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AutoCITE
Automated Delivery of CI Therapy With Reduced Effort by Therapists

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Background and Purpose—To evaluate the effectiveness of a device that automates Constraint-Induced Movement therapy (CI therapy), termed AutoCITE, when only partially supervised by therapists.

Methods—Twenty-seven participants with chronic stroke trained with AutoCITE for 3 hours per day for 10 consecutive weekdays. Participants were assigned to 1 of 3 groups in a fixed irregular order (ie, in alternating blocks): supervision from a therapist for 100%, 50%, or 25% of training time.

Results—The effect sizes of the treatment gains for the 3 groups on the Motor Activity Log (MAL) were very large and for the Wolf Motor Function Test they were large (all $P<0.001$) but were not significantly different from one another. Gains were comparable to those previously reported for participants who received an equal amount of standard one-on-one CI therapy without the device. At 1-month and long-term follow-up, gains from pretreatment on the MAL were also significant ($P<0.001$).

Conclusion—These results demonstrate that AutoCITE training with greatly reduced supervision from a therapist is as effective as standard one-on-one CI therapy. (***Stroke***. 2005;36:1301-1304.)

Key Words: stroke ■ rehabilitation ■ treatment outcome

Clinical trials from several laboratories have shown that survivors of stroke with chronic mild to moderately severe arm motor impairment who are given Constraint-Induced Movement therapy (CI therapy) exhibit a large increase in the amount of use of the more affected upper extremity that transfers to the life situation.[1–8] CI therapy consists of 3 main components: (1) concentrated task-based training by the technique termed "shaping"[8,9] for many hours per day for a period of 2 or 3 weeks; (2) transfer techniques to effect generalization of treatment gains from the laboratory/clinic to the life situation; and (3) restraint of the less-affected extremity for a target of 90% of waking hours. Clinical implementation of the technique is hindered by the large amount of costly one-on-one therapist supervision needed during the training component of the therapy.

We have developed a device termed AutoCITE (automated CI therapy extension) that automates the training portion of CI therapy and is as efficacious as standard CI therapy.[9] AutoCITE could potentially reduce the cost of the therapy by allowing participants to perform the training in the clinic with only partial therapist supervision. This is significant given the current health care climate of cost containment, in which provision of services by health care payers is being cut back sharply for physical rehabilitation.

However, if AutoCITE is to succeed as a device that reduces the workload of clinical staff, it must be demonstrated that the effectiveness of the AutoCITE is not diminished when participants use it with only partial supervision from therapists.

AutoCITE is conceptually similar to recently developed devices in the area of robotics telerehabilitation (involving remote interaction between therapist and patient), virtual reality, and powered assistive devices.[10,11] However, to our knowledge, this is the first controlled study involving a device of this type that compares the efficacy of a device against a comparable nonautomated treatment. The results of this comparison are needed to justify clinical use of such devices.
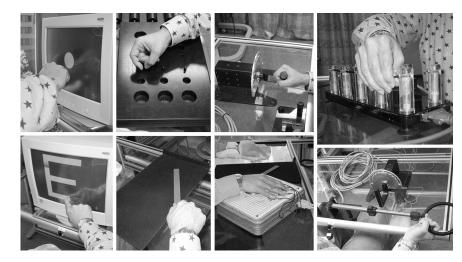
Materials and Methods

Apparatus

The AutoCITE consists of a computer, 8 task devices arrayed in a cabinet on 4 work surfaces, and an attached chair. The computer provides simple 1-step instructions on a monitor that guides the participant through the entire treatment session. Completion of each instruction is verified by sensors built into the device before the next instruction is given. The participant is able to select tasks from a menu displayed on the monitor using 2 pushbuttons. Once a task has

Task devices. Top row (left to right), Reaching, peg board, supination/pronation, threading. Bottom row (left to right), Tracing, object-flipping, finger-tapping, arc-and-rings.

been chosen, the appropriate work surface is manually pulled out and locked over the participant's lap. The computer program guides the participant through a set of 10 30-second trials in which the objective is to repeat a task as many times as possible. After 10 trials, the task menu is displayed and the subject can select the next task. Several types of performance feedback and encouragement are provided on the computer monitor, simulating the type of verbal behavior engaged in by a therapist. The time remaining on each trial is shown on the computer monitor. The number of successful repetitions is displayed after each trial and set of trials in the form of a bar graph.

The activities are based on tasks currently used in CI therapy. In each case, sensors measure key aspects of the task, and performance is automatically measured. The 8 activities available, depicted in the Figure, are: reaching, tracing, peg board, supination/pronation, threading, arc-and-rings, finger-tapping, and object-flipping. A description of each of these tasks has been presented elsewhere.[9]

Subjects

Twenty-seven participants with mild to mild/moderate chronic stroke were recruited in sequence from a list of individuals making contact with the project to request standard CI therapy. Chronicity was >1 year for all individuals. Participant characteristics and initial motor scores are presented in Table 1. All participants could extend at least 20 degrees at the wrist and 10 degrees at each of the finger joints while at the same time having greatly reduced use of the extremity in the activities of daily living. Participants were excluded if they had balance problems, excessive pain in any joint of the extremity, were too high-functioning (>2.5 Motor Activity Log [MAL] score), or had uncontrolled medical problems, excessive spasticity, or cognitive problems as indicated by a score on the

Mini-Mental State Examination of <24 as in previous work.[1] The protocol was approved by the local institutional review board and each patient signed an informed consent form.

Procedures

All subjects were asked to wear a padded safety mitt on their less-affected hand for a target of 90% of waking hours over a 2-week period.[1] On each weekday, subjects received training using the AutoCITE for 3 hours. Participants were assigned to 50% or 25% supervision from the therapist in a fixed irregular order (ie, in alternating blocks). Participants who received 100% supervision had been treated and tested previously.[9] A heavy floor-to-ceiling curtain was placed between the AutoCITE and the therapist's desk. The therapist set-up the participant on AutoCITE and then retreated behind the floor-to-ceiling curtain while the participant performed the tasks. The therapist only returned to change tasks, change the difficulty of tasks, or when a participant requested assistance (which occurred 1.7 times per hour.). In the remainder of the allotted interaction time for that patient, the therapist supplemented the encouragement and feedback provided on the computer monitor. The difficulty of the tasks was varied using shaping guidelines derived from previous CI therapy research.[8,9] Shaping involved progressively increasing the difficulty of a task in small steps and providing frequent positive feedback and encouragement. Testing was performed just before and after the intervention. The tests included the Wolf Motor Function Test (WMFT)[1,12] and the MAL.[1] The WMFT measures performance time and functional ability on 15 tasks and the strength of shoulder flexion/elbow extension and grip in 2 tasks. Functional ability is rated from videotape by masked raters trained to a high level of reliability ($r>0.9$).[12] The MAL is a structured interview that provides a measure of spontaneous use of the more affected upper extremity in the life situation. It obtains information on how much (Amount of Use scale) and how well (Quality of Movement scale) the more impaired arm was used for accomplishing important activities of daily living. The version used here had 14 items; only the Quality of Movement scale is reported because Quality of Movement scale and Amount of Use scale scores were highly correlated ($r=0.91$). Details of the treatment and testing procedures are described elsewhere.[1,9,13]

Data Analyses

Group differences for categorical variables (gender, side of dominance, and paresis) were tested by χ^2; age, chronicity, and initial motor scores were tested using univariate analyses of variance. Repeated-measures analyses of variances were used to evaluate the effect of treatment. Significant results from the analyses of variances for the MAL were followed by pair-wise comparisons using Tukey's tests. The magnitude of the treatment effects was indexed using d', a within-subjects measure of effect size. By the standards of the meta-analysis literature, small, medium, and large d' values are 0.14,

TABLE 1.   Participant Characteristics and Initial Motor Scores

	Percentage Supervision		
	100% (n=9)	50% (n=9)	25% (n=9)
Age	56.3±10.5	64.5±8.1	59.6±12.1
Chronicity, y	5.3±3.7	5.7±4.9	5.5±2.7
Male/female	7/2	6/3	8/1
Paresis, right/left	6/3	6/3	3/6
Dominance, right/left	9/0	8/1	7/2
MAL, max=5	1.1±0.42	1.3±0.53	1.13±0.60
WMFT FA, max=4	2.8±0.50	2.7±0.33	2.7±0.29
WMFT PT, sec	3.7±1.4	3.5±1.6	3.9±1.3

Values are mean±standard deviation. None of the between group differences were significant (median, $P=0.55$; range, 0.26−0.98).

TABLE 2.   Treatment Gains on Motor Tests

	AutoCITE (% Supervision)				Standard CI Therapy
	100%	50%	25%	Combined	
Changes from Pretreatment to Post-treatment					
MAL	2.0±0.37	2.0±0.48	1.9±0.74	2.0±0.54†	1.9±0.6†
WMFT FA	0.1±0.11	0.2±0.10	0.2±0.17	0.1±0.14†	0.2±0.3*
WMFT PT	−1.0±1.26	−0.7±1.08	−0.9±0.76	−0.9±1.0†	−2.3±2.3†
Changes from Pre- to 1-Month Follow-up					
MAL	1.5±0.87	2.0±0.40	2.0±0.61	1.8±0.67†	1.9±0.7†
Changes from Pre- to Long-term Follow-up					
MAL	1.4±0.65	1.6±0.49	1.5±0.85	1.5±0.66†	1.2±0.9†

Values are mean±standard deviation. None of the between group differences in improvement from pretreatment (ie, group × testing occasion effects) were significant. Significance levels are noted for change from pretreatment within all AutoCITE groups combined and a previously run CI therapy group (n=21), which received one-on-one therapist-administered training and is included here for ease of reference. Long-term follow-up was obtained >6 months after treatment for all individuals in each of the groups.

*$P<0.05$; †$P<0.001$.

0.35, and 0.57, respectively.[14] Individual test scores that were greater than 3 standard deviations from the mean were considered outliers. On this basis, the WMFT performance time scores of 2 participants were excluded. Follow-up MAL data were excluded from 2 subjects who experienced serious medical problems that impeded their physical activity for extended periods shortly after the end of treatment. The medical problems were judged (by V.W.M.) to be unrelated to participation in this study.

Results and Discussion

There were no significant differences before treatment between the 100%, 50%, and 25% supervision groups on the MAL and WMFT or in the demographic or stroke characteristics measured (Table 1). The time logging procedure used by the experimenter was successful in controlling the amount of supervision: average supervision times were 50.2±2.5% and 25.3±2.3% in the 2 reduced supervision groups, respectively. Furthermore, the intensity of training did not differ significantly between groups; mean tasks per hour for the 100%, 50%, and 25% supervision groups were 3.5±1.7, 3.5±0.67, and 3.2±0.96, respectively.

Participants in all 3 groups combined showed significant changes in real-world arm use over all post-treatment testing occasions (MAL: $P<0.001$). At post-treatment the mean gain on the MAL was 2.0±0.54 points ($P<0.001$, $d'=3.7$). This very large improvement was retained at 1-month follow-up (Table 2). At long-term follow-up, there was ≈16% decrement from post-treatment (−0.5±0.54, $P<0.05$). Relative to pretreatment, however, the gains retained at long-term follow-up were still large (Table 2). Participants also showed large improvements in arm motor ability (WMFT; Table 2).

Most importantly, with respect to the primary question addressed in this experiment, there were no significant differences in treatment outcome among subjects that received 100%, 50%, and 25% supervision (Table 2). The fact that no significant differences were found between the 100% and reduced supervision groups does not preclude the possibility that a minimal clinically important difference (MCID) existed, but was not detected because of the sample size. The MAL, which is a measure of real-world arm use, has been

used extensively in CI therapy research and the MCID has been defined by van der Lee et al to be values >10% of full scale, or 0.5 points.[7,15] Power to detect a reduction in effectiveness larger than the MCID at post-treatment in the 50% and 25% supervision groups relative to the 100% group was adequate (>0.84). Furthermore, differences between the 100% and partial supervision groups in gains from pretreatment on the MAL were less than the MCID at post-treatment and both follow-ups (Table 2).

This work represents a successful step toward automation of the training component of CI therapy. In previous work, we showed that AutoCITE training when supervised 100% of the time by a therapist is as effective as standard one-on-one CI therapy. This study shows that there was no loss of effectiveness when the AutoCITE training was supervised for only 50% or 25% of the time. These results justify continued investigation into automated forms of CI therapy. They suggest that with AutoCITE, one therapist may be able to treat multiple patients at one time.

Acknowledgments

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