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Portable Upper Extremity Robotics is as Efficacious as Upper Extremity Rehabilitative Therapy: A Randomized Controlled Pilot Trial

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Abstract

Objective—To compare the efficacy of a repetitive task specific practice regimen integrating a portable, electromyography-controlled brace called the “Myomo” versus usual care repetitive task specific practice in subjects with chronic, moderate upper extremity impairment.

Subjects—16 subjects (7 males; mean age = 57.0 ± 11.02 years; mean time post stroke = 75.0 ± 87.63 months; 5 left-sided strokes) exhibiting chronic, stable, moderate upper extremity impairment.

Interventions—Subjects were administered repetitive task specific practice in which they participated in valued, functional tasks using their paretic upper extremities. Both groups were supervised by a therapist and were administered therapy targeting their paretic upper extremities that was 30-minutes in duration, occurring 3 days/week for 8 weeks. However, one group participated in repetitive task specific practice entirely while wearing the portable robotic while the other performed the same activity regimen manually..

Main Outcome Measures—The upper extremity Fugl-Meyer, Canadian Occupational Performance measure and Stroke Impact Scale were administered on two occasions before intervention and once after intervention.

Results—After intervention, groups exhibited nearly-identical Fugl-Meyer score increases of ≈ 2.1 points; the group using robotics exhibited larger score changes on all but one of the Canadian occupational performance measure and Stroke Impact Scale subscales, including a 12.5-point increase on the Stroke Impact Scale recovery subscale.

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Conclusions—Findings suggest that therapist-supervised repetitive task specific practice integrating robotics is as efficacious as manual in subjects with moderate upper extremity impairment.

Keywords

Rehabilitation; stroke; hemiplegia; rehabilitation

Stroke frequently causes lasting motor impairments that undermine independence. For example, 30–70% of survivors remain unable to functionally use their paretic upper extremities at rehabilitation discharge,¹ and 50% continue to exhibit upper extremity weakness 6 months after stroke.² Additionally, stroke incidence remains stable³ while stroke risk factors (e.g., advanced age, obesity) are becoming more common. Consequently, the prevalence of stroke survivors with motor impairments is expected to increase over the next decade.⁴

To address these impairments, device-driven approaches have been developed, including upper extremity robotic systems.^{5,6} Yet, evidence supporting these systems is equivocal,^{e.g.,7} and their cost and size limit widespread clinical and home use. Given the efficacy of upper extremity approaches emphasizing repetitive task-specific practice,^{e.g.,8,9,10,11} a portable, electromyography triggered, robotic brace (called the “Myomo”) was developed, allowing patients to make active upper extremity practice attempts with mechanical assistance. To date, Phase I, uncontrolled, pilot studies^{12,13} have reported reduced upper extremity impairment following repetitive task specific practice integrating the Myomo in patients with moderate upper extremity impairment. However, it remains unclear whether this regimen is as efficacious as repetitive task specific practice that is manually delivered by a therapist. Because repetitive task specific practice is frequently used in stroke clinical environments,¹⁴ studies optimizing its delivery are needed. Given diminishing rehabilitative contact time, alternative repetitive task specific practice delivery methods would also be beneficial.

As a next step, the purpose of this Phase IIa, randomized, controlled pilot study was to determine the efficacy of a repetitive task specific practice regimen integrating the Myomo in subjects with chronic, moderate upper extremity impairment. Using the upper extremity Fugl-Meyer¹⁵ as the primary outcome measure, the efficacy of this strategy was compared to the efficacy of a time-matched, manual repetitive task specific practice regimen. Accomplishment of this purpose was fundamental to estimating the Myomo’s treatment effect and optimizing measures for clinical and research use. To our knowledge, this was the first randomized controlled trial of any portable upper extremity robotics strategy. The study was also significant given the paucity of evidence-based, easily-administered, automated treatment strategies for stroke survivors exhibiting moderate upper extremity impairment.

Method

Subjects

Volunteers were recruited using approved advertisements distributed to local stroke support groups and outpatient rehabilitation clinics. To qualify for the study, volunteers had to meet the following inclusion criteria: (a) upper extremity Fugl Meyer¹⁵ score 10 and 25; (b) detectable EMG in the biceps brachii of the paretic upper extremity; (c) stroke experienced > 12 months prior to study enrollment; (d) a score 24 on the Folstein Mini Mental Status Examination;¹⁶ (e) age 21–75; (f) experienced one stroke; (g) discharged from all forms of physical rehabilitation; (h) Myomo brace fit on paretic upper extremity properly and without discomfort (i.e., no discoloration or discomfort observed in 10 minutes of use during

fitting). Exclusion criteria were: (a) < 21 years old; (b) excessive pain in the paretic hand, arm or shoulder, as measured by a score ≥ 5 on a 10-point visual analog scale; (c) excessive spasticity at the paretic elbow, as defined as a score of ≥ 2 on the Modified Ashworth Spasticity Scale;¹⁷ (d) currently participating in any experimental rehabilitation or drug studies; (e) apraxia (< 2.5 on the Alexander scale¹⁸); (f) severe sensory loss in paretic hand (Nottingham Sensory Assessment¹⁹ at least 75% of normal); (g) severe language deficits (score < 2 on NIH Stroke Scale²⁰ question 9); (h) stroke that occurred in the brainstem; (i) current medical history of uncontrolled cardiovascular, or pulmonary disease, or other disease that would preclude involvement in a therapeutic treatment; (j) history of neurological disorder other than stroke; (k) other significant pain, skin irritation, or other upper extremity comorbidities that could be exacerbated by the use of the device.

Apparatus

The Myomo e100 (Figure 1) is a Food and Drug Administration–approved, lightweight (4 lb, 6 oz), wearable system that continuously monitors surface EMG signals from either the belly of the biceps brachii or the lateral head of the triceps. These signals control the powered neurorobotic orthosis and assist the active muscle with movement of the paretic upper extremity. The EMG can also be used to provide passive assistance in the opposite direction when the muscle being targeted relaxes (e.g., when the sensor is on the biceps, the Myomo can provide assistance with elbow flexion when the biceps are active, or assistance with passive elbow extension when the biceps are relaxed). The EMG signals are filtered and processed to infer a desired joint torque. The signal processing of the measured surface EMG is accomplished through a system comprises of off-the-shelf EMG sensors, analog signal–processing components, and digital signal–processing components. The signal-processing algorithm enables bidirectional control at the elbow into flexion or extension. The system gain parameter (i.e., amount of assistance in the active assist direction) varies during the course of a session, as the subject fatigues. The base unit for software gain is 12 V of motor voltage per volt of surface EMG voltage. The passive opposing force parameter is generally constant throughout a therapy session, usually changing slightly from session to session to account for changes in muscle tone. Additional technical details describing the device are available by consulting other articles describing the device.¹²

During active paretic upper extremity movement attempts, the user's intention to move is detected via his/her EMG. The treating therapist can then adjust the system parameters to alter the amount of mechanical assistance that the device provides on an as needed basis. Changing the location of the EMG sensor (which can be accomplished without removing the brace) allows the user to alternate between active assistance with elbow flexion or extension, without changing device settings.

Assessments

The upper extremity section of the *Fugl-Meyer Scale* was selected as the primary outcome measure, and was used to assess whether changes occurred in paretic upper extremity impairment. Upper extremity Fugl-Meyer data arise from a 3-point ordinal scale (0=cannot perform; 2=can perform fully), and the upper extremity motor component (66 points) was used. The Fugl-Meyer has been shown to have high test-retest reliability (total=.98–.99; subtests=.87–1.00), interrater reliability, and construct validity.^{21,22}

In addition, the following secondary outcome measures were applied: (a) The *Canadian Occupational Performance Measure*²³ was used to identify performance problems and measure subjects' satisfaction with the tasks used in this study before and after intervention. The Canadian Occupational Performance Measure uses a 10 point Likert scale from 1–10, in which subjects identified their perception of their performance with the tasks, and their

satisfaction with their performance of the tasks. The Canadian Occupational Performance Measure was reported to be a valid, reliable, clinically useful and responsive outcome measure,²⁴ including following stroke.²⁵ (b) The *Stroke Impact Scale*²⁶ is a 64-item self-report measure assessing 8 domains (e.g., strength, hand function, mobility, communication, emotion, memory and thinking, and participation). In previous studies, Stroke Impact Scale domains were examined by comparing the Stroke impact Score to existing stroke measures and by comparing differences in scores across Rankin scale levels. Using these techniques, each domain met or approached the standard of 0.9 alpha-coefficient for comparing the same patients across time. The intraclass correlation coefficients for test-retest reliability ranged from 0.70 to 0.92. For this study, we focused on SIS domains likely to be impacted by upper extremity motor changes, which were strength, hand function, ADL/IADL, mobility, participation, and perception of overall recovery.

Study Design, Randomization, and Interventions

The primary objective of this small, randomized, controlled, Phase IIa trial was to compare determine the efficacy of a repetitive task specific practice program integrating the Myomo versus repetitive task specific practice only, as measured using the upper extremity Fugl-Meyer. To accomplish this purpose, a randomized, controlled, single-blinded, multiple-baseline design was applied.

After completing approved consent forms and passing screening criteria, each subject was administered the assessments on two occasions. The assessments were administered one week apart by the same rater. This multiple baseline design has two purposes: (a) due to their time since stroke, it was probable that subjects were exhibiting stable motor deficits. However, multiple administrations of outcome measures was used to assure that individuals were exhibiting stable motor deficits; (b) the repeated pretesting design was expected to increase the stability of the individual motor estimates, thereby lessening error variance. This was expected to diminish effects of preexisting individual differences. Subjects were then randomly assigned to one of two study conditions using a random numbers table: (a) Myomo only (n = 8); or (b) repetitive task specific practice only (n = 8). Each study condition was assigned a number on the table; subjects were assigned to groups depending on the number that next occurred. Each condition required participation in one-hour, outpatient therapy sessions occurring 3 days/week over a period of eight weeks. The study conditions were, thus, matched in their frequency and duration of treatment contact time. Additionally all therapies were administered in the same location and by the same therapists, who had undergone extensive training to ensure consistency of treatment.

Subjects in both groups were administered a standardized repetitive task specific practice therapy program applied to four common tasks (see Table 1). Two of the tasks were unilateral and two were bilateral in that they emphasized use of both upper extremities actively or to actively assist one another during task performance. Activities included components of muscle control, coordination, strength, endurance, and proprioception in order to perform the purposeful movements, and were chosen because: (a) over the last decade in our laboratory, they had been commonly-cited as tasks that subjects wanted to re-learn; (b) whereas many robotic approaches¹¹ have emphasized unilateral upper extremity use, two of the chosen tasks were purposefully bilateral in nature. An inherent advantage of a portable, wearable robot was the ability to integrate both upper extremities simultaneously during performance of bilateral tasks so that practice conditions are more analogous to how many tasks are typically performed; (c) the tasks could be graded and adapted, so that subjects would be challenged. This was important since challenge is a critical factor underlying learning, cortical plasticity, and subsequent functional change.^{e.g.,27}

To grade the difficulty of the tasks and maintain challenge, the treating therapist manipulated temporal and spatial domains of each task according to motor deficits exhibited by each subject. Specifically, each task in Table 1 was broken into its component segments. Each segment required successful completion before the entire task was “put together.” Therapy was individualized by emphasizing movement segments that targeted the impairments exhibited by each subject. For example, spatial control could be progressed for a subject by progressively moving the object further from the participant, thus imposing greater ranges of joint motion, especially in the affected elbow and forearm, which were the foci of the current intervention. Ultimately, the participant would be progressed to undertake the activities in a standing position, thus imposing postural control and weight shifting demands. Temporal domain elements were likewise engaged by requiring the patient to repeat the task components or total task activity as frequently as possible during a defined time interval.

At the beginning of each Myomo session, the EMG surface electrodes were placed on the belly of the bicep brachii and lateral head of the tricep on the paretic upper extremity, and connected to the control box of the device. The brace was then placed on and strapped to the upper extremity. As with repetitive task specific practice -only subjects, the focus of Myomo treatment sessions was performance of the tasks listed in Table 2, with the paretic upper extremity either actively performing, or actively assisting in the task. The lowest amount of assistance by the device to complete the task was used, and challenge was added to the tasks as described above.

Posttesting

One week after completing the intervention phase, each subject returned to the laboratory, where all instruments were re-administered by the same examiner as before intervention. The rater was blinded to the group to which subjects were assigned.

Results

Applying the aforementioned study criteria, 16 subjects were enrolled (7 males; mean age = 57.0 ± 11.02 years; mean time post stroke = 75.0 ± 87.63 months; 5 left-sided strokes). Figure 1 depicts the flow of subjects through the study. Table 2 provides subject characteristics.

An independent samples t-test was used to compare changes in scores (post-pre) on the Fugl-Meyer, Canadian Occupational Performance Measure, and selected Stroke Impact Scale scores between the two study conditions. The change score was an appropriate outcome variable since no differences in the variance of the pre and post scores was found to be significant via Levine’s test for equality of variances. All tests were adjusted for multiple comparisons via the Bonferroni adjustment.

On the primary outcome measure (Fugl-Meyer), both groups exhibited nearly-identical score increases of ≈ 2 points (Myomo only: 20.75 before intervention to 22.88 post intervention; repetitive task specific practice only: 19.38 before intervention to 21.63 after intervention), resulting in no significant difference in the amount of change between the groups (Table 3). On the secondary outcome measures, the valence of the scores between groups differed on five of the eight measures. Moreover, Myomo subjects displayed more positive score changes on the outcome measures than subjects in the repetitive task specific practice only group (Myomo subjects displayed positive changes on seven of the secondary measures while repetitive task specific practice subjects exhibited positive changes on only three of the secondary outcome measures). Marked, non-significant differences in the magnitude of change were seen in favor of the Myomo group on the Stroke Impact Scale ADL, hand, and

recovery scales, but no significant differences were exhibited between groups on any of the secondary outcome measures.

Discussion

The major study finding was that the amount of change on the Fugl-Meyer (the primary outcome measure) after Myomo-based repetitive task specific practice was nearly-identical to the amount of change exhibited after repetitive task specific practice delivered manually by a therapist, which constitutes usual care in most stroke environments. The amount of Fugl-Meyer change exhibited by subjects using the Myomo in this study was consistent with pilot work leading to this study. For instance, Page and colleagues¹³ reported 2-point Fugl-Meyer changes after a subject engaged in an 8-week Myomo program on which the current study protocol was based. Likewise, a feasibility study by Stein et al¹² showed Fugl-Meyer changes of ≈ 3.5 points ± 3.3 , as well as reduced hypertonicity, as evidenced by Modified Ashworth Spasticity Scale reductions of 2.33 to 4.67 points at the paretic elbow; the joint that is primarily targeted during Myomo treatment. It is also notable that, with the exception of the Canadian Occupational Performance Measure satisfaction scale, outcomes on all measures trended positively for subjects using the Myomo in this trial. Due to the chronicity and stability of subjects' motor deficits and the fact that they were not being administered other upper extremity interventions, changes are likely due to participation in the interventions herein described. Together, these findings warrant moving forward with Phase IIb research, in which a larger sample and alternative Myomo dosing strategies are used.

Previously-developed upper extremity robotic approaches have been proported as efficacious, and have been purchased by individual clinics or entire hospital systems. However, many of these systems remain untested or have negative evidence supporting their efficacy.^{12,13} Moreover, the cost of platform-based upper extremity robotic devices begins at over \$75,000. While the current study was preliminary, the finding of equivalent efficacy between repetitive task specific practice delivered via a \$7500 portable robotic and "usual care" repetitive task specific practice in this trial – and positive data from previous trials – is clinically important in several regards: (a) First, equivalence of treatment effects shown in this study suggest that Myomo-based therapy could occasionally be used as a "stand-alone," semi-automated treatment strategy with patients exhibiting moderate upper extremity impairment. This would enable busy therapists to provide upper extremity therapy with contact guard or, in some cases, distant supervision. Such a capability may partially alleviate the tension between providing client-centered, task specific practice and the need to work with more than one client simultaneously that is becoming increasingly common. (b) Additionally, therapists must often provide significant levels of manual assistance to patients exhibiting moderate upper extremity impairment. This can be physically taxing for the therapist and the client, and such fatigue occasionally diminishes the number of active practice attempts that can be made during a treatment session. Furthermore, many patients exhibiting moderate upper extremity impairment often cannot meaningfully participate in valued upper extremity activities due to the severity of their motor deficits. The burgeoning efficacy of the Myomo approach in people with moderate upper extremity impairment addresses the above concerns, by allowing subjects with moderate upper extremity impairment to independently participate in functionally relevant tasks while using progressively lower levels of therapist assistance.

Device use did not cause significantly larger changes than repetitive task specific practice on any of the outcome measures. However, device use did noticeably impact subjects' perceptions of their upper extremity movement performance, and their ratings of upper extremity recovery to a larger degree than repetitive task specific practice only. For example, as noted previously, subjects administered the Myomo displayed positive

outcomes on all measures except one, whereas outcome measure trends were mixed in subjects administered usual care repetitive task specific practice. Subjects also exhibited markedly larger perceptions of change on the Stroke Impact Scale ADL, Hand, and Recovery Scales. When we spoke informally with Myomo subjects at post-testing, they reported that device use “made performance of some movements easier,” made it “...easier for my arm to try certain tasks that I wouldn’t normally do,” and “made practice more fun.” We believe that there was a tangible perceived benefit associated with having a mechanical device affixed to the paretic upper extremity during repetitive task specific practice that was responsible for at least some of the changes reported on the Stroke Impact Scale by Myomo subjects. Whether the outcomes were real or were attributable to a “placebo effect” associated with wearing the Myomo must be determined in future trials. The extent to which a placebo effect was exhibited can be examined in future work by requiring that all subjects don the device, but by not turning on the device for Myomo subjects. Alternatively, the device could be configured so that its lights illuminate but mechanical assistance is not provided to repetitive task specific practice -only subjects.

Finally, it should be noted that the device was originally developed as an augmentative orthotic to aid upper extremity movements, rather than as a restorative strategy (as tested herein). Thus, while results from this study on its restorative properties were promising, the device’s utility as portable, augmentative, strategy for performing valued activities constitutes a continued asset. This application of the device aligns well with the testimony of one subject, who said: “I don’t know if it will improve my arm (movement) in the long term, but it sure helps me do stuff that I wouldn’t be able to do otherwise...”

Limitations and Future Directions and Limitations

This study had some limitations associated with its method that will be addressed in future work: (a) First, due to the phase in this line of research and the goals typically associated with this phase (i.e., confirm efficacy using a small, well-defined sample; confirm sensitivity of outcome measures; estimate treatment effect), the sample was small. Future studies will enroll a larger sample, again using randomized controlled methods. Additionally, we may wish to add kinematics as an objective, quantitative outcome measure that complements the behavioral measures used in this study. (b) the device tested in this trial was an early-stage iteration, and, as such, occasionally did not work as expected. For example, a total of 5 treatment sessions were interrupted and/or lengthened by having to switch batteries with another device and/or to affix a new device to a particular subject’s upper extremity. Although lightweight, the device was somewhat cumbersome on the paretic upper extremity. Indeed, several subjects reported that the device was “awkward” due to the separate power pack that was worn over the shoulder. The size of this early-stage device also occasionally created problems with the device staying in the appropriate position on subjects’ upper extremities. This facet, and the device’s reliability and therapist ability to control the device in “real time” during sessions have been addressed. Specifically, a newer version of the device is lighter (1pound, 14 ounce), and contains all of the device electronics in the fulcrum of the brace. Moreover, the therapist has more control over device settings using a tablet-based application that allows Bluetooth-based, remote control of the device with 20 different assistance settings. Currently, we are using this new iteration of the device with positive initial findings to be described elsewhere. (c) The nature of the repetitive task specific practice program was limited in the current study, in that we restricted the number of tasks in which subjects could engage to those listed in Table 1. Such restriction was a study strength in terms of maintaining a consistent treatment regimen across subjects. However, studies also show that it is plausible for patients to be integrated in selecting goals for repetitive task specific practice with high therapy efficacy.^{8–10,13} Current work with the newer iteration of the device is, thus, using a battery of > 60 tasks from which subjects can

choose therapeutic activities that are meaningful and motivating. This facet is expected to increase the potency of repetitive task specific practice, whether delivered using robotics or manually. (d) Given the large standard deviation of time post stroke onset in this study, future authors may take the variable of post stroke chronicity into statistical control by using, for example, and analysis of covariance to parse out the impact of chronicity on treatment effect. This was not plausible due to the relatively small sample size enrolled in this pilot trial.

Conclusion

Existing robotic strategies targeting the paretic upper extremity are limited by their efficacy, portability, and ability to be integrated into “real world” upper extremity activities. This study adds to a growing body of evidence supporting the efficacy of a portable robotic device that allows integration of the moderately-impaired upper extremity into functional use. Results suggest that repetitive task specific practice using the Myomo robotic device is as efficacious (and, in some cases, more efficacious) than usual care repetitive task specific practice.

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Clinical Messages

- Repetitive task specific practice performed while the patient wears a portable robotic brace appears to be as efficacious as repetitive task specific practice.
- Practice incorporating the robotic device impacts subjects' perceptions of their upper extremity movement performance, and their ratings of upper extremity recovery to a larger degree than repetitive task specific practice only.

Figure 1. Flow diagram for this study
“RTP” denotes repetitive task specific practice

Table 1

Movement Focus and Purposeful Activity

Body movement focus	Purposeful Activity
Bilateral shoulder flexion and elbow extension	Lifting laundry basket
Bilateral shoulder extension and elbow extension	Transfer from sitting to standing
Unilateral shoulder flexion and elbow flexion	Drinking from an adapted cup
Unilateral shoulder flexion and elbow extension	Turning on/off a light switch

Table 2

Subject Demographics

Variable	Myomo	Repetitive Task Specific Practice
Male	3	8
Right-handed	8	7
% Hemiparetic Side Right	4	3
Average of Time since stroke (months and standard deviation)	44.7 (38.4)	106.8 (114.6)
Average of age (years and standard deviation)	59.0 (12.9)	58.5 (9.5)

Table 3

Scores and Changes by Study Group

Measure	Myomo			Repetitive Task Specific Practice				p-value	Effect Size
	PRE-1	PRE-2	POST	Change	PRE-1	PRE-2	POST		
Fugl-Meyer	20.75 (4.83)	22.88 (5.74)	22.86 (7.01)	+2.13 (2.6)	19.38 (4.63)	21.63 (5.71)	21 (7.54)	0.93	0.09
Canadian Occupational Performance Measure	4.45 (2.2)	4.53 (2.05)	4.17 (2.26)	+0.75 (1.5)	5.14 (2.43)	4.79 (2.48)	4.76 (1.78)	0.43	0.41
Canadian Occupational Performance Measure Satisfaction	4.28 (2.27)	3.75 (1.55)	4.03 (2.06)	-0.53 (1.0)	4.84 (2.46)	4.09 (1.87)	4.3 (1.81)	0.23	0.27
Stroke Impact Scale Strength	12.88 (1.73)	14.25 (2.19)	13.14 (2.34)	+1.38 (1.8)	12.5 (3.59)	14.13 (3.44)	12.5 (1.87)	0.85	0.20
Stroke Impact Scale ADL	37.25 (4.1)	39.38 (2.92)	41.57 (2.88)	+2.13 (3.9)	42.75 (4.4)	40.88 (6.22)	44.17 (5.27)	0.32	2.43
Stroke Impact Scale Mobility	39.13 (5.11)	40.38 (3.25)	42.86 (1.46)	+1.25 (2.5)	40.25 (3.58)	41.25 (3.54)	41.67 (3.08)	0.25	0.17
Stroke Impact Scale Hand	9 (5.07)	11 (5.26)	11.29 (6.45)	+2.00 (7.8)	11.5 (7.31)	10 (4.66)	10 (6.57)	0.33	1.01
Stroke Impact Scale Participation	27.75 (8.26)	29.13 (8.25)	31 (6.98)	+1.38 (6.1)	32.75 (5.8)	32.57 (7.63)	37 (4.38)	0.49	0.73
Stroke Impact Scale Recovery	58.13 (14.38)	70.63 (18.02)	67.86 (23.6)	+12.50 (16.7)	60.88 (15.37)	65 (18.71)	60.83 (24.98)	0.33	1.01
Stroke Impact Scale Total	216 (25.47)	232.25 (21.19)	239.86 (23.25)	16.25 (18.9)	239.43 (17.5)	235.57 (23.47)	247 (22.29)	0.027	2.48

Note. Numbers in parentheses denote standard deviation. "ADL" denotes "activities of daily living"; "PRE-1" denotes scores obtained during the first administration of outcome measures; "PRE-2" denotes scores obtained during the second administration of outcome measures; "POST" denotes scores obtained after the intervention period.