Remodelling the protocol of lower limb constraint-induced movement therapy: a pilot randomized controlled trial

Khalid Aliyu Danlami[1], Auwal Abdullahi[2]
[1]Department of Physiotherapy, Murtala Muhammad Specialists Hospital Kano, Nigeria
[2]Department of Physiotherapy, Bayero University Kano, Nigeria

Abstract

During constraint-induced movement therapy (CIMT), the tasks practiced have been traditionally measured using hours. Recent studies have indicated that it is equally effective and easier when the number of repetitions is used for this purpose.

Aim: The aim of this study is to compare the use of number of repetitions and hours of task practice as measures of dose during lower limb CIMT in patients ≤6 months post-stroke.

Methods: The sCIMT group performed the same 4 functional tasks, 40 times each, 2 times a day; the tCIMT group performed the tasks for 2 hours a day. In both groups, the unaffected limb was constrained for 90% of waking hours. The control group received conventional therapy, 2 hours per day. Both the interventions and the control were carried out 5 times in a week for 4 weeks. Data were collected using the Fugl-Meyer Assessment (FMA) scale for motor function of the lower limb at baseline and post-intervention. The data obtained were analyzed using descriptive statistics, the Kruskal-Wallis test, Mann-Whitney U test and Wilcoxon signed- rank test at $p<0.05$.

Results: The results showed significant improvement in Fugl Meyer motor scores in sCIMT and tCIMT groups post-intervention, though higher in the sCIMT group ($p<0.05$).

Conclusion: sCIMT improves the impairment after stroke.

Key words: stroke, constraint-induced movement therapy, dose, motor recovery, lower limb and task repetition

Introduction

Stroke can result in impairment of the upper and lower limb motor function.. The impairment in the lower limb motor function can cause reduced gait parameters, such as walking speed, and shifting of the centre of pressure and mass to the unaffected limb [1], This in turn may result in disability in walking, which can impose participation restriction and reduce the quality of life.

The motor impairment resulting from stroke can be managed using an effective rehabilitation technique known as constraint-induced movement therapy [2]. This technique originated from a translational study in rhesus monkeys [3], which was subsequently piloted in humans and provided encouraging results [4].

Although the original technique focused on constraint of the unaffected limb and forced use of the affected limb, there have been tremendous modifications over the years which included mass task or shaping practice and transfer package [5]. Consequently, there are many studies on CIMT which earned it a strong theoretical foundation in terms of neurophysiological, kinematic and motor performance or function evidence [6-8]. However, almost all the studies were performed on the upper limb; the studies carried out on the lower limb in stroke are scarce [1, 9-10] and their protocols involved one-off practice and measurement [1], practice and casual observation of a single patient [9] and forced use [10]. Similarly, there was a case series study regarding 4 patients with multiple sclerosis [11]. Its results have demonstrated substantial improvement in perceived lower extremity use and minor improvement in true motor function following the use of 3.5 hours of task and shaping practice, transfer package and procedures discouraging the use of unaffected limb for 3 weeks.

Likewise, in a group of stroke patients, forced use was given for 1.5 hours per day, 5 times a week for 2 weeks [10]. However, this protocol involving the use of duration in hours of task and/or shaping practice as a dose measure of CIMT has been argued not to clearly specify how much task is being practiced in upper limb rehabilitation [12]. Consequently, the protocol using the number of repetitions of task and/or shaping practice as a measure of dose was proposed, which has been shown to be very effective in previous studies [13-14] in chronic patients and patients within 4 months post stroke, respectively. Furthermore, studies delineating the required dosage for recovery are needed [15]. The aim of this study is to remodel the protocol of lower limb CIMT and compare the effectiveness of the protocols using duration in hours and number of repetitions of task/shaping practice as measures of dose.

Material and Methods

Participants

A randomized controlled trial (RCT) was carried out to demonstrate the comparative effects of lower limb CIMT using the number of repetitions of task practice (sCIMT) and duration in hours of task practice (tCIMT) as measures of dose during CIMT. The study population consisted of stroke patients attending physiotherapy at the Murtala Muhammad Specialists Hospital (MMSH) and Muhammad Abdullahi Wase Specialists Hospital in Kano, Nigeria. The study was approved by the Kano State Hospitals Management Board Ethics Committee (HMB/GEN/488/VOL.1). Additionally, it was registered with Pan African Clinical Trial Registry (PACTR201730020732205) available on www.pactr.org.

The inclusion criteria were ≤ 6 months post-stroke, lower limb impairment, ability to follow verbal and visual instructions, no significant cognitive impairment (Minimental state examination score ≥ 17) and low risk of fall (Tinetti gait and balance score ≥24). Participants were randomized into 3 groups using simple random sampling. A research assistant blinded to the aim of the study and the randomization process was asked to write numbers 1 to 22 on the pieces of opaque paper. The numbers represented each of the study participants. The papers with numbers were folded, mixed up severally in a small bowl; subsequently, 3 intern volunteers (who were blinded to the aim of the study and the randomization process) representing sCIMT, tCIMT and control groups were asked to choose 7 folded pieces of papers each, which left one piece of paper. The assistant wrote 0 on 2 pieces of papers, folded them, mixed them up severally with the remaining one in the bowl and subsequently asked each of the representatives of the 3 groups to pick one piece of paper. Whenever the number other than zero was picked up, the participant corresponding to that number was added to the study group.

Intervention and Comparator

The sCIMT group performed sit-to-stand, as well as forward and backward stepping, stair climbing and descending (only the first stair was used), and side-to-side stepping with the affected limb, 40 times each per session for 2 sessions a day, 5 times a week for 4 weeks. Thus, each participant in the group performed 240 repetitions per session (480 repetitions in 2 sessions). Similarly, the tCIMT group practiced the same tasks as the sCIMT group, but for 2 hours a day, 5 times a week for 4 weeks. In both groups, the unaffected limbs were constrained using a tight knee brace for about 90% of waking hours throughout the study duration. The control group received usual physical therapy including passive movement, therapeutic positioning, strengthening exercise and over-ground gait training for 2 hours a day, 5 times a week for 4 weeks. All tasks were initially administered by a physiotherapist, but patients and relatives were taught how to carry out the tasks at home. Additionally, logbooks were designed to monitor and evaluate compliance at home. Moreover, the patients came on a weekly basis for monitoring and evaluation.

Results

The instrument used for data collection was the lower limb Fugl-Meyer scale (motor function subscale), which has been reported to be valid and reliable [16-17]. The motor function subscale has 17 items which are scored on a 3-point ordinal scale (0–2); therefore, the total scores of the subscale range from 0 to 34. Outcomes were assessed at baseline and 4 weeks post-intervention by a therapist who was blinded to the groups. The data obtained were analyzed using descriptive statistics for the demographics and inferential statistics (ANOVA) for inter-group differences in age and time since stroke and the Kruskal-Wallis test for differences in the side affected, type of stroke and sex). The Kruskal-Wallis with Mann-Whitney U test for post-hoc comparisons (when there is a significant

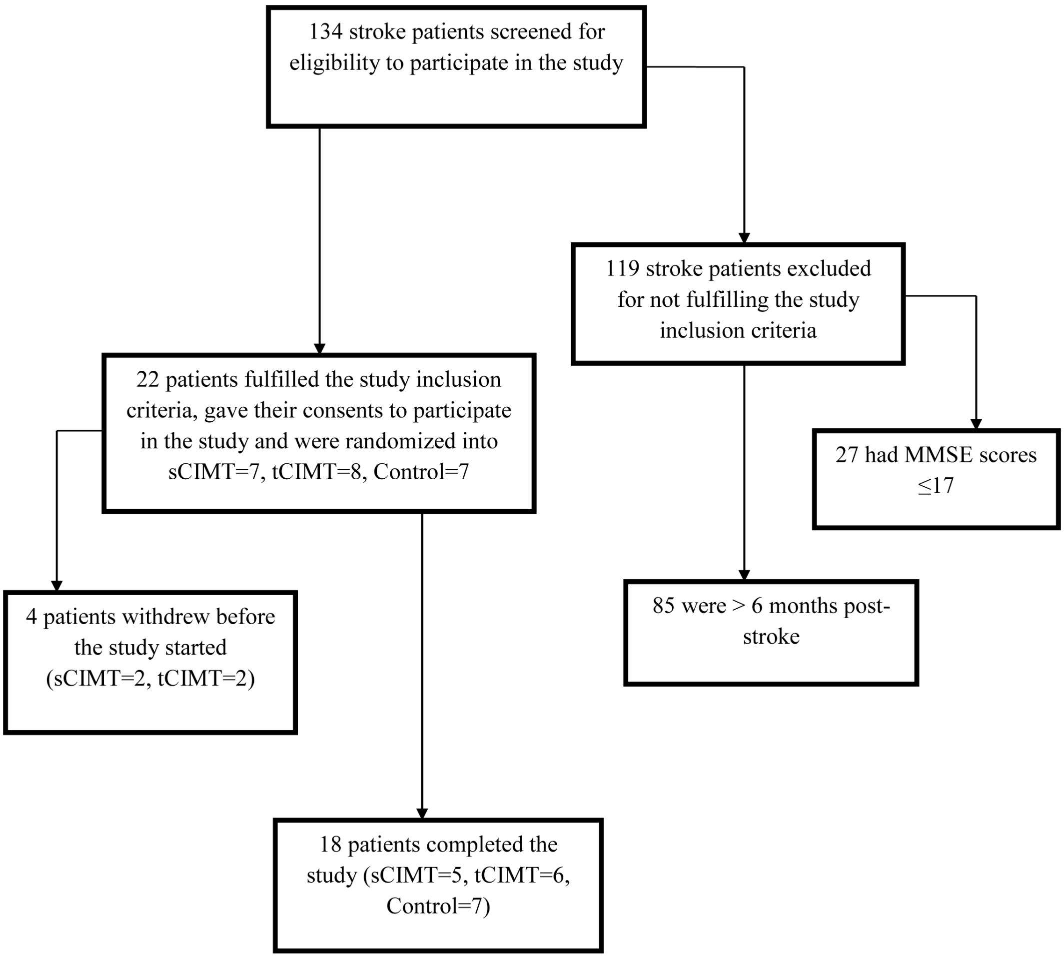

Fig. 1: The study flow chart

difference across the groups) was used for inter-group differences and the Wilcoxon signed rank test for intra-group differences in the Fugl-Meyer lower limb scores (motor function subscale) at baseline and 4 weeks post intervention. In each case, the effect sizes were calculated. A total of 18 patients completed the study; sCIMT (n=5), tCIMT (n=6) and control (n=7) with the age range 40-65. The patients did not differ significantly for age, sex, time since stroke, type of stroke and side affected (p>0.05) (Table 1, fig.1)

Intra-group analysis

The Wilcoxon signed rank test revealed a statistically significant improvement in motor impairment in the sCIMT group; p<0.05 - a large effect size. There was no statistically significant improvement in motor impairment observed in the tCIMT group; p>0.05 - a moderate effect size. Similarly, there was no statistically significant improvement in motor impairment in the control group: p>0.05 - a moderate effect size (Table 2)

Inter-group analysis

At baseline, the Kruskal-Wallis test revealed no significant inter-group differences in lower limb motor impairment measured by the lower limb Fugl-Meyer scale (p>0.05). However, at 4 weeks post-intervention, there were significant inter-group differences (p>0.05).

The post-hoc analysis using the Mann-Whitney U test revealed a significant difference between sCIMT and tCIMT; p<0.05 -a large effect size, and between sCIMT and Control; p<0.05 - a moderate effect size. However, there was no significant difference between tCIMT and Control; p>0.05 - a small effect size. (Table 3).

Discussion

The study findings showed significant improvement in motor impairment in the sCIMT and tCIMT groups compared with the control group, with the sCIMT group showing a significantly higher improvement. The previous studies in both stroke and multiple sclerosis have demonstrated the benefitial effects of lower limb CIMT on various rehabilitation outcomes. Gray and Culham have reported shifting of the centre of pressure and mass towards the unaffected limb following the use of CIMT strategies in patients with stroke [1]. Similarly, the best effort (motor function) and real world arm use (perceived motor function) have been reported to improve following the use of 3.5 hours of lower limb CIMT for 3 weeks in patients with multiple sclerosis [18]. Additionally, gait parameters, including speed and symmetry, mobility and quality of life have been shown to improve following 1.5 hour of task practice per day for 2 weeks [10].

Although there seems to be no studies comparing the two different protocols of lower limb CIMT prior to this study, there is an emerging evidence of the use of number of repetitions as a measure of dose for the upper limb [13, 19-20]. According to one study (Birkinmeier et al. (2010), about 300 repetitions of task was possible and effective within just 1 hour. Thus, it is clear that the time spent in the study was much shorter, as compared to the studies by Yu et al. [10] and Mark et al. [18]. Therefore, knowing how much task needs to be practiced rather than the hours spent carrying it out may help to reduce time as well as financial and personal costs during CIMT. Previously, a device known as automated constraint-induced therapy extension (AUTOCITE) was used to relieve therapists [21]. The device yielded a tremendous success. However, one may be tempted to ask about making efforts to relieve patients by making the rehabilitation time and cost effective.

Furthermore, repetition in stroke rehabilitation is important. An increase in the amount of practice can help improve motor recovery [15].

Consequently, techniques such as treadmill gait training have been used to achieve massive task repetition [22]. Similarly, repetitive facilitation exercise to the tune of 100 repetitions for 2 weeks has been shown to improve the motor function of the hemiplegic upper limb [23]. Additionally, the protocol using number of repetitions as a measure of dose of task practice seems to be simple, easy to track by both patients and relatives, and easy to determine how much task practice is required for functional improvement.

In this study, we used constraint of the knee of the unaffected limb for 90% of waking hours. Although constraint of the unaffected limb during lower limb CIMT was used in children with cerebral palsy (CP) [24] and in a forced use study in stroke patients by Yu et al. [10], the previous studies [9, 18] about stroke did not use any constraint, which could be due to the fact that those studies involved adults who can comply with the instructions on discouraging the use of the unaffected limb. Additionally, it has been shown that the use of constraint in upper limb CIMT may not be necessary as there is no significant difference when constraint is used or otherwise [25]..

Furthermore, the study by Shumway-Cook et al. included patients with a moderate risk of fall having scores ≥ 24 [26]. However, gait and balance are intricately interdependent and inseparable. Thus, further studies should consider enrolling patients with a moderate risk of fall and determine whether there is improvement in balance following the new protocol of CIMT.

Conclusion

The use of number of repetitions of task practice as a measure of dose of lower limb CIMT seems to be simple and more effective than the use of duration of task practice.. However, this result should be interpreted with caution since the sCIMT group seems to be much younger and less impaired than the other two groups, even though no statistically significant inter-group differences in these variables were observed. Nonetheless, further research to confirm our results is warranted.

References:

1) Gray CK, Culham E.Sit-to-Stand in People with Stroke: Effect of Lower Limb Constraint-Induced Movement Strategies. Stroke Res Treatment 2014; http://dx.doi.org/10.1155/2014/683681

2) Taub E, Miller NE, Novack TA, Cook IEW, Fleming WC, Nepomuceno CS, Connel JS, Crago JE. Technique to improve chronic motor deficit after stroke. Archive of Phys Med Rehabil 1993; 4: 347-354

3) Taub E, Berman AJ. Avoidance conditioning in the absence of relevant proprioceptive and exteroceptive feedback. J Comp Physiol Psychol 1963; 56 (6): 1012-1016

4) Ostendorf CG, Wolf SL. Effect of forced use of the upper extremity of a hemiplegic patient on changes in function. A single-case design. Phys Therap 1981; 61(7):1022-8.

5) Stock R, Thrane G, Askim T, Karlsen G, Langørgen E, Erichsen A, Gjone R, Anke A. Norwegian Constraint-induced therapy multisite trial: Adherence to treatment protocol applied early after stroke. J Rehabil Med 2015; 47: 816–823

6) Wolf SL, Winstein CJ, Miller JP, Taub E, Uswatte G, Morris D, Giuliani C, Light KE, Nichols-Larsen D. Effect of constraint induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial. JAMA 2006; 296:2095-2104.

7) Wu C-Y, Lin K-C, Chen H-C, Chen IH, Hong WH. Effects of modified constraint-induced movement therapy on movement kinematics and daily function in patients with stroke: a kinematic study of motor control mechanisms. Neurorehabil Neural Repair 2007; 21: 460–466.

8) Sawaki L, Butler AJ, Leng X, Wassenaar PA, Mohammad YM, Blanton S, Sathian K, Nichols-Larsen DS, Wolf SL, Good DC, Wittenberg GF. Constraint-Induced Movement Therapy Results in Increased Motor Map Area in Subjects 3 to 9 Months After Stroke. Neurorehabil Neural Repair. 2008 Sep-Oct;22(5):505-13. doi: 10.1177/1545968308317531

9) Numata K, Murayama T, Takasugi J, Oga M. Effect of modified constraint-inducedmovement therapy on lower extremity hemiplegia due to a higher-

motor area lesion. Brain Inj 2008; 22(11):898-904. doi: 10.1080/02699050802425436.

10) Yu W-S, Liu W-Y, Wong A W-K, Wang T-C, Li Y-C, Lien H-Y. Effect of forced use of the lower extremity on gait performance and mobility of post-acute stroke patients J. Phys. Ther. Sci. 2015; 27: 421–425

11) Mark VW, Taub E, GitendraUswatte G, Bashir K, Cutter GR, Bryson CC, Bishop-McKay S, Bowman MH. Constraint-Induced Movement Therapy for the Lower Extremities in Multiple Sclerosis: Case Series With 4-Year Follow-Up. Arch Phys Med Rehabil 2013; 94:753-60

12) Abdullahi A. Is time spent using constraint induced movement therapy an appropriate measure of dose? A critical literature review. Int J Ther Rehabil 2014; 21(3): 140-146

13) Birkenmeier RL, Prager EM, Lang CE. Translating Animal Doses of Task-Specific Training to People With Chronic Stroke in 1-Hour Therapy Sessions: A Proofof- Concept Study. Neurorehabil Neural Repair 2010;24(7): 620–35

14) Abdullahi A, Shehu S. Standardizing the Protocols of Constraint Induced Movement Therapy in Patients within 4 months post-stroke: A Pilot Randomized Controlled Trial. Int J Phys Med Rehabil 2014; 2:4. Doi:10.4172/2329-9096.100025

15) Bosch J, O'Donnell MJ, Barreca S,Thabane L, Wishart L.Does Task-Oriented Practice Improve Upper Extremity Motor Recovery after Stroke? A Systematic Review. ISRN Stroke, 2014. http://dx.doi.org/10.1155/2014/504910

16) Gladstone DJ, Danells CJ, Black SE. The Fugl-Meyer assessment ofmotor recovery after stroke: a critical review of its measurement properties. Neurorehabil Neural Repair 2002; 16:232–240

17) Sullivan KJ, Tilson JK, DPT, Cen SY, Rose DK, Hershberg J, Correa A, Gallichio J, McLeod M, Moore C, Wu SS, Duncan PW. Fugl-Meyer Assessment of Sensorimotor Function After StrokeStandardized Training Procedure for Clinical Practice and Clinical Trials. Stroke 2011; 42:427-432

18) Mark V, Taub E, Bashir K, et al. Constraint-Induced Movement therapy can improve hemiparetic progressive multiple sclerosis. Preliminary findings. Mult Scler 2008;14:992-4.

19) Abdullahi A, Shehu S, Dantani BI. Feasibility of High Repetitions of Tasks Practice during Constraint Induced Movement Therapy in an Acute Stroke Patient. Int J Therap Rehabil 2014; 21(4): 190-195.

20) Abdullahi, A., Shehu, S.Abdurrahman, Z and Bello, B. Determination of Optimal Dose of Tasks Practice during Constraint Induced Movement Therapy in a Stroke Patient with Severe Upper Limb Pain. Indian J Physiother Occup Therap 2015; 9(1):198. DOI: 10.5958/0973-5674.2015.00039.8

21) Lum PS, Taub E, Schwandt D, Postman M, Hardin P, Uswatte G. Automated Constraint-Induced Therapy Extension (AutoCITE) for movement deficits after stroke. J Rehabil Res Dev. 2004;41(3A):249-58

22) Mehrholz J, Pohl M, Elsner B. Treadmill training and body weight support for walking after stroke. Cochrane Database of Systematic Reviews 2014*, Issue* 1*. Art. No.: CD002840. DOI: 10.1002/14651858.CD002840.pub3.*

23) Kawahira K, Shimodozono M, Etoh S, Kamada K, Noma T, Tanaka N. Effects of intensive repetition of a new facilitation technique on motor functional recovery of the hemiplegic upper limb and hand. Brain Inj 2010; 24:10,1202-1213, DOI: 10.3109/02699052.2010.506855

24) Cerebral Palsy Alliance (2016). Constriant Induced Movement Therapy for the leg (CIMT-Leg). Accessed from https: // www. cerebralpalsy.org.au on 6/03/2017

25) Brogårdh, C, Vestling M, Sjölund BH. Shortened constrained induced movement therapyin subacute stroke-no effect of using a restraint: a randomized controlled study with independent observers. J Rehabil Med 2009; 41: 231–236

26) Shumway-Cook A, Woollacott MH. Motor Control: Theory and Practical Applications. *2nd ed. Philadelphia, Pa: Lippincott, Williams & Wilkins;* 2001.

Corresponding author address:

Auwal Abdullahi

Email: aabdullahi.pth@buk.edu.ng

Table 1: Demographic characteristics of the study participants

SN	Variable	sCIMT (n=5)	tCIMT (n=6)	Control (n=7)	p-value
1	Age	48.20±7.89	55.67±9.00	54.14±6.87	0.292
2	Sex (M/F)	1/4	2/4	6/1	0.058
3	Time since stroke	41.20±33.54	74.67±55.93	75.50±47.88	0.124
4	Type of stroke (I/H)	4/1	4/2	7/0	0.287
5	Side affected (L/R)	3/2	4/2	2/5	0.362

Key: M/F=Male/Female, I/H=Ischaemic/Haemorrhagic, L/R=Left/Right

Table 2: Differences between baseline and post- intervention according to Fugl-Meyer Scores

	Baseline	Post-intervention	Z	p	r
sCIMT (n=5)	24.00	28.00	-2.070	0.038*	0.92
tCIMT (n=6)	24.50	25.00	-1.518	0.129	0.62
Control (n=7)	24.00	24.00	-1.190	0.234	0.45

*=significant at p<0.05

Table 3: Inter-group differences in Fugl-Meyer scores at baseline and post-intervention

	sCIMT (n=5)	tCIMT (n=6)	Control (n=7)	X^2	p
Baseline	24.00	24.50	24.00	0.115	0.94
Post-intervention	28.00	25.00	24.00	7.261	0.03*
Post- hoc analysis sCIMT vs tCIMT, U=2.000, Z=-2.407, p=0.016*, r=0.73 sCIMT vs Control, U=4.000, Z=-2.216, p=0.027*, r=0.64 tCIMT vs Control, U=15.000, Z=-0.809, p=0.418, r=0.22					

*=significant at p<0.05