Number of repetitions versus duration in hours as dose measures of task practice during constraint-induced movement therapy: A pilot randomized controlled trial

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Abstract

Background: Constraint-induced movement therapy (CIMT) is used in rehabilitation of the upper limbs after stroke. However, its protocol, especially the issue of doses, seems not clear as duration of task practice in hours is used as a measure of dose.

Background: The aim of this study is to compare the use of number of repetitions of task practice (sCIMT) and duration in hours (tCIMT) as dose measures during CIMT in chronic stroke patients.

Methods: The sCIMT group performed the same 8 functional tasks 20 times, 2 times a day, 5 times a week for 6 weeks with the affected upper limb. The unaffected upper limb was constrained in an arm sling for 90% of the waking hours during the period of the intervention. The tCIMT group performed 2 hours of task practice (8 tasks) convenient for them with the affected upper limb and constraint of the unaffected upper limb for 5 hours a day, 5 days a week for 6 weeks. The study data were collected using the Wolf motor function test (WMFT) at baseline, 2, 4 and 6 weeks post-intervention. The data were analyzed using the repeated measures ANOVA, independent t-test, and ANCOVA at $p<0.05$.

Results: The results showed significant differences ($p<0.05$) in WMFT functional ability between baseline, and 2, 4 and 6 weeks post-intervention in the sCIMT group. However, there were no significant differences ($p>0.05$) between sCIMT and tCIMT in WMFT functional ability and performance time at baseline, and 2, 4 and 6 weeks post-intervention.

Conclusion: sCIMT is effective and comparable to tCIMT. Moreover, its protocol seems clearer, simpler and more practicable.

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

Introduction

Stroke is a neurological condition characterized by rapidly developing clinical symptoms and/or signs of focal and at times global loss of cerebral function lasting more than 24 hours or leading to death with no apparent causes other than of vascular origin (Hatano, 1976). The consequence of stroke is impairment of brain functions, motor, sensory/ perceptual and cognitive ones (Hendricks et al., 2002; Lang et al., 2013). The impairments can manifest as limb movement and speech difficulties, neglect and apraxia (Čengić et al., 2011; Sun et al., 2014). An important post-stroke deficit is impaired upper limb function, which occurs in about 80% of cases (Nakayama et al., 1994). In the ensuing 2-3 years after stroke, about 25-45% of patients may regain some functions (Broeks et al., 1999); whereas about 50% will continue to have long-term functional impairments (Parker et al., 1986; Olsen, 1990).

One of the rehabilitation techniques for upper limb impairments after stroke is the constraint-

induced movement therapy (CIMT). CIMT involves restraining of the sound limb for a certain period, mostly about 90% of the waking hours and encouraging mass practice of functional tasks with the affected limb (Taub and Berman, 1963; Ostendorf and Wolf., 1981; Taub et al., 1993; Wolf et al., 2006). The available evidence shows that the technique is effective for improving moderate and mild impairment (Wolf et al., 2006; Sirtori et al., 2009; Peurala et al., 2012; Thrane et al. 2014). However, like many rehabilitation techniques, CIMT seems to lack clarity of protocols, especially in regard to doses (Pollock et al., 2014; Abdullahi, 2014).

The lack of clarity in protocols is evident in literature data, which describes different formats concerning the parameters of treatment using CIMT, in particular the duration of restraint of the sound limb and treatment, as well as types of tasks performed with the affected limb. In the EXCITE trial (Wolf et al., 2006 and Uswatte et al. (2006), 6 hours of task practice with the affected limb and constraining the unaffected limb for 90% of the waking hours were used. Similarly, shorter durations of CIMT, e.g. 3 hours and constraint for 90% of the waking hours (Brogardh et al., 2009) or 2 hours and constraint for 6 hours (Dromerick et al., 2009) for 2 weeks have also been reported.

The seemingly contestable claim found in the literature is that shorter duration of CIMT is superior to longer duration of CIMT (Nijland et al., 2011; Peurala et al., 2012; Sirtori et al., 2009) in acute, sub-acute and chronic patients. However, according to a retrospective analysis (Kaplon et al., 2007) of signature CIMT, which involves 6 hours of task practice and constraint for 90% of the waking hours, only 3.5 hours are actually spent by patients on task practice. Likewise, Stock et al. (2015) have reported that only 33% of the total time of a rehabilitation session during CIMT is spent on pure motor activity; the remaining time is used for feedback, task set up and rest, which suggest that the time patients stay during a rehabilitation session is irrelevant.

Recently, there have been reports (Birkinmeier et al., 2010; Abdullahi et al., 2014; Abdullahi & Shehu, 2014; Abdullahi et al., 2015) of a simple, clear and cost effective method of administering CIMT. This method uses the number of repetitions of task practice spread over sessions per day as a measure of dose during CIMT. According to these reports, 300-320 repetitions of task practice per day are sufficient for motor recovery; moreover, this range of repetitions is comparable in terms of effectiveness of CIMT using hours of task practice as a dose measure. However, the use of the number of repetitions of task practice and duration in hours as measures of dose has not been compared in chronic stroke patients. The aim of this study is to answer the following questions:

1) What will be the effect of the use of number of task practice repetitions as a dose measure during CIMT on the motor function in patients 6 months post-stroke?
2) What will be the effect of the use of number of task practice repetitions as a dose measure, on the motor function in patients ≥ 6 months post-stroke, as compared to the use of task practice duration in hours?

Methods

The study was a randomized controlled trial (RCT) with the pretest-posttest design approved by the Research Ethics Committee of Aminu Kano Teaching Hospital. The study population included chronic stroke patients (≥6 months post-stroke) attending the physiotherapy department, Aminu Kano Teaching Hospital (AKTH). The inclusion criteria were clinical diagnosis of haemorrhagic or ischemic stroke, patients ≥6 months post-stroke at baseline, patients with no significant cognitive impairment as indicated by scores of ≥17 on the

mini-mental state examination (MMSE), patients with ≥ 20° of wrist extension and ≥ 10° of extension of all digits, patients with no severe aphasia and severe shoulder pain that could affect therapy.

Twenty-three stroke patients were assessed for the eligibility to participate in the study. Out of this number, only 13 patients fulfilled the study inclusion criteria. The remaining 10 patients did not fulfil the inclusion criteria and were excluded from the study. Only 10 /13 included patients gave their informed consent to participate in the study and they were randomized into the standardized CIMT (sCIMT) group (n=5) and traditional modified CIMT (tCIMT) group (n = 5) using sealed opaque envelopes (Fig. 1)

The instruments used in the study were a full-circle goniometer, the Wolf motor function test (WMFT), mini-mental state examination (MMSE), a stop watch, visual observation and counting of repetitions of tasks. The WMFT consists of 15 timed functional tasks and two strength-based tasks (Wolf et al, 1989). and is a reliable and valid test of upper limb motor function (Sawaki et al, 2008). The functional ability was scored 0 to 5, with higher scores representing better function. Performance time was rated in seconds using a stop watch.

The study participants were assessed at baseline, 2, 4 and 6 weeks post-intervention in both sCIMT and tCIMT groups. The sCIMT group performed the same 8 functional tasks, each 20 times, 2 times a day, 5 times a week for 6 weeks with the affected limb. The details of the functional tasks performed were described in the previous study (Abdullahi et al., 2014). The unaffected limb was constrained in an arm sling for 90% of the waking hours during the period of intervention. The tCIMT group performed 2 hours of tasks practice (8 tasks) convenient for them with the affected upper limb and constraint of the unaffected upper limb for 5 hours a day, 5 days a week for 6 weeks. No additional therapy was given to the upper limbs during the study period in both groups.

The intra-group data in sCIMT and tCIMT groups were analyzed using repeated measures ANOVA, while the inter-group data were checked using the independent t-test. All analyses were carried out using SPSS version 12 at $p<0.05$. Moreover, in order to increase the likelihood of detecting inter-group differences, a one-way analysis of covariance (ANCOVA) was conducted to determine the effect of the covariate (baseline scores) on the post-interventions scores in the sCIMT and tCIMT groups.

Results

The study population included ten patients aged 30-78 years (mean age -58.80±14.33 years), the post-stroke time range of 8-49 months (mean time - 28.70±12.40), 7 females and 3 males, 6 and 4 patients with right-sided hemiplegia, respectively.. Nine patients had ischaemic stroke and only 1 had haemorrhagic stroke. Analysis of the inter-group differences (using an independent t-test for age and time since stroke, and the Mann-Whitney U test for the type of stroke, the side affected and sex) showed no significant inter-group differences ($p>0.05$) (table 1)

Determination of intra-group differences using one-way repeated ANOVA

WMFT results (functional ability)

In the sCIMT group, there was a significant difference in motor function between baseline versus 2, 4 and 6 weeks (Wilk's lambda=0.02, $F=(3,5)=29.20$ $P=0.03$, multi-variate partial eta squared=0.98). Analysis of groups revealed significant differences between baseline and 4 weeks (mean difference=- 0.82, 95% CI; -1.13 to -0.52, p=0.001), baseline and 6 weeks (mean difference=- 1.30, 95% CI; -1.90 to -0.70, p=0.003),

2 and 6 weeks (mean difference=-0.98, 95% CI; -1.49 to -0.46, p=0.005) and 4 and 6 weeks (mean difference=-0.47, 95% CI; -0.93 to -0.02), p=0.04.

In the tCIMT group, there was no significant difference in motor function between baseline versus 2, 4 and 6 weeks (Wilk's lambda=0.l7, F=(3,5)=3.21, p=0.25, multivariate partial eta squared=0.83). The results of analysis are presented in table 2.

WMFT results (performance time)

In the sCIMT group, there was no significant difference in the speed of motor activity between baseline versus 2, 4 and 6 weeks (Wilk's lambda=0. l83, F(3,5)=2.97, p=0.26, multivariate partial eta squared 0.82). Likewise, in the tCIMT, there was no significant difference in the speed of motor activity between baseline versus 2, 4 and 6 weeks (Wilk's lambda=0.13, F(3,5)=4.54, p=0.19, multivariate partial eta squared 0.87) (table 2).

The effectiveness of standardized constraint-induced movement therapy (sCIMT) and traditional constraint-induced movement therapy (tCIMT) compared using an independent t-test

WMFT results (functional ability)

At baseline, there was no significant difference between the sCIMT (mean=2.34, SD=0.52) and tCIMT groups (mean=3.01, SD=0.48) t (10) =-2.15, p=0.06 two-tailed). The magnitude of the difference in the mean (mean difference=-0.68, 95% CI; -1.4 to 0.05) was very large, (eta squared=0.37). Likewise, at 2 weeks, there was no significant difference between the sCIMT (mean=2.66, SD=0.77) and tCIMT groups (mean=3.20, SD=0.32) t (10) = -1.45, p=0.19 two-tailed). The magnitude of the difference in the mean (mean difference= -0.54, 95% CI; -1.4 to 0.32) was again very large, (eta squared=0.21). At 4 weeks, there was no significant difference between the sCIMT (Mean=3.16, SD=0.52) and tCIMT groups (mean=3.60, SD=0.38) t (10) =- 1.52, p=0.17 two-tailed. The magnitude of the difference in the mean (mean difference 0.44, 95% CI; -1.10 to 0.22) was very large, eta squared 0.22. At 6 weeks, there was also no significant difference between the sCIMT (mean=3.64, SD=0.66) and tCIMT groups (mean 3.65, SD=O.40) t (10) =-0.38, p=0.97 two-tailed, yet the magnitude of the difference in the mean (mean difference=-0.01, 95% CI; - 0.81 to 0.79) was very small, eta squared=0.02. (table 3 and figure 2).

WMFT results (performance time)

At baseline, there was no significant difference between the sCIMT (mean=3.94, SD=2.10) and tCIMT groups (mean=4.10, SD=1.60) t (10) =-0. l4, P=0.89 two-tailed). The magnitude of the difference in the mean (mean difference=-0.16, 95% CI; -2.88 to 2.56) was very small, eta squared<0.01. Likewise, at 2 weeks, there was no significant difference between the sCIMT (mean=3.63, SD=1.84) and tCIMT groups (mean=3.52, SD=0.67) t (10) =0.12, P=0.91, two-tailed; the magnitude of the difference in the mean (mean difference=0.10, 95% CI; -1.91 to 2.12) was very small, eta squared<0.01. Similarly, at 4 weeks, there was no significant difference between the sCIMT (mean=2.96, SD=1.99) and tCIMT groups (mean=3.05, SD=1.10) t (10) = - 0.09, p=0.93, two-tailed). The magnitude of the difference in the mean (mean difference=-0.09, 95% CI; -2.44 to 2.25) was very small, eta squared=0.01. At 6 weeks, there was also no significant difference between the sCIMT (mean=2.22, SD=0.72) and tCIMT groups (mean=2.19, SD=0.74) , t(10) =0.06, P=0.95, two-tailed. The magnitude of the difference in the mean (Mean difference=0.03, 95% CI; - 1.03 to 1.09) was very small, eta squared <0.01). (table 3 and fig.3).

Effects of a covariate (baseline scores) on post-intervention scores

WMFT results (functional ability)

At 2 weeks, the Levene's test indicated variance homogeneity - p=0.84, i.e. the variances were equal and the assumption was been violated. After adjusting for baseline scores, the test of inter-subject effects showed no significant differences (p=0.53) 2 weeks after intervention, (F(l, 10) =0.44, partial eta squared 0.06). Moreover, a strong relationship was found between the baseline and post-intervention scores at 2 weeks as indicated by partial eta squared of 0.76, meaning that the covariate explained 76% of the variance in the dependent variable.

At 4 weeks, the Levene's test result showed p=0.13, i.e. the variances were equal and the assumption was not violated. After adjusting for baseline scores, the test of inter-subject effects showed no significant differences (p=0.99) 4 weeks post-intervention (F(l, 1 0)<0.0 1 partial eta squared <0.01). There was also a strong relationship between the baseline and post-intervention scores at 4 weeks as indicated by partial eta squared of 0.51, meaning that the covariate explained 51% of the variance in the dependent variable.

At 6 weeks, the Levene's test showed p-value=0.39, i.e, the variances were equal and the assumption was not violated. After adjusting for baseline scores, the test of inter-subject effects demonstrated no significant differences, (p=0.13) 6 weeks post-intervention (F(l,10)=2.99, partial eta squared=0.3). There was also a strong relationship between the baseline and post-intervention scores at 6 weeks as indicated by partial eta squared of 0.55, indicating that the covariate explained 55% of the variance in the dependent variable (table 4).

WMFT results (performance time)

At 2 weeks, the Levene's test result showed p =0.54, signifying that the variances were equal and the assumption was not violated. After adjusting for baseline scores, the test of inter-subject effects showed no significant differences (p=0.54) 2 weeks post-intervention (F(1,10)=0.42, partial eta squared= 0.06). There was also a strong relationship between the baseline and post-intervention scores at 2 weeks as indicated by partial eta squared of 0.92. The above means that the covariate explained 92% of the variance in the dependent variable.

At 4 weeks, the Levene's test result showed p=0.63, thus the variances were equal and the assumption was not violated. After adjusting for baseline scores, the test of inter-subject effects revealed no significant differences (p=0.92) 4 weeks post-intervention (F(1,10)=0.01 partial eta squared =0.001). There was also a strong relationship between the baseline and post-intervention scores at 4 weeks as indicated by partial eta squared of 0.77, indicating that the covariate explained 77% of the variance in the dependent variable.

At 6 weeks, the Levene's test result showed p=0.65, so the variances were equal and the assumption was not violated. After adjusting for baseline scores, the test of inter-subject effects disclosed no significant differences (p=0.19) 6 weeks post-intervention (F(1,l0= 2.99 partial eta squared 0.23). There was also a strong relationship between the baseline and post-intervention scores at 6 weeks as indicated by partial eta squared of 0.62, showing that the covariate explained 62% of the variance in the dependent variable (table 4).

Discussion

The study findings showed the feasibility and effectiveness of the use of repetition of task practice as a measure of dose during CIMT. Most importantly, no significant differences were demonstrated between the use of number of repetitions of task practice and the use of the traditional protocol of CIMT (duration in hours of task practice) as the dose measures. The results revealed steady improvement in WMFT scores at

2, 4 and 6 weeks from the baseline in the sCIMT and tCIMT groups. At 6 weeks, only the functional ability score for the sCIMT group attained minimal clinically important difference (MClD) (+ l.3). MClD is defined as "the smallest difference in score in the domain of interest, which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" (Jaeschke et al., 1989).

Although the tCIMT has been shown to be very effective for improving the motor function and activities of daily living (Wolf et al., 2006; Sirtori et al., 2009), its protocol seems not to be clear as to the extent of task practiced per session (Kaplon et al., 2007; Stock et al., 2015; Abdullahi et al., 2014). Contrastingly, the sCIMT seems to have a clear protocol since the number of repetitions per session and/ or per day required for motor recovery is known. The number of repetitions per day required for motor recovery is reported to be in the range of 300 and 320 per day (Birkinmeier et al., 2010; Abdullahi et al., 2014; Abdullahi & Shehu, 2014). This finding is consistent with the findings of previous studies in animal models, where 400 and ≥600 repetitions of functional tasks were reported to result in motor learning (Kleim et al., 1998; Nudo et al., 1996). Fortunately, 300 repetitions of task practice have been shown to be possible within just 1 hour. This casts doubts on the appropriateness of the use of duration in hours as a measure of dose of task practice during CIMT as both high- or low-dose task practice repetition is possible within a short or long time.

The above findings are relevant for the healthcare system. Stakeholders, such as the patients, their informal caregivers, health professionals and health management organizations (HMOs) would appreciate it if they knew the amount of task practice required for improvement. In Japan, for instance, the HMOs only pay for CIMT which does not exceed 5 hours (Kagawa et al., 2013; Amano et al., 2015). If the HMOs knew that the required amount of task practice for motor recovery could be performed within fewer hours than they pay, spending could be reduced.. Thus, patients and their caregivers would claim for fewer premiums they pay to the HMOs. In developing countries where the patients and/ or their relatives pay for health services, this finding would be a welcome development for them to claim for less charge. This study, however ,has some limitations, for instance, small sample size.

Conclusion

Using the number of repetitions is an effective measure of dose of task practice during CIMT. Its effectiveness is comparable to that of the traditional CIMT, which uses the duration in hours, which has been previously shown to be effective for improving the upper limb motor function and activities of daily living (ADL). Moreover, using the number of repetitions can prove superior to traditional CIMT as it seems to be clear, simple and cost effective.

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Table 1: Characteristics of the study participants

Characteristics	sCIMT (n=5)	tCIMT (n=5)	p-value
Mean age (years)	57.20±9.50	56.40±12.27	0.94
Mean time since stoke (months)	25.60±12.34	31.80±13.03	0.46
Sex (M/F)	2/3	1/4	0.51
Side affected (L/R)	1/4	3/2	0.22
Type of stroke (I/H)	5/0	4/1	0.32

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

Table 2. Intra-group differences between baseline versus 2, 4 and 6 weeks post-intervention

Table 2: Within group difference between baseline, and 2, 4 and 6 weeks post-intervention

Scale	Time period	sCIMT				tCIMT			
		n	Mean±SD	F	p-value	n	Mean±SD	F	p-value
WMFT FA	Baseline	5	2.34±0.52	29.20	0.03*	5	3.01±0.48	3.21	0.25
	2 weeks	5	2.66±0.77			5	3.20±0.32		
	4 weeks	5	3.16±0.52			5	3.60±0.38		
	6 weeks	5	3.64±0.66			5	3.65±0.40		
WMFT time	Baseline	5	3.94±2.10	2.97	0.26	5	4.10±1.60	4.54	0.19
	2 weeks	5	3.63±1.84			5	3.52±0.67		
	4 weeks	5	2.96±1.99			5	3.05±1.10		
	6 weeks	5	2.22±0.72			5	2.19±0.74		

Table 3. Inter-group differences at baseline, 2,4 and 6 weeks post-intervention

Table 3: Between groups differences at baseline, 2, 4 and 6 weeks post-intervention

Scale	Time period	sCIMT		tCIMT			
		n	Mean±SD	n	Mean±SD	t-value	p-value
WMFT FA	Baseline	5	2.34±0.52	5	3.01±0.48	-2.15	0.06
	2 weeks	5	2.66±0.77	5	3.20±0.32	-1.45	0.19
	4 weeks	5	3.16±0.52	5	3.60±0.38	-1.52	0.17
	6 weeks	5	3.64±0.66	5	3.65±0.40	-0.38	0.97
WMFT time	Baseline	5	3.94±2.10	5	4.10±1.60	-0.14	0.89
	2 weeks	5	3.63±1.84	5	3.52±0.67	0.12	0.91
	4 weeks	5	2.96±1.99	5	3.05±1.10	-0.09	0.93
	6 weeks	5	2.22±0.72	5	2.19±0.74	0.66	0.95

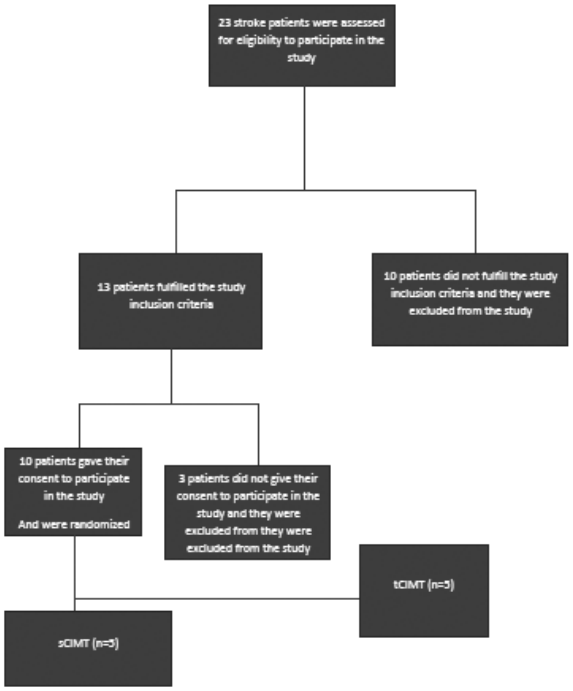

Figure 1. The Study Flowchart

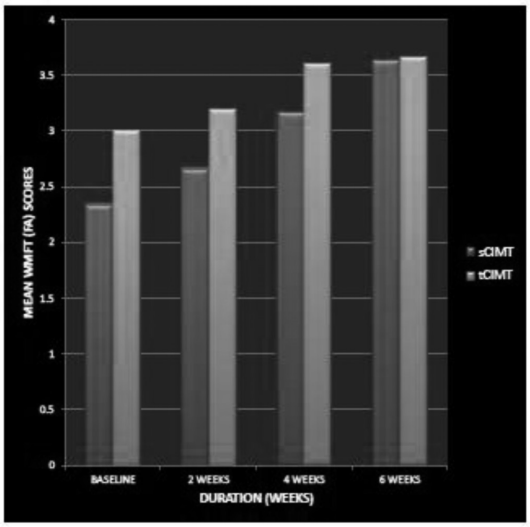

Figure 2

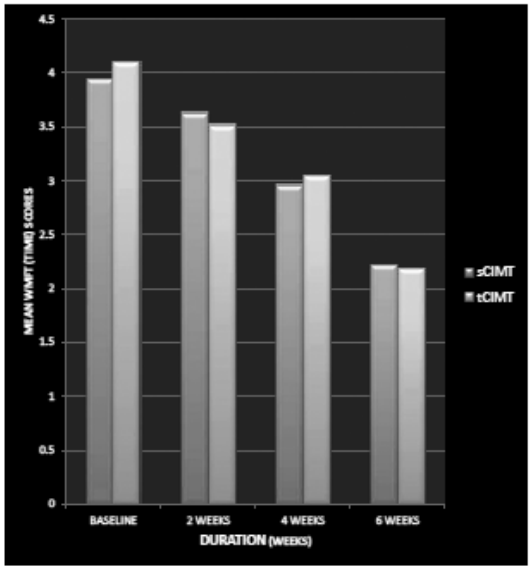

Figure 3

Table 4. Inter-group differences at 2, 4 and 6 weeks post-intervention with baseline scores as covariates

Table 4: Between groups differences at 2, 4 and 6 weeks post-intervention with baseline scores as the covariates

Scale	Time period	sCIMT				tCIMT			
		n	Mean±SD	F	p-value	n	Mean±SD	F	p-value
WMFT FA	Baseline	5	2.34±0.52	29.20	0.03*	5	3.01±0.48		
	2 weeks	5	2.66±0.77			5	3.20±0.32	0.44	0.53
	4 weeks	5	3.16±0.52			5	3.60±0.38	0.000	0.99
	6 weeks	5	3.64±0.66			5	3.65±0.40	2.99	0.13
WMFT time	Baseline	5	3.94±2.10	2.97	0.26	5	4.10±1.60		
	2 weeks	5	3.63±1.84			5	3.52±0.67	0.42	0.54
	4 weeks	5	2.96±1.99			5	3.05±1.10	0.01	0.92
	6 weeks	5	2.22±0.72			5	2.19±0.74	2.13	0.19

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