistive device and without the aid of another person and (5) were capable of following the examiner's instructions. The study was approved by the institutional Ethics Committee (Prot. Number 1380951/2019). The lower extremity Fugl Meyer scale and mini-mental state exam scores characterize the sample. Clinical and demographic data are described in Table 1.

Design

Quasi-experimental research was conducted to provide evidence for the adherence, acceptability and safety of the LE-CIMT intervention. Moreover, the intervention potential to promote gait parameter changes and real-world lower extremity use in people with chronic hemiparesis was tested (pre- and post-test design). Two pretests at baseline were carried out to assess the participants' mobility-related performance variability and establish the reliability of the LE-MAL and lower extremity motor function test (LE-MFT) measures in the study sample. The postintervention assessments were used to analyze the LE-CIMT potentially beneficial effects immediately after the intervention protocol (day 10) and in a 30-day follow-up (Fig. 1).

Intervention

The LE-CIMT intervention protocol was performed at clinical setting and included: (1) intensive supervised task-oriented training given for 3 h/day for 10 consecutive

business days, (2) using the shaping approach as a strategy for motor learning and (3) application of a transfer package. Shaping was chosen according to the patient's needs considering the LE-CIMT protocol previously described by Dos Anjos *et al.*, [11]. A total of 10 different tasks for each patient were designed and divided into even days and odd days. Rest periods were given as often as needed. For each task, the difficulty level was adjusted to the individual's capabilities using modifying the task and/or the environment to ensure the best motor response. As part of the transfer package, a behavior contract was applied on the first day of treatment, a list with 10 tasks was completed by the participant at home every day, and the LE-MAL was administered daily. In the end of the intervention protocol, a written individualized post-treatment home practice program was developed and provided to the participants with the purpose of maintaining stimuli for further progress on the use of the affected lower extremity in the daily living activities [11].

Therapy intervention feasibility

The feasibility of the LE-CIMT was assessed by the adherence, acceptability and safety of the intervention. Acceptability was evaluated using qualitative, semi-structured interviews recorded at the end of the protocol. Face-to-face, in-depth individual interviews started with open questions related to the topic aimed to determine participants' perspectives of the weaknesses, strengths and acceptability of the LE-CIMT. The interview questions were based on a previous study [9].

The interviews were audio-recorded and transcribed verbatim with the program TextStat. The transcribed interviews were converted into quantitative data, including word frequency. The next step was to order similar or dissimilar categories into broader, higher-order categories [12]. Pro Word ClouD software was used to review and organize words and produce a word cloud.

Table 1 Demographic and clinical features of the participants at the study entry

Participant	Age (years)	Sex	Stroke type	Time since stroke (months)	MMSE scores (0–30)	FM LE Scores (0–34)	Ankle-foot orthosis	Assistive device
1	40.3	F	I	78.3	25	16	Yes	Quad Cane
2	68.2	M	U	72.9	30	24	Yes	Single Point Cane
3	59.3	F	I	26.1	30	20	Yes	None
4	55.1	M	I	21.9	22	16	Yes	Forearm Crutch Cane
5	42.3	M	I	40.3	30	34	No	None
6	73.2	M	H	44.9	30	34	No	None
7	58.3	M	I	44.1	18	19	Yes	Quad Cane
8	49.6	M	H	40.9	27	15	Yes	Quad Cane
9	39.6	M	I	34.1	30	20	No	Forearm Crutch Cane
10	61.3	F	I	42.3	18	17	No	None
11	72.4	F	U	81.9	18	28	No	None
12	38.7	M	I	55.2	30	20	Yes	None
Mean (SD)	54.7 (15.7)	NA	NA	48.2 (19.4)	26 (5)	21 (7)	NA	None

F, female; FM, Fugl Meyer; H, hemorrhagic; I, ischemic; LE, lower extremity; M, male; MMSE, mini-mental state examination; NA, not applicable; U, undefined.

Fig. 1

Experimental timeline					
Pretest		Intervention	Posttest		
Week -2	Week 0	Week 1 and 2	Week 3	Week 4 to 6	Week 7
Pre-CIMT		LE-CIMT 10-weekdays	Post-CIMT		Follow up
Test	Retest		✓ Interview		✓ LE-MAL
✓ LE-MAL	✓ LE-MAL		✓ LE-MAL		✓ LE-MFT
✓ LE-MFT	✓ LE-MFT		✓ LE-MFT		✓ TUG
	+		✓ TUG		✓ Gait
	✓ TUG		✓ Gait		parameters
	✓ Gait		parameters		
	parameters				

Experimental timeline summarizing the phases of the study Pre-CIMT: baseline assessments with test-retest procedures (test and 2-week retests) of the LE-MAL and LE-MFT (primary clinical outcomes); in this phase, baseline measures of TUG and spatiotemporal gait parameters (secondary outcomes) were also performed. Post-CIMT: post-training test of the primary and secondary clinical outcomes, and the protocol acceptability assessment by face-to-face interviews. LE-CIMT, lower extremity constraint-induced movement therapy (10-weekdays intensive intervention); LE-MAL, lower extremity motor activity log; LE-MFT, lower extremity motor function test, TUG, timed up and go.

Lower extremity use, functionality and gait parameters

The LE-MAL was used to assess real-world lower extremity use and LE-MFT to measure lower extremity functional ability [13]. Moreover, time up and go (TUG) and spatiotemporal gait parameters were evaluated. Measures data were collected before (pre-CIMT), 3 days (post-CIMT) and 30 days (follow-up) after the LE-CIMT intervention (Fig. 1).

Lower extremity motor activity log

The LE-MAL is a semi-structured interview that consists of questions about the participant's level of assistance, performance and confidence while executing 14 different daily living activities. The result is composed of assistance, functional performance and confidence scales. The arithmetic mean of these three scales is the composite score. Preliminary studies [10,14] indicate that the composite score of the LE-MAL has excellent test-retest reliability ($r=0.93$) in individuals with chronic hemiparesis.

Lower extremity motor function test

The LE-MFT examines execution time and functional ability while performing 16 activities. They are reported based on their average execution time and adjusted functional ability score (arithmetic mean of functional ability and equipment score) [15]. The LE-MFT was developed to test the effect of LE-CIMT intervention on lower extremity functional ability [16]. Test administrations were videotaped and later scored by an independent researcher blinded about the assessment period.

Timed up and go test

Participants were required to stand up from a chair with armrests, walk 3 m with orthosis or assistive devices used

daily at a comfortable speed, turn around, walk back to the chair and sit down. A stopwatch measured the time taken to complete this task in seconds [17]. The use of assistive devices to perform the TUG test was also recorded pre, post and 30-day follow-up.

Spatiotemporal gait parameters

Gait data were collected with seven cameras with the ProReflex Motion Capture System (Qualisys Inc., Gothenburg, Sweden) at a sampling frequency of 120 Hz. Reflexive passive markers were positioned as outlined in a previous study [18]. Afterward, a task habituation trial was carried out, and then, participants were instructed to walk at a self-selected speed along a 10 m walkway 10 times. Use of ankle-foot orthosis was allowed.

Data from three trials of gait assessment (i.e., 2–3 strides) were considered to calculate step length, gait speed, symmetry, cadence and percentage of stance and swing time. Visual 3D software (C-Motion, Inc., Rockville, Maryland, USA) was used to analyze data. All kinematic data were filtered with a fourth-order zero-lag filter, Butterworth low pass at 6 Hz. Finally, kinematic data were processed using Matlab software (The MathWorks, Natick, Massachusetts, USA).

Baseline stability for clinical outcomes

To control for eventual changes related to the treatment, both LE-MAL and LE-MFT outcomes were assessed two times at baseline (2-week apart and without intervention; see Fig. 1) to establish the test-retest reliability of these measures for these measures the study sample. Additionally, the smallest real difference (SRD) was calculated to determine how much the changes are related to this sample's standard error of measurement (SEM).

Statistical analysis

The analyses were performed using the SPSS software for Windows, version 18.0 (SPSS Inc, Chicago, Illinois, USA). The reliability of the LE-MAL and LE-MFT were calculated by the intraclass correlation coefficient (ICC). The ICC consistency agreement coefficients were interpreted considering a value <0.4 as an index of poor reliability, $0.4-0.75$ as fair to good reliability, and >0.75 as excellent reliability [19]. Standard SEM was also calculated using the formula: $SEM = SD\sqrt{1-ICC}$. Based on the SEM, the SRD at the individual level was calculated ($SRD = 2.77SEM\sqrt{2.29}$) [19,20]. Repeated-measures analysis of variance tests were conducted to compare pre, post and 30-day follow-up conditions. The compared variables were LE-MAL, LE-MFT, TUG and spatial-temporal gait parameters. Post-hoc pairwise comparisons using Bonferroni were performed when necessary ($P < 0.05$ for all tests).

Results

Lower extremity constraint-induced movement therapy is a feasible 10-weekdays-intensive intervention

During the 4-month recruitment period, 13 participants consented, one was excluded for not meeting eligibility criteria and 12 were enrolled. Only one participant did not complete the last day of the intervention due to fatigue. Eleven completed all 10 consecutive business days of intervention with 3 h of intensive task-oriented training a day. Each participant performed 320 repetitions per day on average. No severe or unanticipated adverse events were reported during the study.

The 3-day postintervention interviews showed that the overall experience with the intervention was positive. The semantic meaning of the responses is exhibited in Fig. 2, which provides an overview of the words that appear most frequently. The most frequent word observed throughout the interviews was 'good'. The words 'tiring' and 'effort' are also among the most frequent and appeared only in the reports of the answers to the question about how physically demanding the protocol was.

Lower extremity constraint-induced movement therapy improves real-world use and functional ability of the paretic lower extremity

Concerning the reliability of the LE-MAL, the ICC calculated over the two evaluation times before the therapy (baseline) was 0.87 (95% CI, 0.81–0.92), demonstrating excellent reliability for the composite score in the 12 assessed participants. Additionally, the SEM for the composite score of LE-MAL was 0.3 points, and the SRD was 1.2 points. In the post-CIMT evaluation, 10 of 12 participants showed LE-MAL score improvements over the SRD (Fig. 3a). At the 30-day follow-up after the LE-CIMT, all participants but one had raised their LE-MAL scores over 1.2 points (Fig. 3b).

Concerning the reliability of the LE-MFT, the ICC calculated over the two evaluation times before the therapy

(baseline) was 0.99 (95% CI, 0.98–0.99), showing excellent reliability for the adjusted functional ability score (arithmetic mean of functional ability and equipment score) in the 12 assessed participants. Additionally, the SEM for the LE-MFT adjusted functional ability score was 0.2 points, and the SRD was 0.8 points (which represents 8% of the maximum score). In the post-CIMT evaluation, eight participants showed improved LE-MFT adjusted functional ability scores over the SRD (Fig. 3c). Following the 30-day follow-up after the LE-CIMT protocol, 10 participants raised their LE-MFT scores over 0.8 points (Fig. 3d).

The group-level results are shown in Table 2. Significant main effects were seen in LE-MAL composite score [$F(2,22) = 14.023$; $P < 0.001$], assistance [$F(2,22) = 6.12$; $P < 0.01$], functional performance [$F(2,22) = 16.595$; $P < 0.001$] and confidence [$F(2,22) = 13.482$; $P < 0.001$] subscales. The participants had an average improvement of over 66% in both post-CIMT and 30-day follow-up compared to the baseline evaluation for the composite score of the LE-MAL, functional performance and confidence subscales. There was an improvement of 28% in the assistance subscale post-CIMT and 30-day follow-up compared to baseline evaluation. Moreover, significant main effects were seen in LE-MFT adjusted functional ability score [$F(2,22) = 20.983$; $P < 0.001$]. The participants improved by 1.4 (20%) and 1.8 points (26%) in their lower extremity functional ability score of LE-MFT in the 3-day post-CIMT and 30-day follow-up compared to baseline evaluation. There is no difference in the average execution time.

Lower extremity constraint-induced movement therapy does not change timed up and go test execution time but reduces the assistance necessary to complete the test

Although there is a tendency to reduce the time to complete the TUG test, no main statistical effects were seen [$F(2,22) = 3.046$; $P = 0.068$; Table 2]. However, the use of assistive devices to perform the TUG test was reduced for three of the six participants that needed some assistive device in pre-CIMT evaluation.

Lower extremity constraint-induced movement therapy improves spatiotemporal gait parameters

Significant main effects were seen in relative paretic lower extremity stance time [$F(2,22) = 26.151$; $P < 0.001$], in relative paretic lower extremity swing time [$F(2,22) = 26.151$; $P < 0.001$], in relative double support time [$F(2,22) = 17.517$; $P < 0.001$], in relative paretic lower extremity single support time [$F(2,22) = 8.143$; $P = 0.002$] and in symmetry index [$F(2,22) = 4.438$; $P = 0.024$]. Additionally, significant main effects were also shown in the paretic and nonparetic lower extremity step length [$F(2,22) = 5.977$, $P = 0.008$; $F(2,22) = 10.222$, $P = 0.001$,

Table 2 Primary outcome measures for lower extremity real-world use and functional ability before and 3 and 30 days after the intervention protocol

Outcome assessment	Pre-CIMT	Post-CIMT	Follow-up	Post- and Pre-CIMT		Follow-up and post-CIMT		
	Mean (SD)	Mean (SD)	Mean (SD)	Difference (95% CI)	P value	Difference (95% CI)	P value	
LE-MAL	Composite Score	5.2 (1.6)	8.2 (1.4)	8.1 (1.3)	2.9 (1.0–4.9)	0.004	−0.1 (−1.8 to 1.6)	1.000
	Assistance Scale	6.8 (1.9)	8.7 (1.2)	8.7 (1.3)	1.9 (−0.1 to 4.0)	0.066	0.0 (−1.6 to 1.6)	0.563
	Functional Performance Scale	4.3 (1.9)	7.9 (1.5)	7.7 (1.7)	3.5 (1.5–5.5)	0.001	−0.1 (−2.2 to 1.9)	1.000
	Confidence Scale	4.7 (2.2)	8.0 (1.7)	7.8 (1.7)	3.3 (1.1–5.5)	0.004	−0.2 (−2.1 to 1.7)	1.000
LE-MFT	Adjusted Functional Ability Score	6.7 (1.7)	8.1 (1.5)	8.5 (1.0)	1.4 (0.7–2.0)	<0.001	0.4 (−0.3 to 1.2)	0.401
	Average execution time (s)	1.5 (1.0)	1.3 (0.9)	1.2 (1.1)	−0.2 (−0.8 to 0.5)	1.000	0.0 (−0.7 to 0.5)	1.000
TUG test	Time (s)	35.3 (22.1)	32.0 (22.7)	32.5 (23.4)	−3.3 (−7.2 to 0.8)	0.130	0.5 (−2.2 to 3.1)	1.000

CI, confidence interval; CIMT, Constraint-Induced Movement Therapy; LE-MAL, Lower Extremity Motor Activity Log; LE-MFT, Lower Extremity Motor Function Test; TUG, Timed up and Go.

baseline evaluation for the relative paretic lower extremity swing time and single support time (differences between evaluations over 34 and 90%, respectively). Additionally, the nonparetic lower extremity step length was improved by 50% in both post-CIMT and the 30-day follow-up compared to baseline values. However, the LE-CIMT decreases relative paretic lower extremity stance time and relative double support time on post-LE-CIMT and in the follow-up.

Discussion

This study suggests that the LE-CIMT is a feasible intervention because it was well-tolerated, acceptable and achieved participant engagement. The current concept of engagement says that ‘the way the patient and therapist are working together is critical to promoting rehabilitation engagement and self-management of health conditions’ [21]. Individual interviews are used to investigate levels of engagement [22,23]. The high attendance during our study and the positive report with the words ‘good’, ‘improve’, ‘effort’, ‘exercises’, ‘continue’ and ‘people’ suggest that participants were enthusiastic about and engaged with the training protocol.

The patient’s adherence and self-management can be enhanced with strategies to transfer clinical improvements to a real-world context. The transfer package enhanced engagement and self-management because both the therapist and the participant created a daily list of tasks to be performed at home. This ‘patient-centered rehabilitation practice’ approach is related to the patient’s expressed needs, values and expectations.

Moreover, the LE-CIMT intervention was associated with important within-group improvement and retention of the real-world use and functional ability of the lower extremity. Ten participants in our study showed improvements over 1.2 points in LE-MAL composite score immediately and following the 30-day follow-up

after the LE-CIMT. In lower extremity functional ability, most of the participants showed improvement over 0.8 points in LE-MFT adjusted scores in post-CIMT and the 30-day follow-up. These improvements were superior to 12 and 8% of the maximum measure score of 10 points representing the SRD in real-world use and functional ability of the lower extremity for the studied sample. Additional gains in confidence, reduction in the use of assistive devices and optimization of spatiotemporal gait parameters were shown by participants in the 3-day post-LE-CIMT and the 30-day follow-up.

The ability to walk in the community, which means any locomotion that arises outside the home to perform social activities, is relevant to the participation promotion [24,25]. Some critical personal barriers for the low levels of walking in the community in people with chronic stroke are insecurity, poor balance, low gait speed and fear of falling [26,27]. These factors related to confidence seem to interfere mainly in people who present gait speeds between 0.4 and 0.8 m/s. They benefit most from using assistive devices to increase confidence in community walking [28–30]. In this study, participants showed a mean gait speed of 0.4 m/s, and half of the participants experienced a reduced use of the assistive device after the intervention. Despite less assistance, the participants reported greater confidence, as shown by the LE-MAL score, reduced use of assistive devices and greater gait symmetry after intervention training. The change in mean walking speed was not statistically significant, but even small increases of 0.1–0.2 m/s have improved survival [31] and reduced the risk of disability [32] in aging people.

The LE-CIMT is a feasible intervention that improves perceptions of benefits and shows potential beneficial effects in the actual use of paretic lower extremity in daily mobility activities in individuals with chronic hemiparesis. In addition, the increase in lower extremity

Table 3 Spatial and temporal gait parameters before and 3 and 30 days after the intervention protocol

Gait parameters	Pre-CIMT	Post-CIMT	Follow-up	Post- and pre-CIMT	P value	Follow-up and post-CIMT	P value
	Mean (SD)	Mean (SD)	Mean (SD)	Difference (95% CI)		Difference (95% CI)	
Paretic lower extremity stance time (%)	78.1 (8.4)	70.5 (7.6)	69.7 (7.4)	-7.6 (-11.6 to -3.5)	0.001	-0.8 (-3.1 to 1.4)	0.892
Double support time (%)	60.6 (10.8)	37.3 (9.0)	38.7 (8.4)	-23.3 (-38.7 to -8.0)	0.004	1.4 (-0.7 to 3.5)	0.271
Paretic lower extremity single support time (%)	17.5 (5.9)	33.3 (14.9)	31.0 (13.6)	15.8 (1.0-30.6)	0.036	-2.3 (-4.9 to 0.3)	0.096
Paretic lower extremity swing time (%)	21.9 (8.4)	29.5 (7.6)	30.3 (7.4)	7.6 (-3.5 to 11.6)	0.001	0.9 (-1.4 to 3.2)	0.905
Paretic lower extremity step length (cm)	0.40 (0.10)	0.51 (0.15)	0.30 (0.15)	0.10 (-0.08 to 0.30)	0.068	-0.22 (-0.44 to 0.01)	0.063
Nonparetic lower extremity step length (cm)	0.28 (0.17)	0.43 (0.08)	0.43 (0.09)	0.14 (0.03-0.25)	0.013	0.00 (-0.07 to 0.07)	1.000
Symmetry index	0.67 (0.28)	0.82 (0.20)	0.68 (0.31)	0.15 (-0.02 to 0.32)	0.078	-0.14 (-0.34 to 0.06)	0.216
Gait speed (m/s)	0.4 (0.3)	0.5 (0.3)	0.5 (0.2)	NA		NA	
Gait cadence (steps/min)	74.6 (25.1)	76.9 (19.9)	77.2 (24.3)	NA		NA	

CI, confidence interval; CIMT, Constraint-Induced Movement Therapy; NA, not applicable.

use seems to be coupled with decreased assistance and increased confidence. Furthermore, our findings boost randomized controlled clinical trial studies to confirm the intervention effects over a more significant number of participants.

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Conflicts of interest

The authors have no conflicts of interest.

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