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Standardizing the Protocols of Constraint Induced Movement Therapy in Patients within 4 Months Post-stroke: A Pilot Randomized Controlled trial

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Abstract

Background: The protocols of constraint induced movement therapy are heterogeneous, and it is difficult to adopt one particular protocol.

Aim: The aim of this study was to evaluate the efficacy of a standardized constrain induced movement therapy protocol where all the participants will perform same tasks and with same number of repetitions.

Methods: Sixteen stroke patients (6 males, 10 females, with mean age 53.71 years) who were < 6 months post-stroke were randomized into experimental and control groups. The experimental and control groups received standardized CIMT and traditional modified CIMT respectively for 4 weeks. Motor function was assessed at baseline, 2 and 4 weeks post-intervention using WMFT and MAL. The data was analyzed using t-test, one-way repeated measures ANOVA and one-way ANCOVA.

Result: A significant difference was recorded using one way repeated ANOVA in the control group between baseline, and 2 weeks; and 4 weeks post-intervention(Wilk's Lambda = 0.29, p= 0.025) for both AOU, QOU and WMFT. The results recorded using t- test and one -way ANCOVA showed no significant difference between groups. However, there was a strong relationship that existed on the effect of covariate (baseline) on the 2 and 4 weeks post-intervention scores as indicated by large eta squared values. Conclusion: It is possible for stroke patients to perform 320 repetitions of tasks practice (same tasks) per day.

Keywords: Constraint induced movement therapy; Stroke and motor recovery

Introduction

Constraint induced movement therapy (CIMT) is inarguably a rigorously studied motor rehabilitation technique especially for the upper limb. Evidence for it is effectiveness is overwhelming, and this cuts across various outcomes such as neurophysiological behavioural and kinematic [1-6]. Yet, it is application is not pervasive in our clinics; and this could reflect the varied nature in which it is administered. Different studies used different protocols for the tasks administration and limb constraint such as 6,3 or 2 hours and constraint for 90% of the waking hours, 6 or 5 hours respectively [4,5,7,8]. These may leave clinicians totally unsure of which protocol they should adopt in their practice. Thus, simpler protocols which can be easily adopted for CIMT are much needed.

More recently, few studies have tried to determine the number of task repetitions required to improve upper limb function [9,10]. The studies made participants to perform around 320 repetitions of task practice per day. Although, minimal clinically importance difference (MCID) was attained at 4, 6 and 8 weeks post-intervention in the latter study by Abdullahi and colleagues, both studies were limited in that, in the former study by Birkinmeier and colleagues, there was no control group and the latter study was a case study of a single patient. Secondly, the approaches in both studies were not compared with any of the existing CIMT protocols to find out whether they would produce similar, lesser or better effect. Therefore, the aim of the present study was to find out whether 320 repetitions of task practice spread over 2 sessions per day, 5 times a week for 4 weeks can produce a similar, a lesser or a better effect on upper limb motor function than the existing CIMT protocols in patients within 4 months post-stroke.

Method

The study was a randomized controlled (RCT) trial with pre- test - post –test design. The study was approved by the research ethics committees of Aminu Kano Teaching Hospital and Kano State Hospitals Management Board. The population of the study was all inpatients and outpatient stroke patients in Aminu Kano Teaching Hospital and Murtala Muhammad Specialists Hospital. The inclusion criteria include stroke patients who are within < 4 months post-stroke, patients with ≥ 20° of active wrist and ≥ 10° of all digits extensions, patients with no significant cognitive impairments (mini mental scale examination (MMSE) score ≥ 17) and patients who provided consents to participate in the study.

Seventeen consecutive stroke patients were recruited and then simply randomized into the standardized CIMT (n=9) and traditional modified CIMT groups (n=8). Any odd numbered patient was assigned into the standardized CIMT group; and even numbered patient was assigned to the traditional modified CIMT group. The experimental group (the standardized CIMT) performed 320 repetitions of 8 tasks divided in 2 sessions (morning and evening) per day, 5 times a week for 4 weeks. The unaffected upper limb was

constrained for 90% of the waking hours per day, 5 times a week for 4 weeks. The nature of the tasks and other relevant informations are detailed in a previous study [10]. The tasks were initially administered to the patients in the clinic and were then taught to the patients and their relatives for the patients to perform the tasks at home for the whole of the study period already specified above. Compliance with the tasks practice and constraint were monitored using logbooks in which patient relatives fill in daily repetitions of each task and hours of compliance with the constraint.

For the control group (traditional modified CIMT), 2 hours of tasks practice convenient for the patient with the affected upper limb and constraint of the unaffected upper limb for 90% hours of the waking hours per day, 5 times a week for 4 weeks were performed. The tasks were initially administered to the patient in the clinic and were then taught to the patients and their relatives for the patients to perform the tasks at home for the time period already specified above. No additional therapy was given to the upper limb during the study period in both groups. Similar to the standardized CIMT group, compliance with task practice and constraint was also monitored using logbooks.

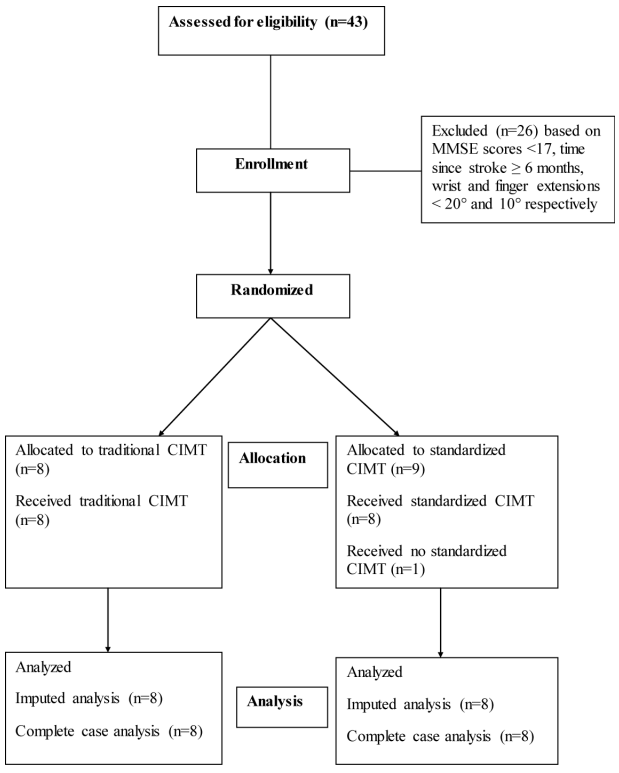

Figure 1: The Trial Profile.

The instruments used in the study were goniometry, Wolf motor function test (WMFT), Motor activity log (MAL), Functional independence measure (FIM), stop watch, visual observation and counting of repetition of task practice and Mini-mental scale examination (MMSE). Wolf motor function test (WMFT) is a reliable and valid test for upper limb motor function consisting of 17 motor tasks rated from 0-5 points [11,12]. Motor activity log (MAL) is a reliable measure of real world arm use [13-15]. The scale measures how the affected hand is used in performing 30 activities of daily living. Although, in its original use, patients are asked to rate the amount of use and how well the affected hand is used, in this study, participants were asked to perform the tasks and these were rated by one of the researchers (SS). Ratings were done on a scale ranging from 0 to 5, with higher scores representing better function.

SN	Study Group	Age (years)	Sex	Side affected	Time since stroke	MMSE scores
1	Experimental	52	F	Right	4 weeks	22
2	Control	60	F	Right	8 weeks	25
3	Experimental	70	F	Left	4 weeks	26
4	Control					
5	Experimental	53	F	Right	8 weeks	28
6	Control	56	M	Left	12 weeks	30
7	Experimental	50	M	Left	16 weeks	29
8	Control	65	F	Left	3 weeks	24
9	Experimental	55	F	Right	12 weeks	25
10	Control	70	F	Right	2 weeks	26
11	Experimental	30	F	Right	8 weeks	28
12	Control	50	M	Left	12 weeks	30
13	Experimental	55	M	Left	12 weeks	29
14	Control	46	M	Left	4 Weeeks	30
15	Experimental	56	M	Left	12 weeks	30
16	Control	53	F	Right	12 weeks	30
17	Experimental	55	M	Right	12 weeks	30

Table 1: Characteristics of Study Participants.

Screening outcomes such as goniometer and MMSE were also used at the beginning (baseline) of the study. The goniometer was used to measure active extension at the wrist; interphalangeal; and metacarpophalangeal joints; whereas, the MMSE was used to screen for patients cognitive abilities as per detailed in the inclusion criteria above. Motor function (WMFT) and perceived motor function (MAL) were assessed at baseline, 2 and 4 weeks post intervention.

Data analysis

The characteristics of the participants such as age, sex and time since stroke were described using mean, table and percentages. The data generated by WMFT and MAL were analyzed using t-test, repeated measures analysis of Variance (ANOVA) and Analysis of Covariance (ANCOVA) to determine the difference between groups, difference within group and the effect of a covariate (baseline scores) on the 2 and 4 weeks post-intervention scores respectively.

Result

Forty three stroke patients were screened for eligibility for the study. Out of this, only 17 were included in the study; 26 were excluded either because of MMSE scores < 17, time since stroke ≥ 4

months or wrist extension < 20°or fingers extension < 10°. See figure 1 for the study flow chart. The mean age of the participants was 53.71 years and the mean time post stroke was 9.24 weeks. Eight of the subjects that participated in the study had right sided affectation and the remaining 9 had left sided affectation. Table 1 shows the characteristics of the study participants.

Scale	Time period	Experimental group (n=8)			Control group (n=8)		
		Mean±SD	F	p-value	Mean±SD	F	p-value
WMFT	Baseline	2.68±0.71	4.32	0.069	2.68±0.71	4.32	0.069
	2 weeks	3.33±0.94			3.33±0.94		
	4 weeks	3.83±1.1			3.83±1.13		
MAL (AOU)	Baseline	2.60±0.73	7.26	0.025*	2.44±0.64	3.19	0.11
	2 weeks	3.39±0.82			3.05±0.92		
	4 weeks	3.84±0.95			3.43±1.29		
MAL (QOU)	Baseline	2.60±0.73	7.26	0.025*	2.44±0.64	3.19	0.11
	2 weeks	3.39±0.82			3.05±0.92		
	4 weeks	3.84±0.95			3.43±1.29		

Table 2: Presentation of ANOVA Results within experimental and Control groups. *=significant at p< 0.05.

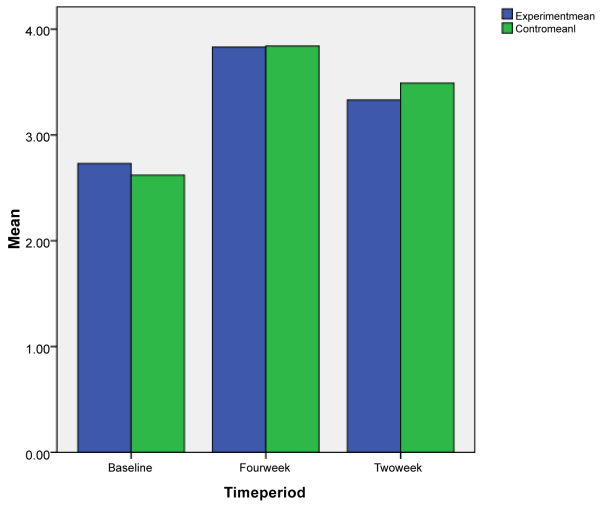

Figure 2: A histogram showing mean WMFT scores at baseline, 2 and weeks post-intervention.

To compare the differences in mean WMFT, MAL (AOU) and MAL (QOU) scores within group between baseline, 2 and 4 weeks post-intervention, a one way repeated measure ANOVA was conducted for both experimental and control groups. The means and standard deviations were presented in table 2 and figures 2, 3 and 4. For the experimental group, there was no significant difference between baseline, 2 weeks and 4 weeks post-intervention; Wilk's lambda = 0.41, F (2,8) = 4.32, P = 0.07, Multivariate partial eta squared = 0.59). For the control group, there was a significant difference between baseline 2 and 4 weeks post intervention, Wilk's lambda = 0.29, F (2, 8) = 7.46, P = 0.024, Multivariate partial eta squared =0.71.

For MAL (AOU), in the experimental group, there was no significant difference between baseline, 2 weeks and 4 weeks post-intervention, Wilk's lambda = 0.49, F (2, 8) = 3.19, p = 0.11, multivariate partial eta square =0.52). For the control group, there was a significant difference between baseline, 2 weeks and 4 weeks post-intervention, Wilk's lambda =0.29,F (2,8) =7.26, p =0.025, multivariate partial eta square =0.71. Similarly, for MAL (QOU), in the experimental group, there was no significant difference between baseline, 2 weeks and 4 weeks post- intervention, Wilk's lambda = 0.49, F (2 ,8) = 3.19, p = 0.11, multivariate partial eta square =0.52). For the control group, there was a significant difference between baseline, 2 weeks and 4 weeks post-intervention.

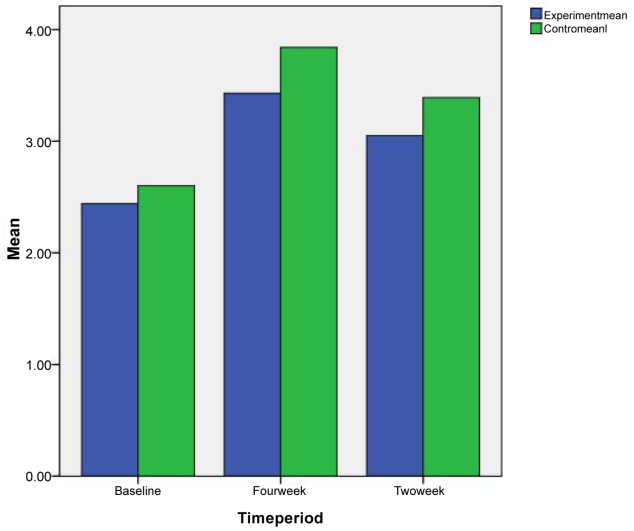

Figure 3: A histogram showing mean MAL (AOU) scores at baseline, 2 and weeks post-intervention.

To compare the differences between experimental and control groups on mean WMFT, MAL (AOU) and MAL (QOU) scores at baseline, 2 weeks and 4 weeks post-intervention, an independent sample t–test was conducted. Table 3 detailed the results for this analysis. At baseline, there was no significant difference in WMFT scores between experimental group (M =2.68, SD =0.71) and control group (M =2.67, SD =0.80; t (16) =0.16, p =0.88, two – tailed). The magnitude of the differences in the means (Mean difference = 0.06, 95% CI: - 0.76 to 0.88) was very small, eta squared = 0.002.

At 2 weeks, there was no significant difference in WMFT scores between experimental group (M =3.3, SD = 0.94) and control group (M = 3.4, SD = 0.90; t (16) = - 0.3, p = 0.72, two tailed). The magnitude of the differences in the means (Mean difference = - 0.17, 95% CI: - 1.15 to 0.82) was very small, eta squared = 0 01.

At 4 weeks, there was no significant difference in WMFT scores between experimental group (M = 0.83, SD = 1.13) and control group (M = 3.88 , SD = 0.79 ; t (16) = - 0.10 , p = 0.92 , two tailed).The

magnitude of the differences in the means mean difference = - 0.05, 95% CI = - 1.09 to 1.00) was very small eta squared < 0.01.

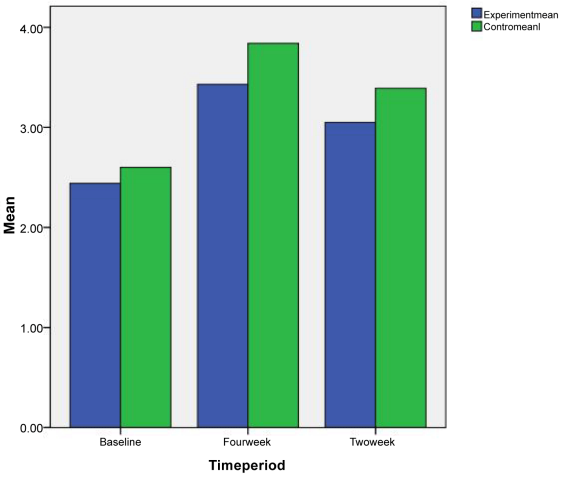

Figure 4: A histogram showing mean MAL (QOU) scores at baseline, 2 and 4 weeks post-intervention.

Scale	Time period	Experimental group (n=8) Mean±SD	Control group (n=8) Mean±SD	t-test		ANCOVA	
				t	P-value	t	P-value
WMFT	Baseline	2.68±0.71	2.62±0.82	0.16	0.88		
	2 weeks	3.33±0.94	3.49±0.90	-0.36	0.72	0.27	0.61
	4 weeks	3.83±1.13	3.88±0.90	-0.10	0.92	0.03	0.87
MAL (AOU)	Baseline	2.44±0.64	2.60±073	-0.47	0.64		
	2 weeks	2.92±1.04	3.44±0.83	-1.11	0.29	1.13	0.53
	4 weeks	3.43±1.29	3.83±0.95	-0.72	0.49	0.29	0.60
MAL (QOU)	Baseline	2.44±0.64	2.60±073	-0.47	0.64		
	2 weeks	2.92±1.04	3.44±0.83	-1.11	0.29	1.13	0.53
	4 weeks	3.43±1.29	3.83±0.95	-0.72	0.49	0.29	0.60

Table 3: Presentation of the Results of Independent Sample t-test and One Way ANCOVA.

For MAL (AOU), at baseline, there was no significant difference between experimental group (M = 2.44, SD = 0.64) and control group (M = 2.60, SD = 0.73; t (16) = - 0.47, p = 0.64, two tailed). The magnitude of the differences in the means (Mean difference = - 0.16, 95% CI: - 0.89 to 0.57) was very small, eta square = 0.02. At 2 weeks, there was no significant difference between experimental group (M = 2.02, SD = 1.04) and control group (M = 3.44, SD = 0.83; t (16) = -1.11, p = 0.29, two tailed). The magnitude of the difference in means (Mean difference = - 0.52, 95% CI: -1.52 to 0.48) was moderate, eta squared = 0.08. At 4 weeks, there was no significant difference between experimental group (M = 3.43, SD = 1.29) and control group (M = 3.84, SD = 0.95; t (16) = -0.72, p = 0.49, two tailed). The magnitude of the difference in means (Mean difference = 0.41, 95% CI: -1.62 to 0.81) was small, eta squared = 0.04

To determine the effect of a covariate (baseline scores) on the mean WMFT, MAL (AOU) and MAL (QOU) scores at 2 weeks and 4 weeks, a one-way analysis of covariance (ANCOVA) was performed. Table 3 detailed the results for this analysis. For WMFT, at 2 weeks post-intervention after adjusting for pre- intervention scores, there was no significant difference between the experimental and control groups, F (1,16) = 0.27, p = 0.61, partial eta squared = 0.02. There was a strong relationship between baseline scores and scores at 2 weeks as indicated by partial eta squared value of 0.31. At 4 weeks post-intervention, there was no significant difference between the experimental and control groups, F (1, 16) = 0.03, p = 0.87. There was a strong relationship between baseline score and scores at 4 weeks as indicated by partial eta squared value of 0.15.

For MAL (AOU), at 2 weeks post-intervention, there was no significant difference between the experimental and control groups, F (1,16) = 1.13, p= 0.53, Partial eta squared= 0.08. There was a strong relationship between baseline scores and scores at 2 weeks as indicated by partial eta squared value of 0.53. At 4 weeks, there was no significant difference between the experimental and control groups, F (1,16) = 0.29, p = 0.60, p = partial eta squared = 0.22. There was a strong relationship between baseline scores and scores at 4 weeks post-intervention as indicated by partial eta squared value of 0.21.

For MAL (QOU), at 2 weeks post-intervention, there was no significant difference between the control and experimental, F (1, 16) = 1.13, P = 0.53, Partial eta squared = 0.08. There was a strong relationship between baseline scores and scores at two week as indicated by partial eta squared value of 0.53. At 4 weeks post-intervention, there was no significant difference between the experimental and control groups F (1,16) = 0.29, p = 0.60, p = partial eta squared = 0.22. There was a strong relationship between baseline scores and scores at 4 weeks post-intervention as indicated by partial eta squared value of 0.21.

Discussion

The aim of this study was to find out the feasibility of standardizing the protocols of CIMT (the tasks practiced, the number of repetitions, and sessions of intervention) in patients within the first 4 months post-stroke. The result of this study showed that there was no significant difference between experimental and control groups respectively in relation to functional ability (using WMFT) and amount of use and quality of use (using MAL).The result also showed that there was a significant difference within group in the functional ability, amount of use and quality of use for the control group.

Similar to the present study, previous and recent studies reported that task practice repetitions ≥ 300 per day was possible.9-10, 19 However, the present study differs from these studies in several ways. For example in the studies by Birkinmeier and colleagues and Abdullahi and Umar, chronic stroke patients were used. In the literature, the fewer the days and/or weeks post-stroke, the better the outcome when rehabilitation is started.1-18 Secondly, even in the

study by Abdullahi and colleagues that reported on acute stroke, only one subject was used. Additionally, the present study was a randomized control trial unlike the studies by Birkinmeier and colleagues and Abdullahi and colleagues which lack controls.

Furthermore, the improvement recorded by this study had attained the expected minimal clinical important difference (MCID) of 1.0- 1.2 and 1.0- 1.2 for WMFT and MAL scores respectively post-intervention. An improvement score of 1.1- 1.2 and 1.24 – 1.26 of MCID from baseline to four weeks for WMFT and MAL was reported respectively. Unlike in the study by Birkinmeier and colleagues which reported < 1.0 for both MAL and WMFT and 8.0 average point for Action Research Arm Test score which was quite smaller than the expected 12 – 17 points change that was estimated in people with stroke. The magnitude of improvement that was recorded in this study could be attributed to the fact that the earlier stroke and the intervention (rehabilitation) the better the recovery outcome [16-19].

Dose-response relationship is a top-most debatable area in neurological rehabilitation [20]. When dose of a rehabilitation is quantified based on the time spent practicing the tasks, it may not necessarily state clearly whether higher or lower dose was practiced [21,22]. In contrast, it is much easier to record and be aware of the amount of task practiced when task repetitions are counted [9,22-24]. Thus, although there were no significance differences on the outcome measures of interest in this study between the use of standardized CIMT and the traditional CIMT, it is much easier to adopt the protocol using the counting of number of task repetitions.

Another peculiarity of this study was that all the patients performed same tasks; and the tasks given to the patients targeted almost all segment of the upper limb activities as dexterity and bilateral trainings were incorporated. Lastly, this study has its own limitations as the sample size is very small and lack of long term follow up.

Conclusion

The data obtained in this study indicates that it was possible for stroke patients who were within 4 months post-stroke to perform 320 repetitions of upper limb task practice spread over 2 sessions per day during CIMT. It is therefore recommended that, therapists should use the standardized form of CIMT in rehabilitation of stroke patients. However, further studies need to be carried out in this field with larger number of participants and for a longer period of time.

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