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Effectiveness of Combined Modified Constraint-Induced Movement Therapy (mCIMT) and Single Osteokinematic Exercises (SOE) on Upper Extremity Motor Function in Stroke: A Randomized Controlled Trial

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Abstract

Background: Restoring upper limb motor function is critical in post-stroke rehabilitation. This study aimed to evaluate the efficacy of combined mCIMT-OE and SOE on upper limb motor function recovery in stroke patients.

Metode: In this open-label, two-arm, parallel-group, superiority randomized controlled trial with a pretest-posttest design, 64 patients with ischemic stroke-related hemiparesis, preserved consciousness (GCS ≥ 14), the ability to follow simple commands, and residual voluntary upper extremity movement were recruited from dr. Zainoel Abidin Hospital, Banda Aceh. Through the stratified permuted block randomization method, participants were evenly distributed into the mCIMT-OE group (n=32) or SOE group (n=32). The Fugl-Meyer Assessment for Upper Extremity (FMA-UE) was utilized as the primary outcome measure for

the six-day intervention.

Result: All randomized participants successfully completed the study and were accounted for in the final analysis. Both groups demonstrated significant improvements in FMA-UE scores ($p < 0.001$). In the mCIMT-OE group (n=32), the mean score increased from 39.31 ± 12.10 to 45.72 ± 12.25 (MD: -6.41; 95% CI: -6.71 to -6.10). Similarly, the SOE group showed a significant increase from 34.88 ± 11.38 to 40.34 ± 12.01 (MD: -5.47; 95% CI: -5.83 to -5.10). No adverse events were reported during the intervention.

Conclusion: Both mCIMT-OE and SOE protocols are safe and effective in improving upper extremity motor function among stroke patients, with mCIMT-OE demonstrating a slightly higher mean improvement.

Keywords: Modified Constraint-Induced Movement, Osteokinematic, Improving Upper Extremity Motor Function, Stroke

1. Introduction

Stroke remains one of the leading causes of long-term adult disability worldwide, severely impacting survivors' quality of life [1-3]. Among the various neurological deficits resulting from stroke, upper extremity motor impairment is particularly prevalent, affecting almost 80% of survivors [4-6]. The loss of upper limb function drastically limits independence in stroke patients' daily living activities [4, 7, 8]. Consequently, restoring upper limb motor function is a primary focus of neurorehabilitation, necessitating the development of highly effective therapeutic strategies [4, 9].

Despite extensive research into post-stroke rehabilitation, optimal therapeutic approaches for upper limb recovery remain under active investigation [10]. Traditional physical therapy often relies on OE focusing on passive and active joint range of motion [11, 12]. While beneficial, OE primarily addresses biomechanical components without consistently overcoming the phenomenon of "learned non-use," where patients neglect the affected limb [13]. To address these limitations, task-oriented training modalities such as mCIMT have emerged as highly reported effective interventions. By actively restraining the unaffected upper limb while intensively practicing functional tasks with the paretic arm, mCIMT directly counters learned non-use and promotes neuroplasticity through massed practice [14-16].

Recent studies have shown that mCIMT can significantly improve upper extremity motor function, arm use, and functional performance in stroke survivors through intensive, task-specific practice of the affected limb [17, 18]. The effectiveness of mCIMT may depend on the patient's baseline motor function, as participation in intensive task-oriented training requires a

minimum level of voluntary movement [19]. Limited joint mobility, muscle stiffness, and abnormal movement patterns may restrict patients' ability to perform repetitive functional tasks, potentially reducing the effectiveness of rehabilitation interventions [20, 21]. Therefore, interventions that improve joint mobility may enhance the effectiveness of task-oriented rehabilitation approaches such as mCIMT [21, 22]. OE based interventions are commonly used in stroke rehabilitation to maintain or improve joint range of motion and facilitate movement performance of the affected upper extremity [20, 23]. While both mCIMT and OE have independently demonstrated positive effects on upper extremity recovery after stroke, evidence regarding the effectiveness of their combined application remains scarce. Therefore, this study aimed to evaluate the effects of mCIMT-OE and SOE on upper extremity motor function among stroke patients.

2. Material and Method

This study employed an open-label, two-arm, parallel-group randomized controlled trial with a 1:1 allocation ratio. Participants were randomly assigned to either mCIMT-OE or the SOE group. No changes were made to the study procedures after trial commencement. Participants were recruited from the inpatient ward of Dr. Zainoel Abidin Regional General Hospital, Banda Aceh, Indonesia. Eligible participants were adults diagnosed with ischemic stroke who presented with unilateral upper extremity hemiparesis, had preserved consciousness (Glasgow Coma Scale score ≥ 14), and were able to follow simple verbal commands. Cognitive function was assessed using the Mini-Mental State Examination (MMSE), with a minimum score of 24 required for inclusion. Additionally, participants were required to demonstrate residual voluntary motor function in the affected upper extremity, including at least 30° of active shoulder flexion and a minimum of 10° of active wrist and finger extension.

A priori sample size estimation was conducted using G*Power software. Based on an expected effect size of 0.80, a significance level (α) of 0.05, and a statistical power of 85%, the minimum required sample size was determined to be 60 participants. To accommodate potential attrition and ensure sufficient statistical power, the sample size was increased to 64 participants, with 32 participants assigned to each group. No interim analyses were planned or conducted throughout the study, and no predefined stopping criteria were established prior to trial initiation.

Participants allocated to the mCIMT-OE group received a combination of OE and mCIMT. The intervention consisted of 30 minutes of OE followed by 60 minutes of mCIMT. The mCIMT protocol emphasized intensive, task-oriented practice and encouraged active use of the affected upper extremity during functional activities. This combined intervention was designed to improve upper extremity motor function, muscle activation, and joint mobility. Participants in the SOE group received osteokinematic exercises only, consisting of active and active-assisted movements aimed at enhancing joint mobility, muscle activation, and upper extremity motor performance. Both interventions were administered for six consecutive days according to a standardized protocol developed by the research team.

The 33 items FMA-UE was used as the primary outcome measure to evaluate upper extremity motor function. Assessments were conducted at baseline prior to the

intervention and immediately after the completion of the six-day intervention period. No changes were made to the pre-specified outcome measures after the commencement of the study. The random allocation sequence was generated using stratified permuted block randomization based on a sequence of random numbers produced through a spin wheel application. Participants were stratified according to gender before randomization to ensure a balanced distribution of gender characteristics across the treatment groups. Within each stratum, permuted blocks of four participants were used to achieve equal allocation between the intervention groups. Allocation concealment was maintained through the use of sequentially numbered, opaque, sealed envelopes prepared by the researcher. Due to the nature of the rehabilitation interventions, blinding was not feasible. Consequently, participants and researcher were aware of the assigned group allocations throughout the study.

Data were analyzed using SPSS statistical software. Descriptive statistics were employed to summarize the demographic characteristics of the participants. Within-group changes in FMA-UE scores from baseline to post-intervention were examined using paired t-tests. A p -value of less than 0.05 was considered statistically significant. The study protocol received ethical approval from the Health Research Ethics Committee of Dr. Zainoel Abidin Regional General Hospital, Banda Aceh, Indonesia (Approval No. 388/ETIK-RSUDZA/2025). Written informed consent was obtained from all participants before their inclusion in the study. Trial Registration: Registered with Indonesian Clinical Research Registry (INA-CRR) No. INA-9FF7BEA.

3. Result

A total of 86 patients were screened for eligibility. Of these, 24 patients were excluded due to not meeting the inclusion criteria or declining to participate in the study. The remaining 64 eligible participants were randomly allocated to either mCIMT-OE group ($n = 32$) or SOE group ($n = 32$). All randomized participants received the assigned intervention, completed the study protocol, and were included in the primary outcome analysis. No participants withdrew from the study, were lost to follow-up, or were excluded from the analysis after randomization. (Fig 1).

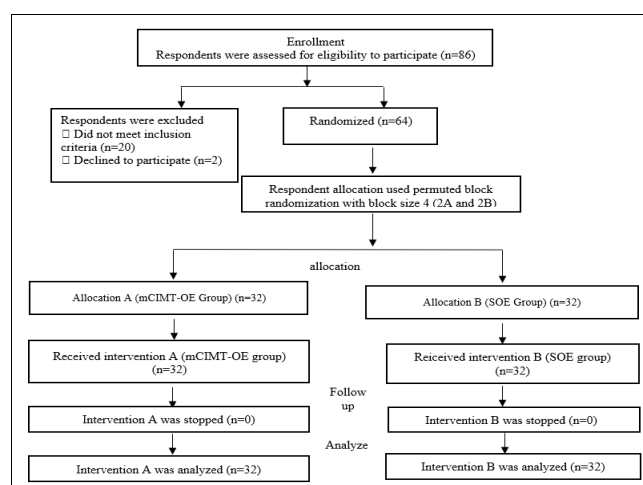


Fig 1: CONSORT Diagram Flow of the Research

Recruitment was carried out from March 4 through May 31, 2026. Outcomes were evaluated at baseline and upon completion of the six-day intervention. The trial was

completed as planned, and no participants or study procedures were terminated prematurely.

a. Demographic characteristic of study

The baseline demographic characteristics of participants, including age, gender, educational level, occupation, and marital status, were comparable between the mCINT-OE and SOE groups. Detailed baseline characteristics are presented in Table 1.

Table 1: Distribution of respondent characteristics

No	Demographic Data	MCINT-OE Group (n=32)		SOE Group (n=32)		Total Respondent (n=64)	
		f	%	f	%	f	%
1	Age (MD±SD)	55,81 ± 13,42		58,75 ± 12,31		57,28 ± 12,86	
2	Gender	32	100	32	50	64	100
	Male	16	50	16	50	32	50
	Female	16	50	16	50	32	50
3	Education Level	32	100	32	100	64	100
	Primary Education	7	21,9	8	25	15	23,4
	Secondary Education	18	56	20	62,5	38	59,4
	Tertiary Education	7	21,9	4	12,5	11	17,2
4	Occupation	32	100	32	100	64	100
	Manual Laborer/Farmer/ Fisherman/ Contract Employee	11	34,4	12	37,5	23	35,9
	Government Employee/ Military/ Police	3	9,4	2	6,3	5	7,8
	Self-employee	6	18,8	6	18,3	12	18,8
	Homemaker	9	28,1	4	12,5	13	20,3
	Unemployee	3	9,4	8	25	11	17,2
5	Marital status	32	100	32	100	64	100
	Married	24	75	21	65,6	45	70,3
	Single/ Never Married	2	6,3	2	6,3	4	6,3
	Widowed/ Divorced	6	18,8	9	9	15	23,4

Based on the data presented in Table 1, the mean age of the participants was 57.28 ± 12.86 years, indicating that the study population was predominantly in the late adulthood stage. The gender distribution was balanced, with males and females each representing 50% of the participants. Most respondents had attained secondary education (59.4%) and were married (70.3%). In terms of occupational characteristics, the largest proportion of participants were employed as manual laborers, farmers, fishermen, or contract employees, accounting for 35.9% of the total sample.

b. mCINT-OE and SOE Group Analysis

All 64 randomized participants, comprising 32 individuals in the mCINT-OE group and 32 in the SOE group, successfully completed the intervention and were included in the final analysis. Assessment of upper extremity motor function using the FMA-UE demonstrated improvements in both groups following the intervention. Detailed results of the FMA-UE assessment are presented in Table 2.

Table 2: Results of the Analysis of Changes in FMA-UE Pre-test and Post-Test Scores in the Two MCINT-OE and OET Intervention Groups

Group	Variable	n	Mean ± SD	Mean Different	95% CI	t	df	p
MCINT-OE	Pre-test	32	39,31 ± 12,1	-6,41	[-6,71- 6,10]	-	43,30	0,001
	Post-test		45,72 ± 12,25					
SOE	Pre-test	32	34,88 ± 11,38	-5,47	[-5,83- 5,10]	-	30,46	0,001
	Post-test		40,34 ± 12,01					

Participants in the mCINT-OE group exhibited a statistically significant improvement in upper extremity motor function, as evidenced by an increase in mean FMA-UE scores from 39.31 ± 12.10 at baseline to 45.72 ± 12.25 following the intervention. The mean change score was 6.41 points (95% CI: 6.10–6.71; $p < 0.05$). Likewise, participants in the SOE group demonstrated a significant improvement in FMA-UE scores, increasing from 34.88 ± 11.38 at baseline to 40.34 ± 12.01 at post-test. The mean improvement was 5.47 points (95% CI: 5.10–5.83; $p < 0.05$). No subgroup analyses or adjusted analyses were performed beyond the primary outcome analysis. Additionally, no adverse events, harms, or other unintended effects attributable to the interventions were observed in either the mCINT-OE or SOE group during the study period.

4. Discussion

The findings of this study demonstrated that the combined mCINT-OE intervention resulted in a significant improvement in upper extremity motor function among patients with stroke ($p = 0.001$). This therapeutic benefit may be attributed to the underlying mechanism of mCINT, which is specifically designed to address functional deficits by restricting the movement of the unaffected limb, thereby encouraging intensive and repetitive use of the paretic upper extremity [24]. Such structured and task-oriented practice serves as a key stimulus for promoting meaningful improvements in motor performance [25].

The clinical relevance of this intervention is underscored by the fact that approximately 80% of stroke survivors experience upper extremity motor impairments that adversely affect their ability to perform activities of daily living [26]. The present findings further support the growing body of evidence indicating that mCINT is a promising rehabilitation approach, particularly when implemented as part of a multimodal therapeutic strategy rather than as a stand-alone intervention [27].

This study also confirmed that osteokinematic exercise as a stand-alone intervention contributed significantly to improvements in motor function among patients with stroke ($p = 0.001$). From a biomechanical perspective, post-stroke individuals frequently exhibit reduced movement efficiency during the reach-and-grasp phase, characterized by limited

shoulder flexion and restricted elbow and wrist extension [28]. Osteokinematic-based interventions may serve as an effective corrective approach to address these pathological compensatory movement patterns by improving structural integrity and optimizing movement mechanics [29]. The effectiveness of osteokinematic exercise is consistent with findings from various manual mobilization techniques, such as Maitland mobilization and Mobilization with Movement (MWM), both of which have been shown to reduce spasticity and improve shoulder joint range of motion (ROM) in individuals following stroke [30, 31]. Furthermore, the beneficial effects of this intervention may extend to the distal segments of the upper extremity through fast flexion-extension (FFE) movements, which have been reported to enhance the flexibility and mobility of the small joints of the hand [32].

Importantly, no adverse events were observed during the intervention period, suggesting that both mCIMT-OE and SOE are safe and well-tolerated rehabilitation approaches for patients with stroke. Therefore, the observed improvements in motor function may be considered clinically meaningful when balanced against the minimal risk associated with the interventions.

The superior outcomes observed in the mCIMT-OE group may be attributed to the complementary mechanisms of the two interventions. While osteokinematic exercise primarily targets joint mobility and movement quality, mCIMT promotes repetitive task-specific practice and cortical reorganization through increased use of the affected limb. The integration of these approaches may therefore facilitate both biomechanical recovery and neuroplastic adaptation, resulting in greater improvements in upper extremity motor function.

a. Limitations

Despite the positive findings, several limitations should be acknowledged. First, blinding of participants and therapists was not feasible due to the nature of the interventions, which may have introduced performance bias. Second, the sample size was powered primarily to detect differences in the primary outcome and may have been insufficient for subgroup or exploratory analyses. Third, this study was conducted at a single rehabilitation center and outcomes were assessed only immediately after the intervention, limiting both the generalizability of the findings and the evaluation of long-term treatment effects.

In addition, the combined mCIMT and OE intervention was administered over a relatively short period of six days. Although this duration was selected based on the recommendations of Yang *et al.*, (2023), it may not fully reflect the effects achievable through longer-term rehabilitation programs. Another limitation relates to outcome assessment. FMA-UE evaluations were performed by the principal investigator, who underwent independent training using the assessment protocol provided by the University of Gothenburg. Despite adherence to standardized procedures, the absence of independent or multiple raters may have increased the potential for subjective assessment bias and limited the evaluation of inter-rater reliability.

Furthermore, although participant allocation was performed using permuted block randomization to reduce allocation imbalance, conventional block randomization methods may still carry a degree of allocation predictability, potentially

increasing the risk of selection bias. Finally, the considerable heterogeneity in clinical indicators associated with the application of both intervention suggests that variability in patient characteristics and treatment responses may not have been fully controlled.

b. Generalisability

The findings of this study may be generalizable to patients with stroke who present with upper extremity motor impairments and have clinical characteristics similar to those included in the present trial. Given that the mCIMT-OE protocol is relatively simple, low-cost, and does not require specialized technological equipment, its implementation may be feasible in a variety of rehabilitation settings, particularly in resource-limited environments. However, caution should be exercised when extrapolating these findings to patients with markedly different clinical profiles, severe cognitive impairments, advanced neurological deficits, or other stages of stroke recovery. Furthermore, as the study was conducted in a single rehabilitation center, the external validity of the findings should be confirmed through larger multicenter trials involving more diverse patient populations.

5. Conclusion and Recommendation

Both groups demonstrated statistically significant improvements in FMA-UE scores, with mCIMT-OE demonstrating a slightly higher mean improvement. To address the limitations related to the relatively short intervention duration, as well as the potential for assessment and selection bias, future studies are recommended to incorporate longer intervention and follow-up periods, utilize independent assessors to enhance objectivity, and implement more rigorous strategies to control for clinical heterogeneity and optimize randomization procedures. Such methodological refinements may strengthen the evidence base and improve the validity and generalizability of findings regarding the effectiveness of combined rehabilitation interventions in stroke recovery.

6. Other Information

This trial was prospectively registered with INA-CRR under registration number INA-9FF7BEA. A detailed study protocol was developed prior to participant recruitment and is available from first author and corresponding author upon reasonable request. This research received no external funding, and no funding agency, institution, or sponsor had any role in the study design, data collection, data analysis, interpretation of the findings, manuscript preparation, or the decision to submit the manuscript for publication.

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