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EVALUATION OF CONSTRAINT-INDUCED THERAPY COMPARED TO A CONVENTIONAL PHYSICAL THERAPY PROGRAM WITH MOTOR AND COGNITIVE PERFORMANCE IN POST-ACUTE STROKE PATIENTS: PILOT PROJECT OF A RANDOMIZED CLINICAL TRIAL

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Abstract: Background: Stroke is one of the leading causes of long-term disability, resulting in persistent motor and cognitive impairments that limit independence and quality of life. Constraint-Induced Movement Therapy (CIMT) has demonstrated efficacy in enhancing motor recovery after stroke through neuroplastic mechanisms; however, its impact on cognitive performance remains less explored. **Objective:** To compare the effects of Constraint-Induced Movement Therapy and conventional physical therapy on motor and cognitive performance in patients recovering from an acute stroke. **Methodology:** This single-blind, randomized clinical pilot trial included eight post-acute stroke patients (aged 47–79 years) allocated equally to two groups: one received CIMT for 3 hours per day over 15 consecutive days, and the other received individualized conventional physical therapy twice weekly for 6 months. Cognitive performance was assessed using the Mini-Mental State Examination (MMSE), Rey Auditory Verbal Learning Test (RAVLT), and other standardized neuropsychological tests. Motor function was evaluated with the Wolf Motor Function Test (WMFT), Motor Activity Log (MAL), and Barthel Index. Assessments were performed before and 15 days after the interventions. **Results:** The CIMT group (62.0 ± 3.92 years) and the control group (61.0 ± 16.49 years) showed improvements in both cognitive and motor domains. MMSE scores increased from 21.0 ± 5.48 to 23.5 ± 4.04 in the CIMT group and from 21.3 ± 5.38 to 22.05 ± 5.6 in the control group ($p = 0.24$). RAVLT scores improved more in the CIMT group (3.3 ± 1.75 to 7.3 ± 1.5) than in the control group (5.3 ± 6.19 to 5.5 ± 5.80; $p = 0.015$). WMFT scores rose from 51.5 ± 11.45 to 62.8 ± 13.38 in the

CIMT group and from 52.5 ± 6.5 to 61.25 ± 6.19 in the control group ($p = 0.26$). **Conclusion:** Both interventions improved motor and cognitive performance; however, CIMT produced slightly greater gains, suggesting potential benefits for integrated neuroplastic recovery. Larger trials are required to confirm these findings.

Keywords: Stroke rehabilitation; Constraint-Induced Movement Therapy; Motor recovery; Cognitive performance; Neuroplasticity.

INTRODUCTION

Stroke is a cerebrovascular disease and a leading cause of disability in Western countries (DOBKIN, 2005). In the United States, it represents the principal cause of disability, with approximately 730,000 cases per year (WINSTEIN, 2003). In Brazil, according to the Ministry of Health, over 68,000 deaths from stroke are recorded annually, representing one of the main causes of death and disability in the country and generating a substantial economic and social impact (DATASUS, 2013).

Stroke is defined as a rapidly developing clinical sign of focal loss of cerebral function, of presumed vascular origin, lasting more than 24 hours (SOUSA, 2012). Its etiology is multifactorial, with one of the most frequent causes being insufficient cerebral blood supply due to arterial occlusion or vascular hemorrhage (FEIGIN, 2003). The incidence of ischemic stroke is approximately 60% of cases, with the middle cerebral artery being the most commonly affected (YEE SIEN, 2007).

After central nervous system (CNS) injury, the brain exhibits neuroplasticity, defined as the ability of neurons to alter their function, neurochemical activity, or structure in response to changes; this is an adaptive process that occurs within the CNS. Neuroplasticity is associated with learning, memory, and cellular recovery following injury (WOOLF and SALTER, 2000). It enables the CNS to store and retrieve information, which can be reactivated through environmental stimuli (JOHANSSON, 2004).

Similar to other tissues, the CNS has the capacity for adaptation, recovery, or compensation for neuronal loss and disruptions in neural architecture (ANTUNES, 2006). Numerous studies in both animal models and humans have shown that neural plasticity compensates for motor function loss after stroke (TAKEUCHI and IZUMI, 2012). Following cerebral ischemic injury, a cascade of molecular, genetic, physiological, and anatomical events occurs, allowing non-lesioned brain structures to reorganize. These events are often associated with recovery of lost function (DANCAUSE and NUDO, 2011).

In post-stroke patients, motor task performance is associated with altered patterns of cortical motor activation, with increased activity in motor areas of the contralesional hemisphere (CALIL, 2007). This occurs due to adaptive plasticity mediated by recruitment of non-primary motor cortical areas or contralesional hemisphere structures (HAGGARD, 2000). Functional MRI studies in post-stroke patients have shown that execution of upper limb motor tasks is associated with bilateral activation of primary and premotor cortical areas and greater connectivity between ipsilesional and contralateral prefrontal and premotor cortices, even when individuals have intact motor areas. Improved motor control of the hemiparetic side was associated with increased activation of prefrontal areas involved in memory, cognition, and visuospatial transformations. These findings suggest that neuroplasticity links aspects of motor control to modulation of prefrontal activity, thereby stimulating cognitive processes (DENNIS, 2011).

The most common deficit caused by stroke is motor impairment, often hemiplegia, defined as a loss or limitation of muscular function or mobility (LIN, 2009). Approximately 70–80% of patients experience upper limb motor dysfunction (HUSEYINSINOGLU, 2012). Even mild upper limb impairment negatively impacts quality of life due to difficulties performing activities of daily living (ADLs) (NICHOLS-LARSEN, 2005).

Cognitive deficits are also common, affecting approximately 64% of patients, with significant consequences for quality of life and independence (LEES, 2013). Some studies indicate that post-stroke cognitive deficits may accelerate the onset of Alzheimer's disease (MARZOLINI, 2013). Despite its prevalence, few randomized studies exist on cognitive rehabilitation approaches (PINTER and BRAININ, 2012).

Various interventions are employed in physical therapy and neuropsychology to rehabilitate motor and cognitive function in post-stroke patients (LANGHORNE, 2009). Evidence supports early initiation of motor rehabilitation for enhanced recovery (VAN, 2012). A large, randomized trial, known as AVERT, demonstrated significant benefits of early mobilization within 24 hours of symptom onset (BERNHARDT, 2006). The main goal of early mobilization is to remove patients from bed as quickly as possible (BERNHARDT, 2008). Beyond motor benefits, psychological improvements have been reported, with significant quality-of-life gains observed three months post-intervention (CUMMING, 2008). Aerobic and resistance exercises have also been shown to improve cognition in post-stroke patients (MARZOLINI, 2013).

In cognitive therapy, stimulation and social interaction have been used in rehabilitation (CUMMING, 2013). Language practice and memory stimulation are also employed (PINTER and BRAININ, 2012). However, the effects of memory and cognitive rehabilitation remain poorly understood due to the lack of randomized studies validating these methods (LANGHORNE, 2011).

Despite the availability of multiple therapeutic resources, few techniques target the simultaneous rehabilitation of cognition and motor function. Constraint-Induced Therapy Movement (CIMT) has been primarily studied in post-stroke patients (SILVA, 2010). CIMT is a behavior-based rehabilitation program aimed at improving use of the limb affected by neurological injury (TAUB and USWATTE, 2006). Initial studies using primate models demonstrated motor gains, and subsequent human studies confirmed improvements in motor function. CIMT is now applied to patients with CNS injuries resulting in motor sequelae (TAUB, 2012).

CIMT emphasizes fundamental components such as task-oriented repetitive training, restraint of the unaffected limb, and behavioral techniques, all aimed at cortical reorganization (WOLF, 2008). The technique is based on the theory of "Learned Non-Use", which reduces the use of the unaffected limb to force repeated use of the affected limb, resulting in the formation of new motor engrams (TAUB, 2002). Functional MRI studies during CIMT have shown increased brain activity associated with enhanced neuroplasticity, correlating with improved motor performance at therapy completion (STARK, 2012; KÖNONEN, 2012; WU, 2010).

Animal studies, in which rats subjected to cerebral ischemia underwent CIMT, demonstrated motor recovery associated with reorganization of the somatosensory cortical network (JOO, 2012). In humans, improvements in upper limb motor skills were observed in two randomized groups: one treated within nine months post-injury and another within fifteen months. Both groups showed significant motor improvements, with the earlier intervention group achieving superior fine motor outcomes (LANG, 2013).

Chronic post-stroke patients with mild-to-moderate upper limb deficits also showed functional gains following CIMT (TAUB, 2013; LIN, 2009; AZAB, 2009), with significant improvements even in those with moderate-to-severe motor sequelae (BONIFER, 2005). CIMT has been associated with improved quality of life (DETTMERS, 2005), reduced spasticity (confirmed via electromyography) (KAGAWA, 2013), and long-term functional benefits, with gains persisting four years post-intervention (BROGARDH, 2009).

A systematic review of 14 randomized controlled trials using CIMT demonstrated that it is increasingly employed for motor rehabilitation, showing significant improvements in upper limb function compared to other physiotherapeutic approaches (HAKKENNES and KEATING, 2005). Although some studies reported cognitive improvements following CIMT, cognition was not the primary focus, leaving the effect on cognitive function uncertain (TAUB, 2003).

The role of CIMT in rehabilitating motor and cognitive function remains incompletely explored. Therefore, it is crucial to investigate improvements in motor and cognitive function in post-stroke patients following CIMT-based rehabilitation.

METHODOLOGY

This pilot project was characterized as a single-blind randomized clinical trial, with an intervention group receiving Constraint-Induced Movement Therapy (CIMT) and a control group receiving conventional physical therapy. The study compared the effect and value of an intervention (preventive or therapeutic) with controls in humans, in which the investigator randomly assigned the intervention factor using a randomization technique (KESTENBAUM, 2009).

After project approval by the IRB of the Hospital de Clínicas de Porto Alegre (HCPA) under protocol 572.34, the sample selection phase began. The study population consisted of post-acute stroke patients, regardless of sex or socio-demographic conditions, aged 47–79 years, treated by the Neurovascular team of the Neurology Service at HCPA and Hospital Nossa Senhora das Graças (HNSG) in Canoas, who had not undergone thrombolytic therapy.

Four assessments of motor and cognitive performance were conducted at baseline, 15 days, 3 months, and 6 months after the initial evaluation in both groups. The intervention group received CIMT for 15 consecutive days, while the control group received conventional physical therapy twice weekly for 6 months. This report presents only partial results of the study.

Patients were initially contacted by phone, and the researcher invited them to participate, explaining all study procedures and administering a brief screening questionnaire covering confidential medical information (medical history and exclusion criteria). Volunteers meeting initial inclusion criteria were invited for an evaluation, which included personal and sociodemographic data collection and dementia assessment using the Clinical Dementia Rating (CDR). Patients with a CDR score of 0 were included.

After this selection interview, the researchers handed the protocols to a researcher not involved in the selection process, who conducted randomized allocation to one of the two groups. Blinding of the researcher was not possible, as they were aware of group allocations. Following allocation, patients were assessed for cognitive and motor function.

Inclusion criteria included patients with ischemic or hemorrhagic stroke in the acute phase (up to 6 months post-diagnosis), NIHSS scores of 0–17 (0 = normal, 0–5 = mild deficit, 5–17 = moderate deficit), and CDR = 0. All participants provided informed consent.

Exclusion criteria included blindness, deafness, lack of social engagement, aphasia, illiteracy, moderate to severe depression, or other neurological pathologies. CIMT was contraindicated for patients with upper limb flaccidity (inability to perform voluntary movement), balance deficits (risk of falls), cognitive impairments, or upper limb bone deformities. The Berg Balance Scale was used to assess fall risk, and the Beck Depression Inventory was used to identify depressive symptoms as exclusion criteria.

Assessments were conducted at baseline and 15 days post-initial evaluation in both groups. Motor performance was evaluated using the Wolf Motor Function Test (WMFT) and Motor Activity Log (MAL), which were designed to assess mild-to-moderate hemiplegic motor function, particularly in CIMT. Activities of daily living (ADL) were assessed using the Barthel Index, which measured independence.

Cognitive function was assessed with the following instruments: Mini-Mental State Examination (MMSE), Clock Drawing Test (CDT), evaluating cognitive skills including memory, visuoconstructive perception, planning, and executive function, WAIS-III Digit Span subtest, assessing attention span and working memory, Boston Naming Test, evaluating visual object naming, Verbal Fluency Test, assessing semantic memory retrieval and storage, Rey Auditory Verbal Learning Test (RAVLT), evaluating memory and learning and Instrumental Activities of Daily Living (IADL).

Intervention Protocols

Constraint-Induced Movement Therapy (CIMT)

The CIMT intervention protocol was based on three fundamental principles:

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1. Task-oriented repetitive training of the more affected upper limb for 3 hours per day for 2 consecutive weeks.
2. Restraint of the less affected upper limb for 90% of waking hours during the treatment period using a constraint glove.
3. Behavioral techniques to reinforce adherence and transfer clinical gains to real-world activities, including home--based practice.

The tasks were based on Shaping, a training method grounded in behavioral principles, where the motor goal was achieved through incremental steps. Each task was performed for 30 seconds, with therapist feedback for correction. Three shaping activities were included.

Task Practice, a less structured technique, involved functional activities based on ADLs performed with the affected limb, including: folding towels of different sizes, opening drawers, using a key in a lock, picking up the phone, putting on socks and shoes, using a fork or spoon to eat, carrying objects, and combing hair.

Conventional Physical Therapy

Two weekly sessions of individualized conventional physical therapy were conducted for 50 minutes each over 15 days. Sessions were conducted at the Clinicas Integradas de Saúde, Unilasalle, and the HCPA Clinical Research Center. Exercises were divided into Session A and Session B (Table 1), including passive stretching, weight transfer, scapular mobilization, neuromuscular facilitation, and gait training.

Session A	Session B
Passive stretching of the upper limb flexor chain and lower limb extensor chain.	Passive stretching of the upper limb flexor chain and lower limb extensor chain.
Weight shifting of upper and lower limbs.	Scapular mobilization.
Sliding taping on the upper limb extensors.	Dissociation of the scapular and pelvic girdles.
Isometric exercises for muscle strengthening of the upper limb extensors.	Proprioceptive Neuromuscular Facilitation (PNF): - Scapular diagonal: posterior-depression and anterior-depression - Pelvic diagonal: posterior-depression and anterior-depression - Functional and primitive diagonals of upper and lower limbs - Trunk diagonal Gait training

Table 1: Exercises provided during physical therapy sessions.

RESULTS

The data presented represented partial results of the study, comprising evaluations completed to date. Eight post-stroke individuals were randomized into two groups of four patients each. The intervention group received CIMT, and the control group underwent conventional physical therapy. All patients were assessed before and after 15 days of treatment.

Sample Characteristics

Ten patients were initially included in the study. One patient was hospitalized before re-evaluation, and another withdrew due to financial issues. Therefore, the sample included four patients per group, with Group 1 receiving CIMT and Group 2 receiving conventional physical therapy (FC). The mean age of Group 1 was 62.0±3.92, and Group 2 was 61.0±16.49 (p=0.91). In Group 1, the majority were female (n=3, 75%), while Group 2 had an equal distribution of sexes (50%, p=0.465). Socioeconomic distribution, schooling, handedness, hemiplegic side, and marital status are detailed in Table 2.

Cognitive Performance

Both groups scored 0 on the CDR, indicating no dementia before or after intervention. No statistically significant differences were observed in MMSE scores between groups. In RAVLT, the CIMT group improved from 3.3±1.75 to 7.3±1.5, while the FC group changed from 5.3±6.19 to 5.5±5.80. Phonemic and semantic verbal fluency, Clock Drawing Test, Boston Naming Test, and WAIS Digit Span showed improvements in both groups, though differences were not statistically significant. IADL scores indicated increased independence after interventions. Cognitive results are summarized in Table 3.

Motor Performance

In WMFT, CIMT scores improved from 51.5±11.45 to 62.8±13.38, and FC scores from 52.5±6.5 to 61.25±6.19. MAL scores increased by 22.3 points in CIMT and 17.5 points in FC. Barthel Index scores also increased, indicating greater functional independence, although differences between groups were not significant. Motor results are presented in Table 4.

DISCUSSION

The literature had demonstrated the advantages of CIMT in post-stroke motor rehabilitation, in both acute and chronic phases, showing superiority over other therapies (SILVA & TAMASHIRO, 2010). CIMT emphasized task-oriented repetitive training, restraint of the unaffected limb, and behavioral techniques to promote cortical reorganization (WOLF, 2008).

The "Learned Non-Use" theory guided CIMT, reducing use of the healthy limb to promote repeated use of the affected limb, leading to new motor engram formation (TAUB, 2002). Studies using MRI observed increased cerebral activity and neuroplasticity, including memory-related areas, during CIMT (STARK, 2012; KÖNONEN, 2012; WU, 2010). This likely contributed to memory improvements in the CIMT group observed in this study.

Previous trials, including Smania et al. (2012) and Huseyinsinoglu et al. (2012), reported greater motor gains in CIMT compared to conventional therapies, though some measures showed no significant differences. Mohammed et al. (2009) found similar improvements in Barthel Index scores between groups. In this study, functional gains were observed in both groups, with CIMT showing slightly greater improvements.

Cognitive outcomes were less explored in the literature. Improved motor control was associated with increased activation in prefrontal regions involved in memory and cognition (DENNIS, 2011). Both groups in this study showed cognitive improvement, consistent with the neuroplasticity hypothesis. Lin et al. (2009) also reported improved IADL performance regardless of CIMT duration, similar to our findings.

Variable	Group 1	Group 2	p
Age	62.0 ± 3.92	61.0 ± 16.49	0.91
Sex	3 (75%)	2 (50%)	0.465
Education (years)	6.0 ± 2.83	4.75 ± 2.56	0.504
Laterality	4 (100%)	3 (75%)	0.285
Paretic side	2 (50%)	1 (25%)	0.465
Marital status			0.392
- Married	1 (25%)	3 (75%)	
- Widowed	1 (25%)	1 (25%)	
- Divorced	1 (25%)	0 (0%)	
- Single	1 (25%)	0 (0%)	
Socioeconomic status			0.05
- B2	3 (75%)	3 (75%)	
- C1	1 (25%)	1 (25%)	

Table 2: Sample Characteristics.

Variable	Pre-Treatment	p	Post-Treatment	p
CDR	0 ± 0		0 ± 0	
MMSE	21.0 ± 5.48	0.950	23.5 ± 4.04	0.241
Below cutoff	4 (100%)		2 (50%)	
Above cutoff	0 (0%)		2 (50%)	
RAVLT	3.3 ± 1.75	0.556	7.3 ± 1.5	0.015
Phonemic Fluency	12.0 ± 12.25	0.359	14.8 ± 15.9	0.718
Semantic Fluency	11.5 ± 3.0	0.359	10.75 ± 2.22	0.766
Clock Drawing	2.8 ± 1.71	0.693	3.8 ± 1.5	0.094
Boston Naming	12.0 ± 3.83	0.742	13.0 ± 2.45	0.537
Digit Span	6.8 ± 2.75	0.449	7.3 ± 4.03	0.560
IADL	2.5 ± 3.0	0.708	1.75 ± 2.06	1.00

Table 3. Cognitive performance of patients before and after intervention.

Variable	Pre-Treatment	p	Post-Treatment	p
WMFT	51.5 ± 11.45	0.884	62.8 ± 13.38	0.256
MAL	86.0 ± 41.12	0.673	108.3 ± 32.17	0.549
Barthel Index	90.1 ± 10.0	0.488	97.5 ± 2.89	0.437

Table 4. Motor performance of patients before and after intervention.

CONCLUSION

Post-stroke patients may develop both motor and cognitive sequelae. Motor rehabilitation therapies are well-supported, whereas cognitive rehabilitation techniques have limited evidence. Few therapies address both motor and cognitive function simultaneously.

Both CIMT and conventional physical therapy provided benefits in motor and cognitive recovery, with no significant differences between groups. Patients receiving CIMT achieved higher scores in follow-up evaluations for both cognitive and motor outcomes, though these gains were not statistically significant. A larger sample size could potentially reveal statistically significant differences.

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