Evidence Supports That CIMT is More Effective in Improving Upper Extremity Functioning than Traditional Stroke Rehabilitation in Adults who Experienced a Stroke less than Nine Months Ago

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CLINICAL SCENARIO:

- **Client population**
  - Adults who experienced a stroke less than nine months prior to study
    - Age: 45 years of age and older
    - Stage of Recovery: Subacute (Less than 9 months post-stroke)

- **Treatment context**
  - One study completed CIMT as an inpatient intervention
  - The other two studies completed CIMT as an outpatient intervention, meaning that the clients came in to complete therapy. However, since the mitt is worn 90% of the day, the intervention was implemented anywhere the participant went during the study.

- **Problem/condition**
  - According to the American Stroke Association (ASA), having a stroke is the third leading cause of death and the number one leading cause of disability in the United States. Each year, 795,000 people in the United States have a new or a recurrent stroke and 137,000 of these people die (ASA, 2011). For those who survive, the functional limitations that occur as a result of having a stroke can be profound.
  - One study found that up to 85% of people who had a stroke experienced hemiparesis in an upper extremity immediately after the stroke and up to 75% of these people continued to have functional limitations six months after their stroke (Wolf, Weinstein, Miller, Taub, Uswatte, Morris, Giuliani, Light, & Nichols-Larsen, 2006).
  - These numbers are solidified by statistics from the Center for Disease Control and Prevention (CDC). Between the years 2005 and 2006, 4 million people visited physician offices, hospital outpatient clinics, and emergency departments with stroke as their primary diagnosis. Furthermore, 829,000 inpatient residents and 99,400 home health care patients had stroke as their primary diagnosis (CDC, 2006).
  - While it is evident through these numbers that health care services are being used among this population, it is necessary to find a rehabilitation program that is effective so that more of these people can function independently. Currently, traditional approaches to rehabilitation have been ineffective in relation to improving upper extremity deficits following a stroke. Therefore, more research is needed on rehabilitative approaches that are effective with improving upper extremity functioning.

- **Intervention**
  - CIMT is a rehabilitative approach that involves wearing a mitt or shoulder sling on the uninvolved upper extremity, following a stroke. Typically, the sling is worn for 90% of a person’s waking hours except when the person is completing tasks where safety and balance are of concern. While the restraint is on, the CIMT user completes at least 4 hours of intense therapy per day, which includes shaping and functional task training. Users are encouraged through this restraint and therapy that they should use their affected upper extremity and not compensate with their uninvolved extremity.
• How the Intervention works
  o A stroke occurs when a blood vessel is not able to transport an adequate amount of blood to an area of the brain, either because of blockage or rupture. Without adequate blood flow and oxygen, brain cells in these areas die and their function is no longer possible. These effects occur within the first 24-48 hours following a stroke, while a person is still in the acute care area of a hospital (Gillen & Burkhardt, 2004).
  o During this time, it is likely that the individual who had the stroke will, unsuccessfully, try to use their affected extremity to complete a number of tasks. They may become frustrated because their affected extremity does not work as well as their unaffected extremity and subconsciously may switch to using their unaffected extremity for more tasks. Simultaneously, hospital staff are desperately trying to stabilize the patient in order to get the patients out of the hospital. A variety of adaptive equipment and compensatory techniques are introduced to the patient so that they are still able to complete tasks (Gillen & Burkhardt, 2004). Over time, if functional use of the affected upper extremity is not regained, adaptive methods and equipment can compensate for lack of function in the affected UE. However, while compensatory strategies will increase efficiency, lack of use of the affected UE fails to activate the neuronal connections and can lead to “learned non-use” of the arm.
  o Over time, through using these techniques and equipment, the brain learns to not use the affected extremity to avoid failure. This phenomenon is termed “learned nonuse” (Blumenfeld, 2002).
  o When this nonuse occurs, and the affected upper extremity is no longer being utilized, the upper motor neurons that were involved in connections with the primary motor cortex of the affected side are recruited for different areas of the brain. This ability of the brain to reorganize is termed neuroplasticity (Blumenfeld, 2002). The reorganization of upper motor neurons further impacts the person’s inability to use their affected upper extremity.
  o However, with CIMT, a person’s unaffected extremity is restrained and they are forced to use their affected upper extremity during intense, repetitive and shaping tasks. Forced use helps the brain reorganize through re-recruitment of unmasking formerly established upper motor neurons connections and sprouting new neuronal connections.

• OT Framework
  o CIMT fits in with the body functions (neuromusculoskeletal and movement-related functions: control of voluntary movement) and body structures (structure of the nervous system) in the OT Practice Framework.
  o This is an OT intervention because the task training involved as part of the intense therapy usually incorporates movement patterns or direct components of functional activities. Also, the overall goal of CIMT, as an occupational therapy intervention, is that a person will restore function in their affected upper extremity so that they can complete functional activities (ADL and IADL).

• OT Theory
  o CIMT is supported by the motor control and motor learning frame of reference (Cech & Martin, 2002).
    ▪ The Motor control theory looks at a person’s ability to move: motor learning theory describes how movement can be learned/restored.
    ▪ CIMT, forces a person to use their affected extremity that is limiting their performance of an occupational task in intensive, repetitive ways. When this
When forced use occurs, the brain reorganizes so that connections can be made between upper motor neurons and the primary motor cortex.

- This frame of reference has foundations in psychology (learned nonuse) and neuroanatomy (plasticity of the brain) (Cech & Martin, 2002).

FOCUSED CLINICAL QUESTION:
- Patient/Client Group: Adults who experienced a stroke less than nine months ago
- Intervention: Constraint-induced movement therapy
- Comparison Intervention: Traditional stroke rehabilitation therapy
- Outcome: Improved functional ability of the affected upper extremity

SUMMARY:
- Does constraint-induced movement therapy improve functional ability of the affected upper extremity when compared to traditional stroke rehabilitation therapy for adults who experienced a stroke less than nine months ago?
- Search Results
  - Eight databases were searched and ten relevant articles were located.
  - Three randomized controlled trials (RCT) were critiqued
    - The articles were selected based upon their rigor, date of study, relevancy to topic, and participant characteristics.
      - A 5/10 PEDro score indicates that a study is rigorous. One article (Sawaki et al., 2008) had a 5/10 PEDro score. Between the two other articles, one had a 6/10 (Myint et al., 2008) and the other had an 8/10 (Wolf et al., 2008). Based on these PEDro scores, each of them were rigorous.
      - All of the articles chosen were from the past five years. One article was from 2006 and the other two were completed in 2008.
      - All three of the articles were attempting to determine whether CIMT had an effect on upper extremity functioning.
      - All of the critiqued articles involved participants who were adults, first time stroke patients, and experienced their stroke within the last 9 months.
        - CIMT improves UE functioning in adults, who experienced a stroke less than 9 months ago, more effectively than traditional stroke rehabilitation.

CLINICAL BOTTOM LINE:
- CIMT does improve the function ability of the affected UE for adults, who experienced a stroke less than 9 months ago, in comparison to traditional stroke rehabilitation. It is uncertain whether CIMT, specifically, helps improve grip strength in this population.

Limitation of this CAT: This critically appraised paper was reviewed by an occupational therapy graduate student and the course instructor.

SEARCH STRATEGY:
Table 1: Search Strategy

<table>
<thead>
<tr>
<th>Database Searched</th>
<th>Search Terms</th>
<th>Limits Used</th>
<th>Inclusion and Exclusion Criteria</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Database/Source</th>
<th>Search Criteria</th>
</tr>
</thead>
</table>
| CINAHL plus with full text                          | • CIMT AND Stroke  
• CIMT AND CVA  
• CIMT AND Stroke AND Upper Extremity  
• CIMT AND CVA AND Upper Extremity  
• Constraint-induced movement therapy AND stroke  
• Constraint-induced movement therapy AND upper extremity  
• CIMT AND Adult  
• Stroke AND Adult AND CIMT                                                                 |
| Cochrane collection plus                            | • AND                                                                 |
| Health Professions database                         | • English language  
• More recent than 2002  
• Have more than three participants  
• Peer-reviewed  
• Any type of stroke  
• Adult participants (above the age 18)  
• Needed to involve the UE and CIMT (not mCIMT)  
• Full text                                                                 |
| Journals@Ovid                                       | • AND                                                                 |
| Medline                                             | • English language  
• More recent than 2002  
• Have more than three participants  
• Peer-reviewed  
• Any type of stroke  
• Adult participants (above the age 18)  
• Needed to involve the UE and CIMT (not mCIMT)  
• Full text                                                                 |
| OT search                                            | • English language  
• More recent than 2002  
• Have more than three participants  
• Peer-reviewed  
• Any type of stroke  
• Adult participants (above the age 18)  
• Needed to involve the UE and CIMT (not mCIMT)  
• Full text                                                                 |
| Science Direct                                      | • AND                                                                 |
| Google Scholar                                      | • English language  
• More recent than 2002  
• Have more than three participants  
• Peer-reviewed  
• Any type of stroke  
• Adult participants (above the age 18)  
• Needed to involve the UE and CIMT (not mCIMT)  
• Full text                                                                 |
### RESULTS OF SEARCH

Table 2: Summary of Study Designs of Articles Reviewed

<table>
<thead>
<tr>
<th>Level</th>
<th>Study Design/Methodology of Articles Retrieved</th>
<th>Number Located</th>
<th>Source</th>
<th>Citation (Name, Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SR</td>
<td>Systematic Review (articles)</td>
<td>3</td>
<td>Europa Medicophysica</td>
<td>(Bonaiuti, Rebasti, &amp; Sioli, 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Australian Journal of Physiotherapy</td>
<td>(Hakkennes &amp; Keating, 2005)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cochrane database of systematic reviews</td>
<td>(Sirtori, Corbetta, Moja, &amp; Gatti, 2009)</td>
</tr>
<tr>
<td>Level 1</td>
<td>Randomized Control Trials</td>
<td>6</td>
<td>Neurorehabilitation &amp; Neural Repair</td>
<td>(Baoke, Noser, Ro, Baraniuk, Gaber, &amp; Johnson, 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clinical Rehabilitation</td>
<td>(Dahl, Askim, Stock, Langorgen, Lydersen, &amp; Indredavik, 2008)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clinical Rehabilitation</td>
<td>(Myint, Yuen, Kng, Wong, Chow, &amp; Li, 2008)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Neurocase: case studies in neuropsychology, neuropsychiatry, and behavioural neurology</td>
<td>(Ro, Noser, Boake, Johnson, Gaber, Speroni, et al., 2006)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Neurorehabilitation &amp; Neural Repair</td>
<td>(Sawaki, Butler, Leng, Wassenaar, Mohammad, Blanton &amp; et al., 2008)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Journal of the American Medical Association</td>
<td>(Wolf, Weinstein, Miller, Taub, Uswatte, Morris, &amp; et al., 2006)</td>
</tr>
<tr>
<td>Level 2</td>
<td>Non-randomized control group (two groups)</td>
<td>0</td>
<td></td>
<td></td>
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<tr>
<td>Level 3</td>
<td>Non-randomized control group (one group)</td>
<td>0</td>
<td></td>
<td></td>
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<tr>
<td>Level 4</td>
<td>Single-subject/repeated measures designs</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 5</td>
<td>Qualitative, Case study</td>
<td>1</td>
<td>Physiotherapy Canada</td>
<td>(Ploughman, Shears, Hutchings, &amp; Osmond, 2008)</td>
</tr>
</tbody>
</table>

### STUDIES INCLUDED

**Table 3: Summary of Included Studies**

<table>
<thead>
<tr>
<th>Intervention Investigated</th>
<th>Myint, Yuen, Kng, Wong, Chow, &amp; Li, 2008</th>
<th>Sawaki, Butler, Leng, Wassenaar, Mohammad, Blanton &amp; et al., 2008</th>
<th>Wolf, Winstein, Miller, Taub, Uswatte, Morris, &amp; et al., 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td>Constraint-induced movement therapy with early subacute stroke patients (2-16 weeks post stroke) in Hong Kong and its’ ability to improve function in the hemiplegic upper extremity</td>
<td>Constraint-induced movement therapy with subacute stroke patients (3-9 months post stroke) and its’ impact on motor recovery with the affected upper extremity</td>
<td>Constraint-induced movement therapy with subacute stroke patients (3-9 months post stroke) and its’ effect on restoring function in the affected upper extremity</td>
</tr>
<tr>
<td></td>
<td>• Shoulder sling worn 90% waking hours for 10 days</td>
<td>• Mitt covering the less affected hand 90% of waking hours for 14 days</td>
<td>• Mitt covering the less affected hand 90% of waking hours for 14 days</td>
</tr>
<tr>
<td></td>
<td>• 4 hours therapy/day including shaping</td>
<td>• Up to 6 hours therapy/day focusing on unimanual skill acquisition and functional retraining</td>
<td>• Up to 6 hours/day of therapy including shaping and standard task training</td>
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<tr>
<td></td>
<td></td>
<td>○ Tasks involved grasping, releasing, and manipulation</td>
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<tr>
<td><strong>Comparison Intervention</strong></td>
<td>Conventional therapy by occupational therapy or physical therapy</td>
<td>Usual and customary care:</td>
<td>Usual and customary care:</td>
</tr>
<tr>
<td></td>
<td>• 4 hours therapy/day for 10 days</td>
<td>• Included no treatment, application of orthotics, and/or occupational/physical therapy approaches in various settings</td>
<td>• Included no treatment, application of orthotics, and/or occupational/physical therapy approaches in various settings</td>
</tr>
<tr>
<td></td>
<td>• Neurodevelopmental techniques were utilized (bimanual tasks for UE, compensatory techniques, strength, positioning, mobility training, range of motion)</td>
<td></td>
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</tr>
<tr>
<td><strong>Outcome Variables + Measures</strong></td>
<td>Upper Extremity Function</td>
<td>Upper Extremity Function</td>
<td>Upper Extremity Function</td>
</tr>
<tr>
<td></td>
<td>• Functional test for hemiparetic upper extremity (a scale based on Brunnstrom’s stages of recovery which is comprised of tasks that are pass/fail)</td>
<td>• Wolf Motor Function Test (WMFT) – this is an assessment with 17 tests including 2 force/function based and 15 time based tasks, observed by an evaluator)</td>
<td>• Wolf Motor Function Test</td>
</tr>
<tr>
<td></td>
<td>• Action Research Arm Test (a test with potentially 24 subtests analyzing grasp, grip, pinch, and gross movement. The evaluator rates the performance of the subtests in</td>
<td>• Transcranial Magnetic Stimulation Results (aka TMS: a series of tests involving the placements of electrodes along muscle bellies in the arms and also on the head to</td>
<td>• The number of tasks completed in less than 120 seconds was also counted in this study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Motor Activity Log</td>
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<tbody>
<tr>
<td></td>
<td>relation to these constructs).</td>
<td>determine the motor output and relative amount of activity occurring simultaneously in the brain)</td>
<td></td>
</tr>
<tr>
<td>Motor Activity Log (A questionnaire filled out by the participant and the caregiver if applicable)</td>
<td>• Quality of movement subscale • Amount of use subscale</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Findings</td>
<td>• Through the results obtained by outcome measures, the researchers noted that CIMT improved hand function (grasp, grip, pinch, and gross movement) in the subacute population, in comparison to the control group at post-intervention. This improvement in hand function was still shown at the twelve week follow up session, however it was no longer significant. The control group also improved; however, none of the outcome measures showed a significant improvement at any assessment period. • Functional test for hemiparetic upper extremity: effect size (d)=0.90, ARAT: effect size (d)=4.52 • CIMT can be viewed as a more effective treatment approach in restoring hand function, in comparison to customary care of the same intensity.</td>
<td>• By using the WMFT, the researchers were able to note that the experimental group had a non-significant trend toward improvement in the upper extremity in comparison to the control group over the four-month period. Improvement in grip-strength measurements were significant at all post-baseline visits. • CIMT improves hand functioning for subacute stroke patients more effectively than usual or customary care.</td>
<td>• The results from this study showed that CIMT was more effective in improving function in the upper extremity when compared to receiving customary/usual care for the subacute population. Outcome measures showed that both groups had significant improvements from baseline to post-treatment follow up.</td>
</tr>
</tbody>
</table>
IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH (Synthesis)

Introduction

- Does constraint-induced movement therapy improve functional ability of the affected upper extremity when compared to traditional stroke rehabilitation therapy for adults who experienced a stroke less than nine months ago?

Overall Conclusions

All three of the articles investigated were randomized controlled trials and consistently showed that CIMT had a positive trend for improving functioning of the upper extremity for adults who experienced a stroke less than nine months before treatment. Two of the three studies found statistical significance related to this finding in comparison to usual and customary care. Improvement was measured through the use of various outcome measures (2 studies utilized WMFT, 1 utilized ARAT). Effect sizes were not reported, and unable to be calculated, in two of the articles, due to lack of statistics presented. The third article (Myint et al., 2008) had large effect sizes (d=.90 and d=4.42) related to the improvement of upper extremity functioning. All three studies had strong evidence. The gains made in all of the studies were maintained at the follow-up evaluation (ranging from 4-12 months after initial assessment).

It should be noted that one study (Wolf et al., 2006) found improvement with grip strength, as measured by the WMFT, was not significant. However, the other two studies, through the ARAT and WMFT, found that grip strength improved significantly from baseline to follow-up. All other measures and conclusions regarding upper extremity function were similar between the three studies.

In all of the studies, both the customary/usual care group and the CIMT group improved from baseline to post treatment. However, the changes between scores from baseline to post-treatment for the control group, even if significant, were not as substantial as the changes noted in the CIMT group.

Boundaries

Two of the studies (Myint et al., 2008 & Sawaki et al., 2008) had relatively small sample sizes (43 and 30 respectively). The third study (Wolf et al., 2006) had a very large sample size (222 participants) and therefore these results are more likely to be representative of how the population of adults who experienced a stroke within nine-months, would respond to CIMT. Also, one study (Sawaki et al., 2008), used some of the participants that had been involved in another study that was used (Wolf et al., 2006). It was assumed that the article by Sawaki et al.(2008) involved more people who were note part of the study completed by Wolf et al. (2006).

A few important definitions varied between the three articles. First, the definition of “usual and customary care” was defined by one article as receiving four hours of therapy per day while utilizing NDT principles during bimanual UE training. The other two articles defined “usual and customary care” to include anything from no treatment to various occupational therapy or physical therapy treatments. The authors of these studies were unable to distinguish whether their results were due to the intervention of CIMT or the intensity of CIMT. However, the researchers of these two articles attempted to track the amount of time spent with a therapist through monthly phone interviews with study participants.

Another difference between the studies related to how CIMT was defined. All of the studies involved having participants wear a sling or mitt on their unaffected UE for 90% of all waking hours for two weeks as part of their definition. However, two of the studies had participants involved in therapy for six hours each day and the other study had participants involved in therapy for four hours per day. Replications

of these studies are needed to determine whether the difference in time spent in therapy has an impact on UE functioning.

A third definition that varied was subacute. Two of the studies defined subacute as the stroke having occurred between three and nine months prior to the onset of the study. The third study defined “subacute” as the stroke occurring between two and sixteen weeks prior to the onset of the study. Taking into account both of these definitions, this CAT defined subacute as less than nine months since the onset of the stroke.

Lastly, one of the studies looked at the effect of CIMT on patients that were currently staying in the hospital (Myint et al., 2008). The other two studies both looked at the effect of CIMT in an outpatient center. The results from the two studies that looked at CIMT as an outpatient intervention are more readily generalizable to other contexts.

Implications for Practice
CIMT has been an intervention used in therapy for adult stroke patients for many years and the results of these three studies are consistent with the findings of previous studies. All three studies showed that CIMT has a positive impact on improving UE function in adults who experienced a stroke in the previous nine months. It is still uncertain from the results of these studies whether CIMT improves grip strength. Other interventions may have more consistent success with improving grip strength, and clinicians should keep this in mind when planning treatment sessions.

At this time, there is not any formal certification or training requirements necessary to complete CIMT. However, a number of continuing education credits and training seminars are available nationwide for clinicians interested in learning more about how to utilize CIMT in treatment. At the very least, clinicians should observe a clinic that uses CIMT before implementing this intervention into their own clinic setting.

A clinician wanting to utilize CIMT should also consider whether the client they are working with is eligible for CIMT. Eligibility criteria for CIMT, used in all of the critiqued articles, states that a person must have ≥ 10° (preferably 20°) of active wrist extension, ≥ 10° of thumb abduction/extension and 10° of extension in at least two other digits.

All of the participants in the studies did show improvement throughout the timeframe of the studies. More research needs to be conducted regarding whether the treatment or the intensity of CIMT is more effective. In addition, none of the studies mentioned what types of stroke the participants experienced. This information should be included in future studies so that clinicians can better determine whether their participants are similar to the participants in the sample population.
References


Related Articles


Additional References Used in CAT Paper


APPENDIX (Article Critique)

Article Critique

Title:

Permalink:
http://libweb.uwlax.edu:2732/cgi/reprint/296/17/2095?eaf

Purpose of the Study:
• The purpose of this study was to compare the outcome of upper extremity functioning between CIMT with repetitive practice and traditional rehabilitative therapy in patients who had a stroke 3-9 months prior to the study.
• Research hypothesis:
  o The researchers hypothesized that individuals who were less than nine months post-stroke and who received CIMT would have greater improvement in upper extremity functioning than those receiving usual and customary care (Wolf et al., 2006).

Study Design:
• Level 1: Randomized controlled trial
• There were two groups:
  o Control group received usual and customary care. Some of the people in this group received no treatment, others received occupational or physical therapy within the context of their home, day treatment programs, or outpatient centers. The participants reported what therapy they were receiving to the study’s researchers during a monthly phone call and were offered CIMT at the end of the one year study.
  o Intervention group participated in constraint induced movement therapy. These participants were asked to wear a mitt around their uninvolved side, 90% of the time they were awake, for two weeks (14 days) while completing repetitive activities with their involved extremity.

Setting:
• The intervention occurred wherever the client was because they were asked to wear the mitt for 90% of their awake hours. This meant that if they were going into the community to go grocery shopping, the intervention would take place in the community. As another example, if the client were preparing a meal at home, they would still be wearing the mitt and so the intervention would be occurring within the home environment. The therapy, including shaping and standard task training, occurred in a laboratory setting. This was a multisite research study, with seven clinical sites.

Participants:
• There were 222 participants involved at the beginning of the study and 169 participants at the 12-month follow-up assessment. Reasons for discontinuing the study included withdrawing (29
participants), moved out of the area (4 participants), another stroke (3 participants), deteriorating conditions (8 participants), poor health (3 participants), and death (6 participants).

- All of the participants had experienced a stroke within the previous 3-9 months of enrollment
- There were seven clinical sites participating in this study (Emory University, University of Alabama, University of Florida, Ohio State University, University of Southern California, University of North Carolina, and Wake Forest University. Each site aimed to recruit 40 participants from their respective areas (247 cities total). Details were not provided regarding how the participants were recruited.

Inclusion/Exclusion criteria:

- Inclusion: Participants were included if they experienced a stroke 3-9 months prior to enrollment, which was a first-time clinical ischemic or hemorrhagic CVA (known through neuroimages or written medical reports), had adequate balance while wearing restraint and transferring to and from toilet independently, were able to stand from a sitting position, able to stand for at least 2 minutes with or without upper extremity support, and met either higher or lower-functioning motor criteria
  - Higher-functioning motor criteria: Participants could complete at least 20 degrees of wrist extension and at least 10 degrees of active extension of each MC and IP joint for all digits
  - Lower-functioning motor criteria: Participants had at least 10 degrees of active wrist extension, thumb abduction/extension, and extension in at least 2 additional digits.
  - All of these motions needed to be repeated 3 times in 1 minute.
- Exclusion: Participants were excluded if they scored less than 24 on the mini-mental status examination, if a doctor determined major medical problems could interfere with participation, had a previously clinically documented stroke, had excessive pain in any joint of the paretic extremity, were younger than 18 years old, had insufficient stamina to participate, scored 2.5 or higher on Motor Activity Log, or previously participated in other pharmacologic or physical intervention studies

- Participants were not blind toward grouping.
- Although not directly stated in the article, it is assumed that the sample was obtained through convenience sampling because the participants all came from cities in and around the seven clinical sites mentioned above.

- Key demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CIMT Group (n=106)</th>
<th>Control/Usual Treatment Group (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.0 (13.5)</td>
<td>63.3 (12.6)</td>
</tr>
<tr>
<td>Female</td>
<td>37 (34.9)</td>
<td>43 (37.1)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>71 (67.0)</td>
<td>86 (74.1)</td>
</tr>
<tr>
<td>Black</td>
<td>28 (26.4)</td>
<td>23 (19.8)</td>
</tr>
<tr>
<td>Paresis of prestrike dominant side</td>
<td>50 (47.2)</td>
<td>60 (51.7)</td>
</tr>
<tr>
<td>Ischemic stroke</td>
<td>97 (91.5)</td>
<td>98 (84.5)</td>
</tr>
<tr>
<td># days since stroke</td>
<td>179.8 (66.1)</td>
<td>187.7 (70.8)</td>
</tr>
<tr>
<td># of comorbidities</td>
<td>1.9 (1.4)</td>
<td>1.8 (1.4)</td>
</tr>
</tbody>
</table>

- Researchers mentioned that there were no significant differences between the groups related to demographics, stroke statistics, or co morbid disorders at baseline.
Intervention Investigated:

- Participants in the intervention group were taught how to apply a “protective safety mitt” and were asked to wear it 90% of their waking hours for fourteen days. During these 14 days, each participant in the intervention group participated in up to 6 hours/day of therapy with shaping and standard task training of the affected arm. Outside of this scheduled therapy time, participants were encouraged to practice 2-3 tasks daily at home.

- It was not specified directly in the article who provided treatment; however, from various contextual cues (authors, etc.) it is believed that the treatment providers were physical therapists.
  - All of the evaluators and interventionists went through a standardization process at the University of Alabama in Birmingham. They were also reviewed at 6-month intervals to ensure they were adhering to study protocols.

- The intervention was provided in a laboratory setting. No further details were included regarding when the intervention took place or what the laboratory setting was like.

- The intervention group underwent up to 6 hours of therapy per day for the fourteen-day period. Treatment time in the control group was variable because some patients did not receive any treatment at all. However, others utilized occupational or physical therapy to aid in their rehabilitation. The researchers attempted to track the care received by participants in the control group by calling to check in monthly and by asking them directly at testing sessions.

- Testing/observation/evaluation was conducted by individuals blind to group assignment. Interventionists, however, were not blind to the grouping, as this would have been nearly impossible and would have gone against the aim of the study.

Dependent Variables and Outcome Measures:

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>OT Framework Terms</th>
<th>ICF Level</th>
<th>Outcome Measure</th>
<th>Type of Data Yielded</th>
<th>Score Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Extremity Speed</td>
<td>Activity Demands (Sequence and Timing)</td>
<td>ICF: Body Function (neuromusculoskeletal and movement-related functions)</td>
<td>Wolf Motor Function Test (Timed Tasks)</td>
<td>Ratio</td>
<td>Less time is best, maximum amount of time for one item is 120 seconds (high indicates dysfunction)</td>
</tr>
<tr>
<td>Upper Extremity Strength</td>
<td>Body Functions: Neuromusculoskeletal and movement-related functions (Muscle power)</td>
<td>ICF: Body Function (neuromusculoskeletal and movement-related functions) and structure (structure related to movement/structure of nervous system)</td>
<td>Wolf Motor Function Test (Strength Tasks)</td>
<td>Ordinal</td>
<td>0=does not attempt, 5=normal movement (5 is best)</td>
</tr>
<tr>
<td>Actual use</td>
<td>Activity Demands</td>
<td>ICF: Activities and Motor</td>
<td>Ordinal</td>
<td>0-5 scale, 5</td>
<td>5=normal movement (5 is best)</td>
</tr>
</tbody>
</table>

Secondary outcome measures for this study included the stroke impact scale.

Main Findings:
- All of the participants were assessed at baseline, immediately following treatment, four months post-treatment, eight months post-treatment, and twelve months post-treatment.
  - The CIMT group had statistically significant results with all primary outcomes (WMFT and MAL) immediately following treatment.
    - WMFT
      - Performance Time: Mean=2.38, p<0.001
      - Functional Ability: Mean=2.69, p<0.001
    - MAL
      - Amount of Use: Mean=2.24, p<0.001
      - Quality of Movement: Mean=2.17, p<0.001
  - Also, participants in the CIMT group showed statistical significance at the twelve month follow up with performance time (WMFT subtest), and MAL subscale components.
    - WMFT/Performance time: Mean=2.23, p<0.01
    - MAL
      - Amount of Use: Mean=2.13, p<0.05
      - Quality of Movement: Mean=2.23, p<0.01
  - Both the intervention and control groups had statistical significance, for all outcome measures, when analyzing the change scores from baseline to twelve month follow up.
    - Statistical significance means that p<.05
  - Between groups statistics showed 8-14% of participants showed clinically relevant changes. A clinically relevant outcome occurred if a participant scored a three or higher on task from the MAL. This meant that a participant was using their impaired arm and hand at least 50% as much as prior to the stroke and without assistance from the unimpaired extremity. Direct effect sizes were not calculated for data in this study.

Original Authors’ Conclusions:
- CIMT had an effect on improving the function of the affected upper extremity (according to primary and secondary outcome measures).
  - This improvement in function was better than that of the control group and this difference was statistically significant immediately following the cessation of treatment on all four measures (WMFT performance time/functional ability and MAL AOU/QOM). Furthermore, this significance between groups was upheld through the twelve-month follow up for the WMFT Performance Time and for MAL scores. This means that the individuals in the CIMT group were able to perform tasks faster and perceived their arm...
to be able to do more in the control group, for at least to twelve months after treatment.

- Control participants also had statistically significant results related to upper extremity functioning throughout the one year study. However, larger changes were noted among participants of the CIMT group in comparison to the control group
- No effect was noted between high or low functioning individuals and CIMT or usual and customary care.

Validity:

- In their study, Wolf et. al. said “The EXCITE trial represents the first national, randomized, single-blind study to systematically test” CIMT in this specific population. The researchers believe that they did all of the necessary planning prior to their study in order to ensure high rigor and accurate conclusions (Wolf et. al., 2006, pp. 2096).
  - The researchers determined the appropriate number of people they would need for their study in order to make broad conclusions. Two-hundred-twenty-two is a large number of people for a randomized controlled trial, and given that it occurred throughout seven different locations, the results are more likely to be available for generalization.
  - After recruitment of individuals, the participants were randomized into groups and analyzed to determine whether the two groups were similar based on demographics and other variables (they were equal). It was not possible to keep the participants or the therapists providing treatment blind to which group the participant was in, but the researchers did make sure that that the assessor/evaluator was blind to group allocation.
  - The groups did not receive the same amount of time in treatment because the definition of usual and customary care was very broad. Some people in the group received no treatment at all, while others received occupational or physical therapy. The therapists made phone calls to members of the control group throughout the twelve months of the study in order to determine if control group participants were participating in any type of rehabilitation treatment and how intense this treatment was. At the end of the study, the control group participants were offered to participate in the same CIMT regimen.
  - The authors also addressed that it is possible spontaneous recovery could have occurred in both groups, contributing to the results stated above. In relation to this, they addressed that spontaneous recovery alone could not have been attributed for all of the improvement that occurred.
  - The instruments that the researchers chose to use as outcome measures had good psychometric properties and were used for pre-test, assessments during intervention, and post-testing with each individual. It is possible that participants could have learned how to do some parts of the test between trials, however, this ability to learn would equate with improvement of the affected extremity.
- PEDro score: 8/10
  - Blinding of the participants and therapists was not possible because the participants were wearing a mitt and therefore knew that they were in the intervention group. The participants needed to wear these mitts in treatment and therefore, therapists were not blind to grouping assignment either (PEDro component: 4 + 5)

Interpretation of Results:

• Based on the results of this study, CIMT is an effective approach when compared to usual and customary care. Statistical significance was present for within group changes as well as between-group improvements, with the CIMT group making more substantial changes than the control group.
  o Participants in the intervention group reported using their affected extremity to help perform tasks independently. Caregivers reported this same finding.
  o The amount of tasks the participants were able to perform on the WMFT also increased throughout the duration of the study, more significantly in the intervention group than the control group. The intervention group overall was able to do more tasks both immediately and at the twelve-month follow up evaluation.
  o CIMT participants mentioned that they were using their affected upper extremity at least half as much as prior to the stroke on twice as many MAL items in comparison to the control group. This trend was still present at the twelve-month follow up evaluation.
    ▪ These same participants also reported at twelve months that they were able to do three times the amount of tasks independently with their affected arm (without the help of their unaffected arm) as they had originally reported at baseline. Caregivers verified this same belief in relation to the participant.
• One outcome that was particularly interesting was the WMFT Functional Use score. This was interesting because there was not a significant difference between the intervention and the control group at the twelve-month follow up, but there had been a significant difference with this measure at all of the previous assessment times. The authors mentioned that it made sense for the Performance Time score to have improved because they emphasized speed with repetitions during therapy sessions. However, the researchers never addressed why the functional arm score would not have been significant. It is possible that the CIMT group received the maximum score on this, encountering a ceiling effect, which would not have allowed them to receive a statistically significant score.
• Only 48.8% of those in the control group received clinical care during the time of the study. Thus, there was not an equal intensity of treatment between groups. This is a fatal flaw of the study and it cannot be determined whether the effects noted in the study are due to the CIMT intervention or the amount of time in treatment.
• Treatment effect sizes were not reported in this article and are not possible to calculate given the reported data. However, the researchers outlined that a participant score on a task from the MAL as a three or higher would show a clinically significant outcome. This would mean the participant was using their impaired arm and hand at least 50% as much as prior to the stroke and without assistance from the unimpaired extremity.

Summary/Conclusion: (Take Away Message)
• The treatment time was not equal the control and the treatment groups and therefore, it is not known whether the intervention of CIMT caused the results or the amount of time people in this group were seen for. Future studies should consider replicating most of what was done in this study, as all other parts were rigorous. However, it is imperative that future studies make the amount of time treated between groups equal so that the results can be trusted.
**PEDro Scale: Rating Sheet**


<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Participants were randomly allocated to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received)</td>
<td>Yes: Participants were randomized using an automated, centralized system with an even distribution for sex, prestroke dominant side, side of stroke, and arm functional ability (pg. 2096).</td>
</tr>
<tr>
<td>2. Allocation was concealed</td>
<td>Yes: Participants were gathered by 7 clinical sites but were broken into groups by only 1 clinical site (pg. 2096)</td>
</tr>
<tr>
<td>3. The groups were similar at baseline regarding the most important prognostic indicators.</td>
<td>Yes: Similar with demographic, stroke-related, and cognitive characteristics (pg. 2099)</td>
</tr>
<tr>
<td>4. There was blinding of all participants</td>
<td>No: Not possible given that the intervention group is wearing a mitt</td>
</tr>
<tr>
<td>5. There was blinding of all therapists who administered the therapy</td>
<td>No: Not possible because participants are wearing a mitt during therapy. The control group did not go to therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all assessors who measured at least one key outcome.</td>
<td>Yes: Assessors were blind to group assignment (pg. 2098)</td>
</tr>
<tr>
<td>7. Measures of at least one key outcome were obtained from more than 85% of the participants initially allocated to groups.</td>
<td>Yes: (pg. 2100) 220 participants were allocated to groups, 202 were analyzed at post-treatment (92%).</td>
</tr>
<tr>
<td>8. All participants for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by ‘intention to treat’.</td>
<td>Yes: All available data for all analyses were analyzed by “intention to treat” (pg. 2098).</td>
</tr>
<tr>
<td>9. The results of between-group statistical comparisons are reported for at least one key outcome.</td>
<td>Yes: Listed for all outcomes (pg. 2101).</td>
</tr>
<tr>
<td>10. The study provides both point measures and measures of variability for at least one key outcome.</td>
<td>Yes: (Pg. 2101)</td>
</tr>
<tr>
<td>Eligibility criteria were specified (not included in score)</td>
<td>Yes: (pg. 2096)</td>
</tr>
</tbody>
</table>

**Total score**: 8/10
PEDro Scale: Rating Sheet


<table>
<thead>
<tr>
<th>Criteria</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Participants were randomly allocated to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received)</td>
<td>Yes: Participants drew sealed envelopes which were filled at random with which group the participant would be part of (pg. 113).</td>
</tr>
<tr>
<td>2. Allocation was concealed</td>
<td>Yes: Groups were allocated by sealed envelopes. Any participant could have pulled any envelope. Therefore, no one could have known which group the participant would be in prior to envelop drawing (pg. 113).</td>
</tr>
<tr>
<td>3. The groups were similar at baseline regarding the most important prognostic indicators.</td>
<td>Yes: There was not statistical significance regarding differences between groups on demographic or stroke-related characteristics (pg. 116).</td>
</tr>
<tr>
<td>4. There was blinding of all participants</td>
<td>No: Not possible given that the intervention group is wearing a mitt</td>
</tr>
<tr>
<td>5. There was blinding of all therapists who administered the therapy</td>
<td>No: Not possible because participants are wearing a mitt during therapy. The control group did not go to therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all assessors who measured at least one key outcome.</td>
<td>No: Nothing was mentioned about assessors being blind to group assignment.</td>
</tr>
<tr>
<td>7. Measures of at least one key outcome were obtained from more than 85% of the participants initially allocated to groups.</td>
<td>No: (pg.116) 48 participants were randomized to groups, 37 were still part of the study at the last follow up session (77%).</td>
</tr>
<tr>
<td>8. All participants for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by ‘intention to treat’.</td>
<td>Yes: A modified intention-to-treat analysis was implemented because not all subjects who were randomized received baseline assessment (pg. 115).</td>
</tr>
<tr>
<td>9. The results of between-group statistical comparisons are reported for at least one key outcome.</td>
<td>Yes: Listed for all outcomes (pg. 118).</td>
</tr>
<tr>
<td>10. The study provides both point measures and measures of variability for at least one key outcome.</td>
<td>Yes: (Pg. 121)</td>
</tr>
<tr>
<td>Eligibility criteria were specified (not included in score)</td>
<td>Yes: (pg. 2096)</td>
</tr>
</tbody>
</table>

**Total score:** 6/10
**PEDro Scale: Rating Sheet**


<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Participants were randomly allocated to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received)</td>
<td>Yes: Participants were randomized after determining eligibility (pg. 506).</td>
</tr>
<tr>
<td>2. Allocation was concealed</td>
<td>No: This was not mentioned in the article.</td>
</tr>
<tr>
<td>3. The groups were similar at baseline regarding the most important prognostic indicators.</td>
<td>Yes: No baseline differences were noted between groups (pg. 508).</td>
</tr>
<tr>
<td>4. There was blinding of all participants</td>
<td>No: Not possible given that the intervention group is wearing a mitt</td>
</tr>
<tr>
<td>5. There was blinding of all therapists who administered the therapy</td>
<td>No: Not possible because participants are wearing a mitt during therapy. The control group did not go to therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all assessors who measured at least one key outcome.</td>
<td>Yes: Evaluators were blind with group allocation (pg. 507).</td>
</tr>
<tr>
<td>7. Measures of at least one key outcome were obtained from more than 85% of the participants initially allocated to groups.</td>
<td>No: There were 30 participants for the beginning of the study, however the amount of participants still present at the end of the study was not included in the article.</td>
</tr>
<tr>
<td>8. All participants for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by ‘intention to treat’.</td>
<td>Yes: Intention to treat analyses were preformed for the outcome measure results (pg. 508).</td>
</tr>
<tr>
<td>9. The results of between-group statistical comparisons are reported for at least one key outcome.</td>
<td>Yes: Listed for all outcomes (pg. 508).</td>
</tr>
<tr>
<td>10. The study provides both point measures and measures of variability for at least one key outcome.</td>
<td>No: Mean values and p-values were reported for outcomes, however no other data was present.</td>
</tr>
</tbody>
</table>

Eligibility criteria were specified (not included in score) | Yes: Information was included. Readers were also guided toward another study for additional criteria (pg. 506). |

**Total score:** 5/10