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Critcally Appraised Paper for: “Is modified constraint-induced movement therapy more effective than bimanual training in improving arm motor function in the subacute phase post stroke? A randomized controlled trial.”

Jason Ichimaru
Dominican University of California

Jennifer Sik
Dominican University of California

Kelly Schmidt
Dominican University of California

Kitsum Li
Department of Occupational Therapy, Dominican University of California

AOTA Critically Appraised Papers Series

Evidence Exchange

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CRITICALLY APPRAISED PAPER (CAP) WORKSHEET

Brunner, I. C., Skouen, J. S., & Strand L. I. (2012). Is modified constraint-induced movement therapy more effective than bimanual training in improving arm motor function in the subacute phase post stroke? A randomized controlled trial. *Clinical Rehabilitation*, *26*(12), 1078–1086. https://doi.org/ 10.1177/0269215512443138

CLINICAL BOTTOM LINE

Patients poststroke compose one of the largest demographics treated by occupational therapists in the physical disability setting. Approximately two-thirds of individuals who have had a stroke present with arm function impairment (Kwakkel & Kollen, 2007). Therefore, effective arm rehabilitation in occupational therapy settings is critical to help patients regain functional independence and quality of life. Modified constraint-induced movement (MCIM) therapy has been reported as the superior method of arm rehabilitation for individuals in the subacute phase poststroke, although recent research has also supported bimanual training. This 4-week, randomized controlled, quantitative study compared the effect of MCIM therapy and bimanual task-related training for 30 poststroke participants in the subacute phase.

The intervention approach for the two groups incorporated activities of daily living, each with a unique rehabilitative focus. Although both groups received task-related training with a therapist 4 hr each week for 4 weeks, the MCIM therapy had a unilateral focus, whereas the bimanual training had a bilateral focus. Participants in the MCIM therapy group were asked to wear a mitt on their unaffected limb 4 hr/day, and participants in the bimanual group were encouraged to use both limbs together in bimanual tasks. All participants were required to complete and record 2–3 hr of self-training daily.

Results indicated that both the MCIM therapy and the bimanual training participants improved in functional tasks and motor skills of the affected arm within their group, but no statistical difference was identified between the groups. Thus, the researchers concluded that MCIM therapy was no more effective than bimanual training to improve arm function among patients in the subacute phase poststroke. They determined that further comparison was unnecessary, because any difference in effectiveness would not be clinically relevant.

Application of these conclusions in occupational therapy settings, however, must be considered carefully in light of the small sample size. The initial power calculation necessitated a sample size of 60 participants, yet only 30 participants were obtained. Furthermore, this study lacked a control group, relied on self-report, and contained a number of biases. Site bias and cointervention bias could not be avoided, because participants resided in various settings and might have received other forms of rehabilitation. Timing bias was

likely, because 4 weeks was an insufficient time frame to demonstrate the effect of an intervention on motor function recovery. Contamination might have occurred, given that the MCIM therapy group wore the mitt only 4 hr/day and that bimanual use for tasks at other times of the day could not be prevented.

On the basis of the methodological limitations of the study, the conclusion drawn by the authors that the two intervention methods were equally effective in improving motor arm function in the subacute phase poststroke cannot be supported. Further research comparing the two interventions is recommended. With no method demonstrating clear superiority in this study, occupational therapists should consider every client individually when determining whether MCIM or bimanual training would be an appropriate intervention.

RESEARCH OBJECTIVE(S)

To compare the effect of MCIM therapy and dose-matched bimanual task-related training for patients in the subacute phase after stroke, to determine whether one intervention approach yields better outcomes in arm function

DESIGN TYPE AND LEVEL OF EVIDENCE:

Level I: single-blinded randomized controlled trial

SAMPLE SELECTION

Patients of two hospitals in Bergen, Norway, were invited to participate in this 4-week study. No methods of recruitment and selection were reported.

Inclusion Criteria

To be included in the study, the participants had to be between 2 and 16 weeks poststroke. Eligible participants had to have upper limb paresis, with a minimum of 10° extension of the wrist and fingers on the affected limb. Additionally, participants needed to have significantly limited dexterity, as indicated by a score of less than 52 on the Action Research Arm Test. All participants of this study were patients who had experienced a single ischemic stroke; a single hemorrhagic stroke; or a second stroke, but with no residual motor impairments from the former stroke.

Exclusion Criteria

Additional neurological diseases

- Unstable medical conditions
- Musculoskeletal disorders affecting arm mobility
- A score of less than 24 on the Mini Mental State Examination, indicating severe cognitive impairment

SAMPLE CHARACTERISTICS

N= (Number of participants taking part in the study)	30

#/ (%) Male	19/(63.3%)		#/ (%) Female	11/(36.7%)

Ethnicity	NR

Disease/disability diagnosis	25 participants had ischemic stroke 5 participants had hemorrhagic stroke

INTERVENTION (S) AND CONTROL GROUPS

Group 1: MCIM therapy

Brief description of the intervention	Participants in the MCIM therapy group were expected to wear a mitt on the less-affected arm for 4 hr/day and encouraged to use only the affected arm actively in daily life activities at least 2–3hr/day. This group received task-related arm training with an experienced therapist, who focused on unilateral activities of the affected side when possible. Participants received written self-training exercises that focused on unilateral activities and were adjusted to each participant's current motor capabilities, interests, and needs. Through shaping principles, activities were graded to continually challenge the participants' motor capabilities. Time spent wearing the mitt and practicing the unilateral focused training exercises was recorded in a logbook, which served as a method of monitoring the participants' compliance with the self-training exercises.
How many participants in the group?	The MCIM therapy group had 14 participants. One participant dropped out of the study because of medical problems.
Where did the intervention take place?	The task-related arm training took place in inpatient and outpatient settings. Daily self-training exercises took place in the participants' home and community.
Who Delivered?	Interventions were administered by an experienced occupational or physical therapist.
How often?	Self-training was implemented everyday; participants were asked to wear a mitt on the unaffected hand 4 hr/day and use the affected arm actively at least 2–3 hr/day. Participants received task-related arm training for 4 hr each week. They were expected to complete written self-training exercises three times during the intervention period.
For how long?	4 weeks

Group 2: Bimanual task-related training group

Brief description	Participants in the bimanual task-related training group received task-

of the intervention	related arm training with an experienced therapist, 4 hr/week for 4 weeks. The therapist focused the task-related arm training on bilateral activities, either using both upper extremities or alternating each upper extremity depending on the activity. Participants also received written self-training exercises that focused on bilateral activities and were adjusted to each participant's current motor capabilities, interests, and needs, at least three times during the intervention. Participants were also encouraged to use the affected hand in everyday activities at least 2–3 hr/day. Intervention with the therapist and self-training exercises also used shaping principles to continually create a challenge for the participants. Time spent practicing the bimanual focused self-training exercises was recorded in a logbook, which served as a method of monitoring the participants' compliance with the self-training exercises.
How many participants in the group?	The bimanual task-related training group had 16 participants. One participant dropped out of the study because of medical problems.
Where did the intervention take place?	The task-related arm training took place at inpatient and outpatient settings. Daily self-training exercises took place in the participants' home and community.
Who Delivered?	Task-related arm training was administered by an experienced occupational or physical therapist.
How often?	Self-training was implemented everyday; participants were asked to use the affected arm actively at least 2–3 hr/day. Participants received task-related arm training for 4 hr each week.
For how long?	4 weeks

Intervention Biases: *Check yes, no, or NR and explain, if needed.*

Contamination:

YES ☐ NO ☐ NR ☒	*Comment:* Contamination was not addressed in the article but was possible, because the MCIM therapy group participants could have completed bimanual tasks when they were not wearing their mitt.

Co-intervention:

YES ☐ NO ☐ NR ☒	*Comment:* Cointervention bias was not specifically addressed, but other necessary rehabilitation services might have been provided to participants according to their individual needs.

Timing:

YES ☐ NO ☐	*Comment:* All participants received the same amount of task-related training over a 4-week intervention period, which likely was not sufficient to determine the effectiveness of the intervention.

NR ☒	

Site:

YES ☒ NO ☐ NR ☐	*Comment:* Site bias was likely, because participants received individualized treatment in varied settings (i.e., inpatient and outpatient settings and in their own home), with low therapist contact and a strong emphasis on self-training. As a result, the researchers had limited control over what the participants did and had to rely on entries in the logbooks.

Use of different therapists to provide intervention:

YES ☒ NO ☐ NR ☐	*Comment:* An experienced occupational or physical therapist worked with the participants, but the process was not clearly defined. It is not clear whether an occupational or physical therapist was designated to a specific participant or whether the therapists alternated with the participants throughout the intervention process. Furthermore, consistency during intervention is questionable, given that two therapists provided the intervention and there was no description of how they coordinated to provide unified interventions.

MEASURES AND OUTCOMES

Complete for each measure relevant to occupational therapy:

Measure 1: Action Research Arm Test

Name/type of measure used:	The Action Research Arm Test was the main outcome measure used for this study. This test yields scores ranging from 0 to 57, with higher scores indicating better function.		
What outcome was measured?	Arm motor function		
Is the measure reliable?	YES ☒	NO ☐	NR ☐
Is the measure valid?	YES ☒	NO ☐	NR ☐
When is the measure used?	Pretest, posttest, follow-up 3 months later		

Measure 2: Nine-Hole Peg Test

Name/type of measure used:	The Nine-Hole Peg Test was the secondary outcome measure for this study. The scores are based on the time taken to complete the test activity, recorded in seconds.		
What outcome was measured?	Hand dexterity, with an emphasis on fine motor abilities, to provide data about the accuracy and quality of hand and finger use		
Is the measure reliable?	YES ☐	NO ☐	NR ☒
Is the measure valid?	YES ☐	NO ☐	NR X

When is the measure used?	Pretest, posttest, follow-up 3 months later

Measure 3: Motor Activity Log: Amount of Use

Name/type of measure used:	The Motor Activity Log was a secondary outcome measure based on a scale from 0 to 5, with a higher score indicating more use of the affected arm during 30 daily life activities.		
What outcome was measured?	Structured self-report measurement of amount of use of the affected arm in 30 daily life activities		
Is the measure reliable?	YES ☐	NO ☐	NR ☒
Is the measure valid?	YES ☐	NO ☐	NR ☒
When is the measure used?	Pretest, posttest, follow-up 3 months later		

Measure 4: Motor Activity Log: Quality of Use

Name/type of measure used:	The Motor Activity Log was a secondary measure based on a scale from 0 to 5, with a higher score indicating better quality movement during 30 daily life activities.		
What outcome was measured?	Structured self-report measurement of quality of use of the affected arm in 30 daily life activities		
Is the measure reliable?	YES ☐	NO ☐	NR ☒
Is the measure valid?	YES ☐	NO ☐	NR ☒
When is the measure used?	Pretest, posttest, follow-up 3 months later		

<u>Measurement Biases</u>

Were the evaluators blind to treatment status? *Check yes, no, or NR, and if **no**, explain.*

YES ☒ NO ☐ NR ☐	*Comment:* Raters were blinded by recruiting therapists from other wards who were not involved in the treatment of the study participants.

Recall or memory bias. *Check yes, no, or NR, and if **yes,** explain.*

YES ☒ NO ☐ NR ☐	*Comment:* The Motor Activity Log was liable for memory bias, because participants had to recall the quality of use in their affected arm and the time elapsed while they were participating in 30 daily life activities. The written logbooks also might have been subject to memory bias, because participants might have inaccurately recalled the time spent during self-training exercises.

Others (list and explain):

Self-report bias is likely, because the interventions involved low contact with therapists and relied heavily on self-report in the logbooks. The participants were encouraged to accurately report the training time and time spent wearing the mitt, but individual factors might have influenced their ability to do so. Moreover, the nature of self-reporting and lack of monitoring during self-training in both intervention groups might have affected the accuracy of the outcome measure.

RESULTS

List key findings based on study objectives

Include statistical significance where appropriate ($p<.05$)
Include effect size if reported

The authors conducted an interim analysis because they recruited only 30 of the proposed 60 patients. From baseline to follow-up assessment, both groups experienced improvement on the Action Research Arm Test, with a mean change score of 17.77 ($p < .001$) from MCIM therapy and 15.47 ($p < .001$) from bimanual task-related training. At posttest assessment, 92% of participants (12 of 13) in the MCIM therapy group and 80% (12 of 15) in the bimanual task-related training group showed significant improvements on the Action Research Arm Test (greater than 5.7).

Fewer participants (77% of participants [10 of 13] in the MCIM therapy group and 67% [10 of 15] in the bimanual task-related training group) retained significant improvements on the Action Research Arm Test by the 3-month follow-up assessment. Results of the interim analysis, however, did not show significant difference in change ($p > .05$) between the two groups with respect to age, sex, side of paresis, or test scores in the Action Research Arm Test, Nine-Hole Peg Test, and Motor Activity Log at posttest and follow-up assessments.

The difference in change between the groups on the Nine-Hole Peg Test, the secondary outcome measure, was not statistically significant at posttest or during the follow-up assessment. However, as with the Action Research Arm Test, the participants did show significant individual improvements on the Nine-Hole Peg Test when compared with their own baseline score within their own group. From baseline to the follow-up assessment, the MCIM therapy group obtained a mean change score of 0.18 ($p = .010$) on the Nine-Hole Peg Test, and the bimanual task-related training group obtained a mean score of 0.16 ($p = .002$). These results suggest that neither intervention group showed significant improvement over the other on the Nine-Hole Peg Test.

The mean scores of the Motor Activity Log at baseline in the MCIM therapy group showed little use and poor quality of movement. The amount of use with the affected arm, however, exhibited significant improvements from posttest to follow-up assessment and from baseline to follow-up assessment. From baseline to the follow-up assessment, the MCIM therapy group obtained a mean change score of 1.78 ($p < .001$) on the Motor Activity Log regarding the amount of use, and the bimanual task-related training group obtained a mean change score of 1.40 ($p = .001$). In regard to quality of use, the MCIM therapy group obtained a

mean change score of 1.70 ($p < .001$), and the bimanual task-related training group obtained a mean score of 1.31 ($p = .001$). These results suggest that the two groups did not significantly differ in amount or quality of use of the affected arm.

The self-training exercise logbooks indicated that the recommended 2–3 hr of daily self-training were usually achieved. The MCIM therapy group reported a higher frequency of daily self-training than the bimanual training group. Most patients in the MCIM therapy group wore the mitt less than the targeted 4 hr, with a mean of 213.1 min/day, because of the necessity of using both hands in domestic chores and other activities.

Was this study adequately powered (large enough to show a difference)? *Check yes, no, or NR, and if* ***no****, explain*.

YES ☐ NO ☒ NR ☐	*Comment:* An adequately powered sample size required the inclusion of 60 participants. Only 30 participants were gathered for the study, and 2 participants dropped out during intervention because of medical complications.

Were appropriate analytic methods used? *Check yes, no, or NR, and if* ***no****, explain*.

YES ☒ NO ☐ NR ☐	*Comment:* The researchers used chi-square tests and independent-samples *t* tests to analyze baseline differences between intervention groups. Outcome measures were checked for normal distribution through visual inspection, Kolmogorov–Smirnov test, and Levene's test. Change within group and between groups was examined with paired-sample *t* tests and independent-sample *t* tests, respectively. Analysis of covariance was used to explore differences between groups. Statistical significance was set at $p \leq .05$.

Were statistics appropriately reported (in written or table format)? *Check yes or no, and if* ***no****, explain*.

YES ☒ NO ☐	*Comment:* Statistics were appropriately reported in figures, tables, and written discussions. Mean scores from baseline, posttest, and 3-month follow-up were shown, with comparisons from baseline to posttest and baseline to 3-month follow-up. Significance values and analysis of covariance significance values were accounted for in all comparisons.

Was the percent/number of subjects/participants who dropped out of the study reported?

YES ☒ NO ☐

Limitations:

What are the overall study limitations?

Limitations of the study include the limited sample size, which resulted from problems with recruitment of eligible participants within the expected timeframe. The researchers used an interim analysis and acquired only half of the originally intended 60 participants. Thus, the researchers concluded the study with half of the intended sample size, and the study therefore

lacked power.

This study lacked a control group that only received standard rehabilitation. Because of limited therapist contact and variation in intervention settings, the researchers had little control over what the participants did. Therefore, the researchers had to rely on the logbooks to monitor whether participants had achieved the recommended time of daily self-training. Moreover, the limited training time with the therapists could have weakened the distinctions between MCIM and bimanual therapy. Last, although there was a bilateral focus in the bimanual task-related training group and a unilateral focus in the MCIM therapy group, overlapping intervention approaches could not be prevented in the self-training portion of both programs.

CONCLUSIONS

State the authors' conclusions related to the research objectives.

The researchers concluded that for patients in the subacute phase poststroke, neither the MCIM therapy nor the bimanual training method had clear superiority. Because the MCIM therapy was no more beneficial than bimanual training, the researchers determined that constraining the affected arm may not be necessary for this population. Instead, treatments should encourage the use of unilateral and bimanual tasks. The researchers also felt that further research comparing MCIM therapy and bimanual training may not be necessary, because potential differences between these methods would be small and lack clinical relevance.

Reference

Kwakkel, G., & Kollen, B. (2007). Predicting improvement in the upper paretic limb after stroke: A longitudinal prospective study. *Restorative Neurology and Neuroscience*, *25*(5–6), 453–460.

This work is based on the evidence-based literature review completed by Jason Ichimaru, OTS, Jennifer Sik, OTS, Kelly Schmidt, OTS, and Kitsum Li, OTR/L, OTD, faculty advisor, Dominican University of California.