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ORIGINAL RESEARCH

Influence of constraint induced movement therapy on functional performance in stroke patients: a randomized clinical trial

Influência da terapia de restrição e indução do movimento no desempenho funcional de pacientes com acidente vascular encefálico: um ensaio clínico randomizado

Repercusión de la terapia de restricción y inducción del movimiento en el rendimiento funcional de pacientes con accidente cerebrovascular: un ensayo clínico randomizado

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ABSTRACT | The Constraint Induced Movement Therapy (CIMT) can assist in the recovery of patients with post cerebrovascular accident sequelae. The aim was to assess whether the modified CIMT interferes with the balance and functional mobility of individuals in the chronic phase post-CVA. We conducted a randomized, blinded, clinical trial with 19 patients in the chronic phase post-CVA. Group 1, "no constraint," was submitted only to the paretic upper limb (UL) specific training (shaping). Group 2, "with constraint," was submitted to the paretic UL specific training (shaping) and non paretic UL constraint. The training was carried out 3 times a week for 4 consecutive weeks. The volunteers were evaluated before and immediately after the sessions with the Berg Balance scale (BBS), Timed "up & go" (TUG), evaluation of gait speed and going up and down stairs. Mann-Whitney test showed that the balance (BBS) showed significant improvement (p=0.014) in the group that used the constraint in the intra-group analysis. There was improvement in the gait speed (p=0.050) in the intergroups analysis. It was concluded that the modified CIMT influenced in the balance and gait speed of the Group submitted to the paretic UL specific training and constraint in the non-paretic UL.

Keywords | Stroke; Mobility Limitation; Gait.

RESUMO | A terapia de restrição e indução ao movimento (TRIM) pode auxiliar na recuperação de pacientes com sequelas pós-acidente vascular encefálico. Objetivou-se avaliar se a TRIM modificada interfere no equilíbrio e na mobilidade funcional de indivíduos na fase crônica pós-AVE. Foi realizado um ensaio clínico, randomizado, cego, com 19 pacientes na fase crônica pós-AVE. O grupo 1, "sem restrição", foi submetido apenas ao treinamento específico do membro superior (MS) parético (*shaping*). O grupo 2, "com restrição", foi submetido ao treinamento específico do MS parético (*shaping*) e restrição no MS não parético. O treinamento foi realizado três vezes por semana, durante quatro semanas consecutivas. Os voluntários foram avaliados antes e imediatamente após as sessões com a Escala de Equilíbrio de Berg (EEB), Timed Up and Go (TUG), avaliação da velocidade da marcha e de subir e descer escada. O teste de Mann-Whitney mostrou que o equilíbrio (EEB) apresentou melhora significativa (p=0,014) no grupo que utilizou a restrição, na análise intragrupo. Houve melhora na velocidade da marcha (p=0,050) na análise intergrupos. Concluiu-se que a TRIM modificada influenciou no equilíbrio e na velocidade da marcha do grupo submetido ao treinamento específico do MS parético e restrição no MS não parético.

Descritores | Acidente Vascular Cerebral; Limitação da Mobilidade; Marcha.

RESUMEN | La terapia de restricción y inducción al movimiento (TRIM) puede auxiliar en la recuperación de pacientes con secuelas post-accidente cerebrovascular

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(ACV). Se objetivó evaluar se la TRIM modificada interfiere en el equilibrio y en la movilidad funcional de individuos en fase crónica post-ACV. Fue realizado un ensayo clínico, randomizado, ciego, con 19 pacientes en fase crónica post-ACV. El grupo 1, "sin restricción", fue sometido sólo al entrenamiento específico del miembro superior (MS) parético (*shaping*). El grupo 2, "con restricción", fue sometido al entrenamiento específico del MS parético (*shaping*) y restricción en el MS no parético. El entrenamiento fue realizado tres veces por semana, durante cuatro semanas consecutivas. Los voluntarios fueron evaluados antes y inmediatamente despues de las sesiones con escala de equilibrio de Berg (EEB), Timed Up and Go (TUG), evaluación de la velocidad de marcha y de subir y bajar por escaleras. La prueba de Mann-Whitney mostró que el equilibrio (EEB) presentó mejora significativa (p=0,014) en el grupo que utilizó la restricción en el análisis intragrupo. Hubo mejora en la velocidad de marcha (p=0,050) en el análisis intergrupos. Se concluyó que la TRIM modificada repercutió en el equilibrio y en la velocidad de marcha del grupo sometido al entrenamiento específico del MS parético y restricción en el MS no parético.

Palabras clave | Accidente Cerebrovascular; Limitación de la Movilidad; Marcha.

INTRODUCTION

According to the World Health Organization (WHO), cerebrovascular diseases have been the leading death cause in the world since the 1970s[1]. Due to increased life expectancy and changes in lifestyle of the population, the cerebrovascular accident (CVA) is becoming increasingly common. In addition to the large number of older people affected, it is possible to observe increase of incidence among young people, mainly due to the association with arterial hypertension[2,3]. CVA is a serious public health problem, due to the generation of charge with early retirements and hospitalization expenses[4].

The brain injury results in temporary or permanent neurological deficits, of varied intensities[5]. Among the signs and symptoms observed after brain injury, hemiplegia or hemiparesis stand out as the most common clinical sign of the disease[6]. In addition, hemiparesis patients may exhibit reduced muscle strength and resistance[7], tone change[8], changes in sensory-motor integration, lack of stability and coordination between trunk and limbs during functional activities and gait[9].

In an attempt to decrease the functional deficits, mainly of the paretic upper limb, many techniques have been developed, among them the constraint induced movement therapy CIMT). This technique has been employed to increase the function of the paretic upper limb (UL) post-CVA[10]. The technique, in the original version, consists of repetitive motor activities and guided for up to 6 hours per day, while the non-paretic UL is maintained with a containment device for 90% of awake time[11].

Taub et al.[12] were the first to submit a clinical trial using the CIMT during 90% of the awake time. However, different protocols have been proposed with shorter constraint time, for example, during 6[13] or 5 hours[14]. Studies that investigated the effects of CIMT on the balance and functional performance of gait are scarce in the literature. With the increased use of paretic UL, there may be improvement of the upper limbs and trunk coordination, with balance improvement and the mass center positioning. This study aimed to investigate the possible effects of constraint of the non-paretic UL on balance and functional mobility in post-CVA patients.

METHODOLOGY

This randomized, controlled, blind clinical trial type study, constituted a pilot developed with individuals in the chronic post-CVA phase. It was developed in the Laboratório de Neurociência Aplicada e de Cinesiologia and Avaliação Funcional of the Department of Physical Therapy at the Universidade Federal de Pernambuco (UFPE).

The target population was composed of individuals in the chronic phase post-CVA and the sample consisted of 19 chronic hemiparetic patients, selected from searches on screening files of the Rehabilitation Center of the Instituto de Medicina Integral at the Faculdade Integrada do Recife/Estácio and Hospital das Clínicas. Participants were also called for disclosure on the university radio and waiting lists of projects with CVA in UFPE. The sample selection flowchart can be visualized in Figure 1.

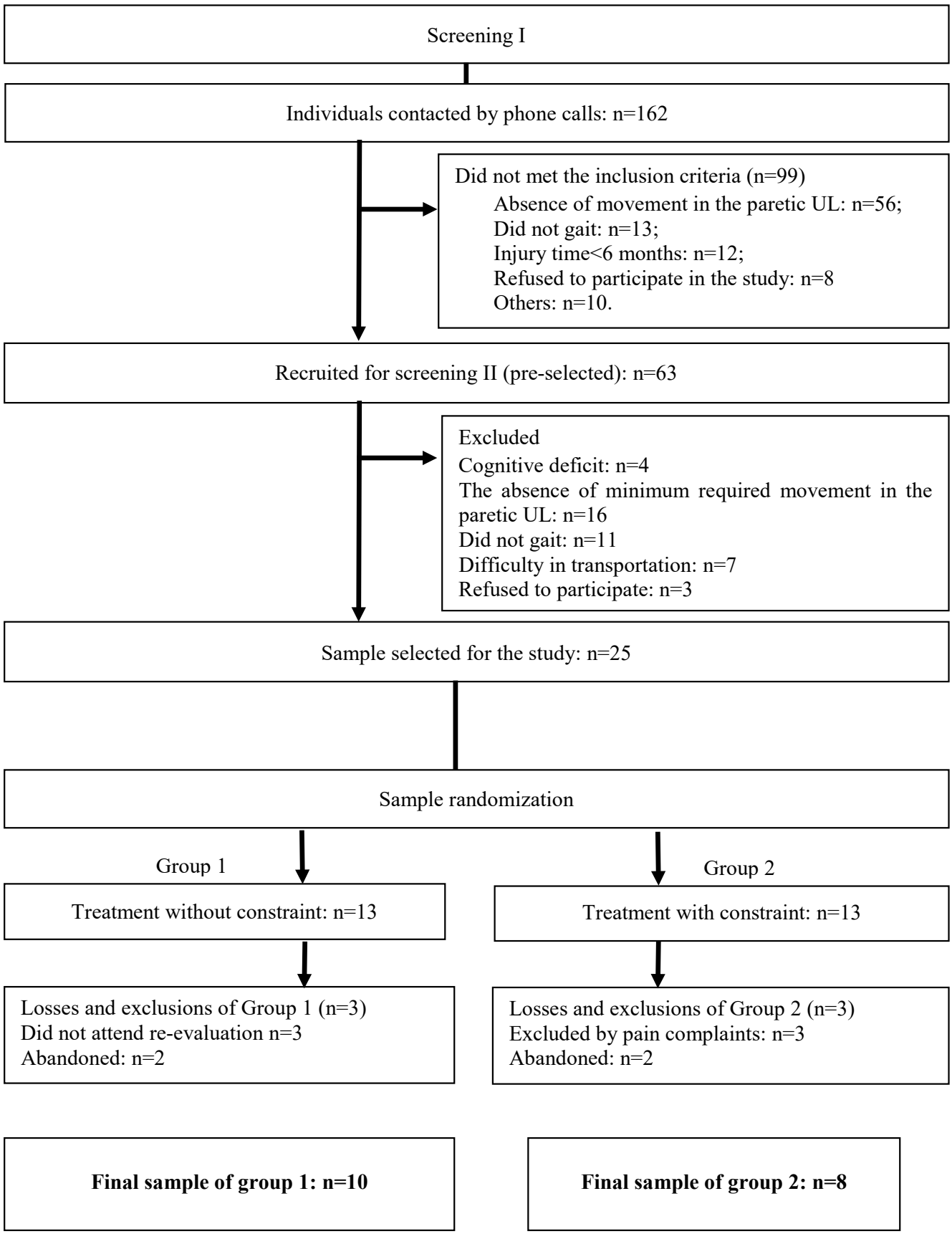

Figure 1. Sample selection flowchart

To be included in the study, it was necessary the diagnosis of ischemic or hemorrhagic CVA, primary or recurrent, for more than 6 months; to be 21 years old or older; understanding to answer the formulated questions, evaluated with the Mini Mental State Examination\ Brazilian version[15]; ability to perform some tasks with the paretic UL (such as to handle dominoes and marbles), ability to move from a sitting to a standing position, to keep the balance standing by at least two minutes. Patients with auditory deficits and/or speech disorders that would cause misunderstanding and difficulty of communication between the interlocutors and/or that performed physical therapy for less than 6 months were excluded from the study.

After the initial screening, anthropometric, demographic and clinical data were collected with a standardized assessment form. After collecting these data, the initial assessment (T0) was performed. At the end of this process, another researcher was told, responsible for sample randomization, the patients enrolled in the study, leaving the evaluator blind in regard to allocations. Composition of the sample and the characterization of groups were only known by the evaluation researcher upon completion of all the revaluations (T1). The evaluations before (T0) and after (T1) the therapeutic sessions were held without the use of constraint, regardless of the group. The randomization was done by means of a numerical sequence table created by a statistician not engaged in the research, in two groups: Group 1 "no constraint" and group 2 "with constraint".

The primary outcome was the Berg Balance Scale and the secondary outcomes were: gait speed, timed "Up and Go" (TUG) and going up and down stairs.

Group 1 "no constraint" was submitted to modified CIMT (based on the shaping activities), without using immobilization of the non-paretic UL. Group 2 "with constraint" was submitted to modified CT (shaping activities) and use of immobilization of the non-paretic UL.

Volunteers were submitted, 3 times a week for 4 consecutive weeks to 40 minutes of the paretic UL specific training. The patient remained sitting in front of a table and each task was timed. Maximum allowable time was 3 minutes to complete each task. During the sessions, it was emphasized to the patient and/or caregiver, in the case of Group 2 "wih constraint", the need for daily use of constraint for 6 hours and the record of activities carried out during the non-paretic UL immobilization hours (e.g., feeding, dressing, etc).

The modified CIMT consisted of complete immobilization of the non-paretic UL and paretic UL training. Complete immobilization of the non- paretic UL was made by using a sling, with the shoulder in adduction and medial rotation, forearm (in 90° bending), wrist and fingers in neutral position, made to measure for each patient.

For use the constraint outside the lab, an agreement among physical therapist, caregiver and patient was established, in which the caregiver should undertake to describe the placement, removal and replacement of the sling in detail in a journal. When the withdrawal of constraint occurred, the patient and/or caregiver would record the reason in a journal.

Descriptive statistics (mean and confidence interval, CI), normality tests (Shapiro-Wilk) and data homogeneity tests (Levene) were calculated for all the measures assessed. For intergroups comparison, in pre- and post-intervention, we used the Mann-Whitney test. The intra-group analysis before and after the intervention was performed by the Wilcoxon test. The significance level adopted was a≤0,05. The software used for data analysis were the Excel 2010 and SPSS (*Statistical Package for Social Sciences*).

All volunteers and their guardians were informed about the goals and procedures of the study and that they could be allocated to any of the study groups. Participation was voluntary, pursuant to Resolution 466/2012 of the National Health Council – CNS. The study was approved by the Ethics and Research Committee of the Center for Health Sciences at UFPE (CEP/CCS/UFPE no. 036/10) and registered in the clinical trials database *Clinical Trials* (http://clinicaltrials.gov) under no. NCT01623973.

RESULTS

The Intergroup analysis (no constraint versus with constraint) before the therapeutic intervention showed that the samples did not differ significantly for most of the variables studied, except for TUG (p=0.022) and going up and down stairs test (p=0.011), as it can be seen in Table 1, which exposes the demographic and clinical data of outcome measures.

Table 2 presents the intra-group analysis, comparing pre-and post-treatment scores for each of the groups.

The group that used constraint, the values obtained on the scale of Berg showed significant improvement (p=0.014), but there was no difference intergroups. The group without constraint did not show significant gains in any of the parameters evaluated.

The comparison between groups, post-intervention, showed difference between the groups in the test Timed "up and go" (p=0.018), going up and down stairs (p=0.014) and gait speed (p=0.050), as indicated in Table 3, with the intergroups analysis in the post-intervention phase.

Table 1. Demographic, clinical and outcome measures assessed data

Variables	Group 1 without constraint	Group 1 with constraint	*p* value
Age (years)	59.5 (52.0;66.9)	52 (42.4; 61.5)	0.278*
Gender, N (%)			
Male	5 (50)	6 (66.7)	0.463
Female	5 (50)	3 (33.3)	
CVA Time (months)	29.3 (11.6; 46.9)	13.7 (7.7; 19.8)	0.095*
CVA Type, N (%)			
Ischemic	9 (90)	6 (66.7)	0.213**
Hemorrhagic	1 (10)	3 (3.33)	
Paretic UL, N (%)			
Right	6 (63.6)	8 (88.9)	0.153**
Left	4 (36.4)	1 (11.1)	
Manual preference, N (%)			
Right	9 (90.9)	9 (100)	0.333**
Left	1 (9.1)	0 (0)	
BBS (Mean; CI)	45.50 (38.86; 52.14)	48.33 (43.5; 53.16)	0.622*
TUG (Mean; CI)	20.67 (13.90; 27.43)	12.29 (9.63; 14.94)	0.022*
Stairs (Mean; CI)	26.75 (16.22; 37.27)	13.37 (9.36; 17.37)	0.011*
Gait speed (Mean; CI)	0.680 (0.44; 0.91)	0.954 (0.74; 1.15)	0.055*

*Mann-Whitney Test; ** Chi square; Berg: balance scale; TUG: Time "up and go" test; Stairs: going up and down stairs

Table 2. Intra-group Analysis, according to Berg Balance Scale, Test Timed "up and go", going up and down stairs and gait speed

Variables	Group 1 (no constraint)		*p value	Group 2 (no constraint)		*p value
	T0	T1		T0	T1	
	℘ (CI)	℘ (CI)		℘ (CI)	℘ (CI)	
BBS	45.5 (38.86; 52.14)	48.3 (41.78; 54.82)	0.074	48.3 (43.5; 53.16)	51.8 (48.51; 55.27)	0.014
TUG	20.6 (13.90; 27.43)	19.8 (12.78; 26.81)	0.721	12.2 (9.63; 4.94)	11.5 (9.29; 13.89)	0.953
Stairs	26.7 (16.22; 37.27)	21.1 (15.61; 26.61)	0.093	13.3 (9.36; 17.37)	13.0 (9.79; 16.36)	0.859
Gait speed	0.6 (0.44; 0.91)	0.7 (0.48; 0.93)	0.201	0.9 (0.74; 1.15)	1.0 (0.81; 1.19)	0.553

* Wilcoxon test; X=Mean; CI: Confidence Interval; BBS: Berg Balance Scale; TUG: timed "up and go" test; Stairs: going up and down stairs

Table 3. Intra-group analysis in post-intervention according to Berg Balance Scale, test Timed "up and go" and going up and down stairs and the gait speed

Variables	Group 1 (no constraint)	Group 2 (no constraint)	*p value
	T1	T1	
	℘ (CI)	℘ (CI)	
BBS	48.3 (41.78; 54.82)	51.8 (48.51; 55.27)	0.591
TUG	19.8 (12.78; 26.81)	11.5 (9.29; 13.89)	0.018
Stairs	21.1 (15.61; 26.61)	13.0 (9.79; 16.36)	0.014
Gait speed	0.7 (0.48; 0.93)	1.0 (0.81; 1,19)	0.050

*Mann-Whitney Test; BBS: Berg Balance Scale; TUG: timed "up and go" test; Stairs: going up and down stairs

DISCUSSION

This study aimed to investigate the possible effects of constraint of the non-paretic UL on balance and functional mobility in post-CVA patients. It was the first study to apply a time of reduced constraint (6 hours), associated with the activities of shaping for 40 minutes, 3 times during the week for 4 consecutive weeks.

Oscillation and coordination among the UL, the trunk and the gravity center are changed in post-CVA individuals[16]. In this study, individuals after using the non-paretic UL constraint showed improvement in the scale of Berg in intra-group analysis. Increased use of the paretic UL may have influenced the improvement of coordination of the upper limbs and the trunk, consequently influenced positively in the balance [17]. Another explanation would be that the non-paretic UL constraint may cause reorganization of the central mass, which is changed after the CVA and usually displaced to the affected side[18].

For the gait speed test, after the intervention, there was significant improvement in the intergroups analysis. The sling increases the feedback of individuals when forcing them to use the affected hemibody. Postural adaptations occur, reducing the horizontal and vertical displacements during the gait. This minor oscillation had positive impact on coordination and speed[19].

Fuzaro et al.[17] observed improvement in gait speed test and TUG. During the gait presented by individuals with CVA, the compensations, motor deficits and non-coordination cause increased energy expenditure and imbalance. Coordination between the upper and lower limbs is essential[20] and CIMT can provide improvement of motor function and quality of life of this population.

Individuals with CVA often neglect the affected hemibody, leading to the increase of their deficits, with this, after the forced usage required by constraint therapy there is a increased proprioception of trunk control, and visual feedback, referred to as possible influences on the improvement of motor skills and functional independence[17]. Lin et al.[21] corroborate this idea that individuals submitted to CIMT improve the personal aspects, such as self-care.

Studies with longer constraint time observed positive effect in numerous tests, such as Action Reserch Arm Test, Fugl- Meyer, Wolf Motor Function Test, Motor Activity Log (MAL) and Stroke Impact Scale (SIS)[10,14,17,21]. Motion patterns presented by post-CVA individuals are correlated with the motor sequelae found. Early onset of therapy has direct influence on functional gains in motor performance and locomotion[22]. This factor can have great influence on homogeneity between the groups.

In this study, the groups were not different in the Timed Up and Go Test (TUG) and the test of going up and down stairs and showed no gains in intra-group analysis. As the groups were formed after the end of assessments, the Timed Up and Go (TUG) variables and the going up and down stairs test presented heterogeneity, making statistical analysis difficult. The criterion of demand flow should be reconsidered in future studies to obtain better sample distribution and higher number of patients in each group.

CONCLUSION

The use of constraint therapy for 6 hours a day positively influenced in the gait speed of hemiparetic individuals. Studies with different times of use of constraint therapy and exercises are indicated to deepen the subject.

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