

The effect of adding robot-assisted hand rehabilitation to conventional rehabilitation program following stroke: A randomized-controlled study

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ABSTRACT

Objectives: This study aimed to investigate the effectiveness of adding robot-assisted hand therapy (HandTutor) to conventional rehabilitation program compared to a conventional rehabilitation program alone in stroke survivors.

Patients and methods: Between March 2012 and December 2012, a total of 33 stroke patients (21 males, 12 females; median age: 56 years; range, 38 to 73 years) were included in this prospective, randomized-controlled study. The patients were randomly divided into two groups as experimental (n=16) and control (n=17). Both groups received conventional rehabilitation for 3 h/day, for two days/week, totally for five weeks, while the experimental group received additional 1-hour robot-assisted hand therapy during each session. Outcome measures were the Fugl-Meyer Assessment, Box and Block Test, Nine-Hole Peg Test, Jebsen-Taylor Hand Function Test, grip strength, and pinch strength. All patients were assessed at baseline, at the end of the treatment, and three months after the treatment.

Results: Both groups showed statistically significant improvements in all the parameters ($p < 0.05$). No significant differences were observed between the groups at any time points ($p > 0.05$). The changes between baseline and three-month follow-up after the treatment revealed that adding robot-aided hand therapy led to greater changes in all the parameters related to functional activities and muscle strength, except for the Fugl-Meyer Assessment.

Conclusion: Adding robot-assisted therapy to conventional rehabilitation may provide greater changes in upper extremity rehabilitation of subacute stroke patients compared to conventional rehabilitation program alone.

Keywords: Functional activities, muscle strength, robot-assisted therapy, stroke.

Stroke is a clinical problem characterized by focal brain damage caused by a cerebrovascular accident.^[1] A rupture or a plug in the intracranial blood vessels may cause stroke and the clinical presentation changes related to the localization of the damage. Motor and/or sensory loss, cognitive impairments, difficulties in oral and swallowing functions, and balance problems might compromise the clinical presentation. However, contralateral hemiparesis is the most common finding.

Hemiparesis in upper extremity, particularly in hand leads more disability, as its functions are more complex and essential for daily living. At hospital admission after stroke, more than two-thirds of patients present with arm paresis,^[2] and the affected arm remains without function in nearly half of all patients six months following stroke.^[3] To address this problem, many different approaches including robot-assisted training have been suggested for upper extremity/hand rehabilitation following stroke.^[4]

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Robot-assisted upper extremity training program aims to improve hand functions and motor, sensory, and cognitive performance by using visual feedback and motivation together, and its clinical utility has been increasing.^[4,5] The most recent Cochrane review on the topic including 45 trials concluded that the electromechanical and robot-assisted arm training might be beneficial for improving activities of daily living (ADLs), and gaining arm functions and muscle strength in stroke survivors.^[4] Besides, in a recent systemic review by the same group, the outcomes of robotic-assisted arm training were comparable with conventional therapy.^[6]

HandTutor (Meditouch Ltd., Rotem Industrial Park, MP Arava, Israel) is a robot-assisted therapy tool consisting of an ergonomic glove which is connected to a software. It allows wrist movements and small hand joint movements and utilizes visual-auditory feedback. The interactive computer game-based exercise program aims to increase gross/fine motor skills, as well as cognitive functions. A pilot study investigated the effectiveness of HandTutor in acute-subacute stroke patients concluded that HandTutor led better results on functional abilities compared to conventional rehabilitation program.^[5] However, the authors suggested that the effectiveness of the HandTutor along with the functional rehabilitation program should be investigated for patients who experience stroke longer in future trials. In the present study, we, therefore, aimed to investigate the effectiveness of adding robot-assisted hand therapy (HandTutor) to conventional rehabilitation program on upper extremity motor improvement and the hand functions in ADLs compared to a conventional rehabilitation program alone in stroke survivors.

PATIENTS AND METHODS

This prospective, randomized-controlled study was conducted at Marmara University Faculty of Medicine, Department of Physical Medicine and Rehabilitation between March 2012 and December 2012. The sample size was calculated based on the study by Carmeli et al.^[5] which reported a change of 13.9 ± 10.9 in the Box and Block Test (BBT) results of the stroke patients following a robot-assisted therapy.^[5] Fifteen patients were found to be adequate for each group (80% of power, and 0.01 significance). However, 37 outpatient patients who consulted to our clinic were found to be eligible.

The diagnosis of stroke was confirmed by a single neurologist by using imaging (computer tomography [CT] and/or magnetic resonance imaging [MRI]) techniques. Inclusion criteria were having the first stroke at least three months from stroke, age between 35 and 75 years, being able to understand the commands, having a mild-to-moderate upper extremity problem which corresponds 30 to 56 points according to the Fugl-Meyer Assessment (FMA), presenting a spasticity score lower than two according to Modified Ashworth Scale, having a difference between involved and uninvolved sides at the BBT (at least half as much of the score in which was achieved by using hemiparetic hand compared to unimpaired hand), and being able to understand and follow the instructions. Patients with cerebellum or brainstem damage, with an orthopedic problem related to upper extremities, with botulinum toxin/phenol/alcohol injection in last six months, with hemianopsia and/or aphasia, with neglect, with balance problem in sitting (patients should maintain the sitting balance for 30 min) were excluded (Figure 1). Finally, a total of 33 stroke patients (21 males, 12 females; median age: 56 years; range, 38 to 73 years) were included in the study. The patients were randomly divided into two groups using opaque envelopes as the control (n=17) and the experimental (n=16) group.

Procedure

Assessments were performed at baseline, immediately at the end of the study, and at the follow-up period (three months later). All assessments were performed by a single researcher. Both groups received conventional rehabilitation program for two days/week for five weeks (10 sessions). However, the experimental group also received a robot-assisted hand therapy by using HandTutor. A single physiotherapist held the rehabilitation sessions for both groups. While the conventional therapy sessions were 3 h long, additional robot-assisted hand therapy lasted 1 h.

Assessments

Demographics and Stroke Related Data

Age, stroke duration, sex, type of stroke, and involved side was evaluated by using a structured form.

Fugl-Meyer Assessment

The FMA was used to evaluate the motor recovery of the upper extremities.^[7] It consists of four parts as arm functions (36 points), wrist functions (10 points),

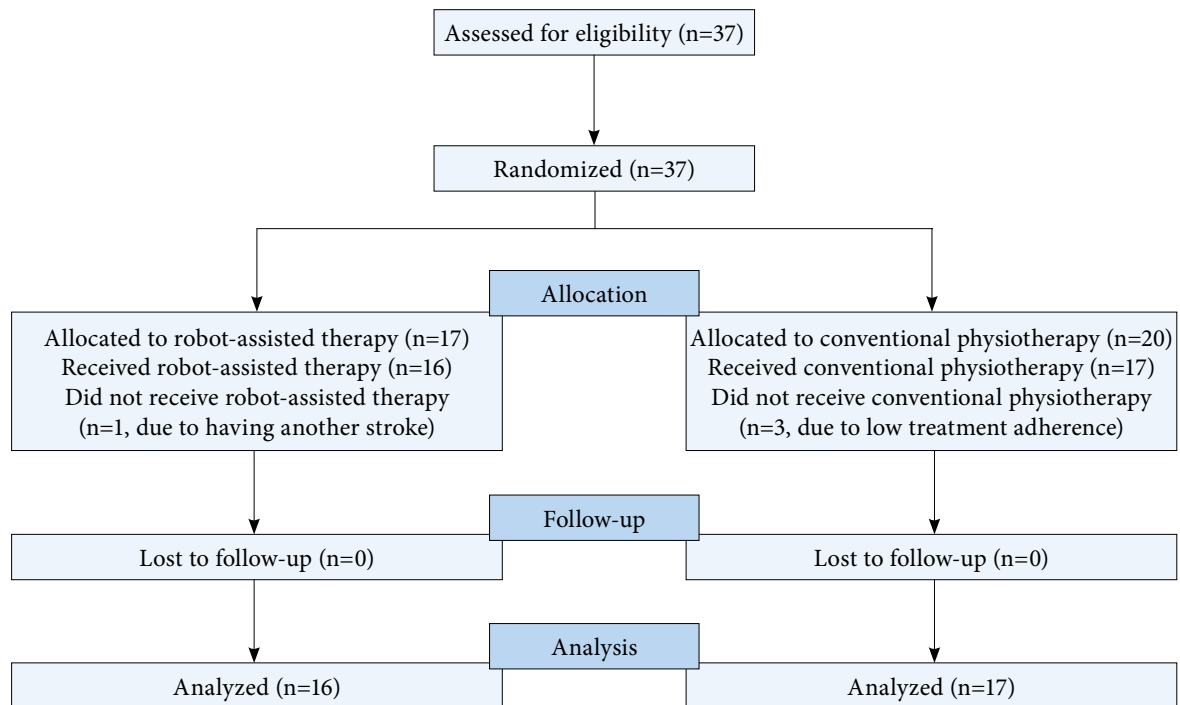


Figure 1. Study flow chart.

hand functions (14 points), and coordination and speed (6 points). The total score (66 points) is formed by summing all the scores.

Box and Block Test

The BBT was used to evaluate the grip ability. The patients were asked to transfer as many as wooden blocks from a box to another in 1 min. The number of the transferred blocks were recorded.^[8] For scoring, at least three blocks should be transferred to another box.

Nine-Hole Peg Test (9HPT)

The 9HPT was used to evaluate the hand dexterity. The test was formed of nine wooden sticks (9 mm diameter) and a standard wooden block which has nine holes (10 mm diameter). The patients firstly were asked to place all the sticks into the holes, and then remove them from the holes randomly as fast as they can. The total time for placing and removing all the sticks was recorded.^[9]

Jebsen-Taylor Hand Function Test (JHFT)

The JHFT was used to simulate the ADLs. The test includes seven subtests of writing, card turning, simulated feeding, stacking checkers, placing small

objects in a container, moving light objects, and moving heavy objects.^[10] The time was recorded for completing each activity. Total score was achieved by summing all the subsets. As some patients had dominant hemisphere involvement and some were illiterate, the writing subtest was not included in the study.

Hand Grip Strength

Hand grip strength was evaluated by using Jamar hand dynamometer (Lafayette Instrument Company, IN, USA). The standard position as offered by the American Society of Hand Therapists (ASHT) were used for the evaluation.^[11] The patients were asked to perform a maximal grip.^[12] Three attempts were given and the average of them was recorded as kg.

Pinch Strength

Pinch strength was evaluated in the same position as in the grip strength evaluation. The Jamar pinch meter (Lafayette Instrument Company, IN, USA) was used for the evaluation.^[13] Maximum lateral pinch strength was evaluated, while the patients grabbed the pinch meter between their thumb and index fingers. Three attempts were provided and the average of them was recorded as kg.



Figure 2. The HandTutor.

Interventions

Conventional Rehabilitation Group (Control Group)

The conventional rehabilitation program consisted of the following program:

- Passive, active, and active assistive (according to the state of the patient) range of motion and stretching exercises for shoulder, elbow, wrist, and fingers (30 min)
- Facilitation and inhibition techniques (30 min)
- Neuromuscular electrical stimulation for wrist extensor muscles for strengthening wrist extensor muscles against spasticity (30 min)
- Strengthening exercises for the involved side (30 min)
- Task-oriented hand exercises such as grabbing spoon, pouring water into a glass, holding the doorknob (1 h)

Robot-Assisted Hand Therapy Group (Experimental Group)

Experimental group received a 1-h additional rehabilitation by using HandTutor (Figure 2). The patients were seated in an erect position in front of a computer while performing the exercises. The maximal extension and flexion degrees in the fingers and in the wrist were recorded into the software prior to exercises. For obtaining a better motor control, isolated wrist and finger exercises were trained by using six games (follow the target, basketball, save the world, car race, snowman, and space war). Each game was played for two times for a total of 60 min.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 21.0 software (IBM Corp., Armonk, NY, USA). The distribution of the data was checked using

TABLE 1
Demographic and stroke-related characteristics between groups

	Control (n=17)				Experimental (n=16)				p
	n	%	Median	IQR 25 th -75 th	n	%	Median	IQR 25 th -75 th	
Age (year)			58	51-64			55.5	53.5-66.5	0.631*
Stroke duration (month)			4	4-15			9	3-35	0.736*
Sex									0.818#
Female	7	41.2			5	31.2			
Male	10	58.8			11	68.8			
Type of stroke									1.000#
Ischemic	10	58.8			10	62.5			
Hemorrhagic	7	41.2			6	37.5			
Involved side									1.000#
Right	8	47.1			7	43.8			
Left	9	52.9			9	56.2			

IQR: Interquartile range; * Mann-Whitney U test; # Chi-square test, p<0.05.

TABLE 2
Comparison of functional and strength related assessments between groups

		Control (n=17)		Experimental (n=16)		p*
		Median	IQR 25 th -75 th	Median	IQR 25 th -75 th	
Fugl-Meyer Assessment						
	Baseline	51	49-54	51	50-53	0.958
	At the end of treatment	57	55-58	56.5	55.5-59	0.606
	Follow-up	61	57-62	60	58-62	0.845
p#	}		<0.001		<0.001	
			<0.001†		<0.001†	
			<0.001‡		<0.001‡	
			0.001¶		0.001¶	
Box and Block Test						
	Baseline	28	21-31	24.5	16-30.5	0.606
	At the end of treatment	36	27-42	41	22.5-49	0.488
	Follow-up	38	34-49	48	31.5-55.5	0.191
p#	}		<0.001		<0.001	
			<0.001†		<0.001†	
			<0.001‡		<0.001‡	
			0.015¶		0.001¶	
Nine Hole Peg Test						
	Baseline	60	45.3-136.3	143.2	53.5-195	0.309
	At the end of treatment	34.5	28.8-59.9	48.7	30.4-95	0.488
	Follow-up	32.5	27.3-70.6	40.4	25.3-90.0	0.683
p#	}		<0.001		<0.001	
			<0.001†		<0.001†	
			<0.001‡		<0.001‡	
			0.653¶		0.001¶	
Jebsen Taylor Hand Function Test						
	Baseline	105.2	69-134.8)	119.3	91.1-213.5	0.326
	At the end of treatment	56.5	46.9-106.2	62.6	44.9-109.7	0.845
	Follow-up	56.8	44.9-91.2	49.1	39.1-86.2	0.465
p#	}		<0.001		<0.001	
			<0.001†		<0.001†	
			<0.001‡		<0.001‡	
			0.619¶		p3<0.001¶	
Pinch strength						
	Baseline	4	3-5	4	2-6	0.817
	At the end of treatment	5	4-6	5.5	3.5-8	0.276
	Follow-up	5	4-7	6.5	5-11	0.157
p#	}		<0.001		<0.001	
			0.034†		0.004†	
			0.002‡		<0.001‡	
			0.016¶		0.005¶	
Grip strength						
	Baseline	10	6-15	12.5	8-20	0.465
	At the end of treatment	12	10-20	15	12-25	0.276
	Follow-up	12	10-20	20	12-30	0.136
p#	}		<0.001		<0.001	
			0.001†		0.003†	
			0.001‡		0.001‡	
			0.551¶		0.015¶	

IQR: Interquartile range; * Mann-Whitney U test; # Friedman test; † Baseline vs. at the end of the treatment; ‡ Baseline vs. follow-up; ¶ At the end of the treatment vs. follow up, p<0.05.

TABLE 3
Comparison of the changes between groups

	Control (n=17)		Experimental (n=16)		<i>p</i>
	Median	IQR 25 th -75 th	Median	IQR 25 th -75 th	
ΔFugl-Meyer Assessment					
Baseline-At the end of treatment	4	3-6	5	4-7	0.101
Baseline-Follow-up	8	6-9	8	6-9	0.606
ΔBox and Block Test					
Baseline-At the end of treatment	8	4-12	12.5	8-21	0.045
Baseline-Follow-up	10	8-16	23.5	15.5-31	0.010
ΔNine Hole Peg Test					
Baseline-At the end of treatment	-31.0	-60.1 - -16.9	-78.9	-113.7 - -20.5	0.074
Baseline-Follow-up	-30.0	-43.4 - -13.2	-90.7	-117.1 - -24.5	0.015
ΔJebsen Taylor Hand Function Test					
Baseline-At the end of treatment	-28.9	-59.2 - -19.5	-55.8	-87.8 - -33.5	0.063
Baseline-Follow-up	-22.5	-59.6 - -19.2	-65.5	-121.4 - -45.0	0.010
ΔPinch strength					
Baseline-At the end of treatment	0	0-1	1.5	0.5-2.5	0.049
Baseline-Follow-up	1	0-2	2.5	2-4.5	<0.001
ΔGrip strength					
Baseline-At the end of treatment	4	2-4	5	0-6	0.382
Baseline-Follow-up	4	2-5	6.5	3.5-12.5	0.012

IQR: Interquartile range; Δ: Delta; * Mann-Whitney U test; *p*<0.05.

the Shapiro-Wilk test and histograms. Descriptive data were expressed in median and interquartile range (IQR 25th-75th). The Mann-Whitney U test was used to compare the groups, Friedman test was used for in-group comparisons, and chi-square test was used for comparing qualitative data between groups. A *p* value of <0.05 was considered statistically significant.

RESULTS

A total of 33 patients completed the study. No significant difference was detected between groups in terms of age, sex, the time from stroke, the type of stroke, and involved side (*p*>0.05, Table 1).

Both groups were similar regarding all outcomes (FMA, BBT, 9HPT, JHFT, pinch strength and grip strength) at baseline (*p*>0.05, Table 2). Significant improvements were detected in both groups related to all parameters at all time points (*p*<0.05, Table 2), except for time points between the end of the treatment and follow-up for JHFT and grip strength in the control group (*p*>0.05, Table 2).

No significant differences were detected between the groups at any time point (*p*>0.05, Table 2).

When the changes between pre- and post-treatment were compared between the groups, significant differences were found in favor of experimental group for BBT, and pinch strength parameters (*p*<0.05, Table 3). Besides, the experimental group showed greater changes for all the parameters than the control group at follow-up compared to baseline, except for FMA (*p*<0.05, Table 3).

DISCUSSION

In the present study, we investigated the effectiveness of adding a robot-assisted hand therapy, which was shown effective for stroke patients previously, to conventional rehabilitation program. Our results showed that adding a robot-assisted hand therapy to conventional rehabilitation might be beneficial. All parameters (FMA, BBT, 9HPT, JHFT, pinch strength and grip strength) were improved in both groups, and there was no significant difference

between the groups at any time points. However, three months after the treatment, adding robot-assisted hand therapy resulted in more changes in all the parameters related to functional activities, and muscle strength compared to conventional therapy alone. On the other hand, we could not detect any significant differences between the groups in the change regarding recovery.

Our findings are in accordance with the other reported studies. The effect of HandTutor was investigated by Carmeli et al.^[5] firstly in acute-subacute stroke survivors (10 days-10 weeks), and the authors detected significant improvements in BBT.^[5] To the best of our knowledge, no other studies utilized the HandTutor in their studies besides Carmeli et al.^[5] However, different haptic devices were used in other studies.

Friedman et al.^[14] investigated the effects of using MusicGlove, a music-based rehabilitation device based on virtual reality and haptic gloves (1 h/day, three days/week, for two weeks), on BBT and 9HPT test in 12 chronic stroke patients and showed that robot-assisted therapy resulted in better outcomes compared to conventional rehabilitation program. Ang et al.^[15] compared the effects of six-week (three times a week) brain-computer interface coupled haptic knob robot, which is a two-degree-of-freedom robotic hand interface for hand grasping and knob manipulation and conventional arm therapy in chronic stroke survivors. They evaluated FMA in baseline, at Week 3, end of the intervention (at Week 6), and follow-up at Weeks 12 and 24. Similar to our results, they reported no significant between group differences at any time points, and significantly larger motor gains in the haptic therapy group at Weeks 3, 12, and 24. Susanto et al.^[16] investigated the effectiveness of 20-session robot-assisted finger training compared to conventional finger training in subacute/chronic (6 to 24 months post-stroke) stroke survivors. Similar to our results, the authors did not find a significant difference between groups for the changes in the FMA at six months. Vanoglio et al.^[17] utilized GloReha Professional (Idrogenet, Lumezzane, Italy), a hand rehabilitation glove that provides computer-controlled, repetitive, passive mobilization of the fingers, with multisensory feedback in their studies. The authors compared the effects of 30 sessions (five days/week) of haptic glove and equal conventional hand rehabilitation on 9HPT, and grip and pinch strength in inpatient patients with stroke. The authors reported greater changes

in the robot-assisted therapy group compared to control group regarding 9HPT, and grip and pinch strength at the end of the study. In our study, we found a significant difference only in the pinch strength at the end of the study. The difference between our results may be related to stage of stroke (acute vs. subacute) and the number of sessions (30 sessions vs. 10 sessions).

In the most recent Cochrane review, robot-assisted arm training improved ADLs, function, and muscle strength of the affected arm in patients after stroke.^[4] However, no significant differences in the effectiveness were reported between different type of robot-assisted therapies for upper extremity rehabilitation. In their systematic review, Mehrholz et al.^[6] investigated 55 studies and reported that the outcomes would be similar whether the device was an end-effector or an exoskeleton (including gloves). One may argue that these results may be affected by the spontaneous recovery. As it is known that the recovery was significant during the first months following stroke,^[18] the patients who had stroke at least three months ago was included in the present study.

The mass repeated practice is crucial for the stroke rehabilitation. Therefore, in the current study, a very intensive rehabilitation program (3 h) was performed. It represents the strength of the present study. However, it is possible that the difference related to changes between groups may be affected from the dose difference of the sessions (control: 3 h vs. experimental: 4 h). The experimental group additionally treated 1 h more with the robot-assisted therapy. However, robot-assisted therapy may be utilized in future for increasing the repeated practice, as our results showed better changes when it was added to the conventional therapy. In the future studies, the utility of HandTutor as a home-based therapy should be investigated. The lack of blind physiotherapists, blind patients, and blind assessors can be considered the main limitations of the study.

In conclusion, adding robot-assisted therapy to conventional rehabilitation program may lead to greater changes compared to conventional rehabilitation alone. Although there was no significant difference between the groups at three months of follow-up, a significant difference may be detected in longer-term studies. However, a comprehensive conventional therapy alone may still be offered to patients who has no chance to receive robot-assisted hand therapy.

Ethics Committee Approval: The study protocol was approved by the Marmara University Faculty of Medicine Ethics Committee (date: 05.04.2012, protocol no: 09.2012.0040).

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Design of the study, data collection, data analysis and interpretation, drafting the article: O.B.; Design of the study, critical revision of the article: G.A.; Data collection: N.S.

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