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Robot training for hand motor recovery in subacute stroke patients: A randomized controlled trial

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ABSTRACT

Background: Evidence of superiority of robot training for the hand over classical therapies in stroke patients remains controversial. During the subacute stage, hand training is likely to be the most useful.
Aim: To establish whether robot active assisted therapies provides any additional motor recovery for the hand when administered during the subacute stage (<4 months from event) in a Mexican adult population diagnosed with stroke.
Hypothesis: Compared to classical occupational therapy, robot based therapies for hand recovery will show significant differences at subacute stages.
Trial design: A randomized clinical trial.
Methods: A between subjects randomized controlled trial was carried out on subacute stroke patients ($n = 17$) comparing robot active assisted therapy (RT) with a classical occupational therapy (OT). Both groups received 40 sessions ensuring at least 300 repetitions per session. Treatment duration was (mean $\pm$ std) 2.18 $\pm$ 1.25 months for the control group and 2.44 $\pm$ 0.88 months for the study group. The primary outcome was motor dexterity changes assessed with the Fugl-Meyer (FMA) and the Motricity Index (MI).
Results: Both groups (OT: $n = 8$; RT: $n = 9$) exhibited significant improvements over time (Nonparametric Cliff's delta-within effect sizes: $dw_{OT\text{-}FMA} = 0.5$, $dw_{OT\text{-}MI} = 0.5$, $dw_{RT\text{-}FMA} = 1$, $dw_{RT\text{-}MI} = 1$). Regarding differences between the therapies; the Fugl-Meyer score indicated a significant advantage for the hand training with the robot (FMA hand: WRS: $W = 8$, $p < 0.01$), whilst the Motricity index suggested a greater improvement (size effect) in hand prehension for RT with respect to OT but failed to reach significance (MI prehension: $W = 17.5$, $p = 0.080$). No harm occurred.
Conclusions: Robotic therapies may be useful during the subacute stages of stroke – both endpoints (FM hand and MI prehension) showed the expected trend with bigger effect size for the robotic intervention. Additional benefit of the robotic therapy over the control therapy was only significant when the difference was measured with FM, demanding further investigation with larger samples. Implications of this study are important for decision making during therapy administration and resource allocation.

Introduction

After the acute phase of stroke, motor recovery of the hand is the slowest and most difficult, and yet the most important part of motor rehabilitation because of its relevance to activities of daily living (ADL).[1] Motor impairment of the hand, limits activities and has an important impact on the occupation of the stroke patient.

Conflict of interest: None. We do not have any relation commercial or academic with the robot maker Tyromotion (Graz, Austria), or its distributor in Mexico, Tecno Lógica Mexicana (TLM) S.A. de C.V. (Mexico City, Mexico).

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Research in neuromotor rehabilitation continues to investigate treatment alternatives to improve rehabilitative outcome. Outcome of the treatment has been shown to be target-area specific. In other words, training tasks emphasizing the shoulder will improve the shoulder, but not the hand.[2] Robot-assisted therapy has been claimed to afford better specificity to the training, a factor often lacking in conventional techniques.[3,4]

Robotic devices have been progressively penetrating neuro-rehabilitation programs.[5–8] Currently there exist several robotic devices designed for training of the paretic hand in patients with sequelae of stroke, e.g. T-WREX (Therapy Wilmington Robotic Exoskeleton),[9] Bi-Manus Track,[10] Gesture Therapy[11] or Haptic Knob,[12] among others. Motor learning is based on repetitive activities that provide sensory and motor processing,[13] requiring attention and orientation.[14] There are several legitimate types of training in neurological rehabilitation; passive,[15–17] active assisted[18–20] and active resisted,[17,21] all of them can be provided with robotic devices. The effectiveness of these devices for motor training has been described within specific parameters of the technology,[18] which relates directly to reduced hospital stays in patients in the acute stage and with increased independence for ADL.[10] The use of robots in neuromotor rehabilitation is believed to have a positive effect favoring attention and reducing the effort of the patient during training because of the robots potential to enhance motor control,[22] specifically in the hand,[7] boost motivation and adherence to treatment,[23] as well as help in multi-sensory and sensorimotor integration.[24]

Despite a number of studies exemplifying the benefits of robot assisted therapies for hand motor recovery[25]; evidence is still controversial. Robotic therapy often uses robots simply as a vehicle to deliver highly repetitive therapy. However, in studies that tried to match the intensity of robotic therapy to the number of movements generated by other forms of therapy failed to show a differential effect.[10] In this sense, several authoritative reviews questioned the superiority of robotic devices compared to conventional treatments for the upper limb,[5,10] and also specifically for hand function.[26] One of the reasons for this evidence to be inconclusive maybe that there is a gap in understanding the mechanisms that might affect the outcome of robot-aided therapy,[18] as well as the bias affecting current research findings.[27] Nevertheless, there appears to be a positive trend toward robot-assisted therapy for the upper limb when compared to conventional treatment modalities with regard to motor recovery.[10,26] Perhaps, robotic tools for neurorehabilitation are effective in reducing motor impairment but they are limited in their ability to improve function.[2] Notwithstanding the above, there is little understanding of the neurological mechanisms involved in functional recovery of the hand,[28–31] perhaps because the routine clinical focus on measures of execution are unrelated to higher-order functions.[31]

The research presented here evaluates the efficiency of a robotic active assisted therapy for hand motor rehabilitation compared to classical occupational therapy. With the precedents that cortical activation and excitability peaks during the subacute stage,[32–34] and that robot-assisted motor training may have advantages for the hand training,[7,25] the hypothesis was that the robot based assistance would outperform classical therapy, if administered during the subacute stage.

Methods

A pre-post parallel-group randomized controlled trial was carried out targeting subacute patients to elucidate the benefits of undergoing robot-assisted therapy over a more classical occupational therapy. The allocation ratio was 8:9. No important deviations from the original protocol occurred.

Subjects

The experiment was conducted in the Neurologic Rehabilitation Unit of the National Institute of Neurology and Neurosurgery (INNN) in Mexico City following approval of the Local Research Ethical Committee. Researcher GRF was in charge of enrollment. Adult patients (>30 years old) with a diagnosis of hemorrhagic or ischemic stroke and who experience severe upper extremity hemiparesis (estimated by the Fugl-Meyer scale >8 and <30) were eligible for inclusion. Exclusion criteria included severe pain and instability in the wrist of the affected arm, severe cognitive impairment, aphasia, hemispatial neglect, apraxia and joint contractures greater than 20° in the affected hand. Instability of the wrist was assessed by physical exploration, and patients presenting it were excluded to avoid possible harm due to the repetitive movements. Cognitive impairment, visuospatial hemineglect (last item) and apraxia were assessed with the Mini Mental State method.[35] Patients with a score less than 27 were excluded. Patients with cognitive impairment were excluded in case they may not be able to follow instructions. Patients with visuospatial hemineglect were excluded because the robot feedback uses the whole visual spatial field. Patients with apraxia were excluded in case they might forget to perform the task. Finally, aphasia was assessed by means of neurological exploration assessing 4 characteristics of language; fluency, auditory comprehension, repetition and naming. This permits identification of the 8 most common types of aphasia. Patients with aphasia were excluded in case they may not understand the instructions.

For the experiment, seventeen ($n = 17$) subacute patients (more than 1 week and less than 4 months since the stroke) agreed to participate. Table 1 summarizes demographic information of the cohort including age, gender, stroke type, time since last stroke and hemiparetic side.

The experimental procedures were explained to them and after signing the authorization and consent form, subjects were randomized to the control or the intervention group following a block randomization scheme (fixed block size = 1) with designation of initial treatment on the block sequence by simple randomization (coin toss), e.g. Intervention-Control-Intervention-Control. No allocation concealment mechanism was implemented. The rehabilitation clinic at INNN is an open space making difficult blinding the assessor to treatment allocation after assignment occurs.

Interventions

All patients attended therapy five times a week until they completed 40 sessions of treatment. The first four sessions were shorter and lasted approximately 40 min. After that, therapy sessions lasted about 1 h (∼60 m) with rest periods according to the ability of each patient. Experimental groups received treatments, whether occupational or robotic, under the supervision of an occupational therapist – LP. Because of the nature of the intervention, blinding the therapist to the treatment was not possible.

The control group received classical occupational therapy. Patients assigned to the control group were treated with massage

Table 1
Cohort demographics and summary of descriptive statistics

Group	Control	Intervention
Number of subjects (n)	8	9
Gender (male/female)	6/2	5/4
Age in years (mean ± std)	55.00 ± 25.78	56.22 ± 13.72
Treatment duration in months (mean ± std)	2.18 ± 1.25	2.44 ± 0.88
Paretic side (right/left)	5/3	6/3
Stroke (ischemic/haemorrhagic)	Ischemic	Ischemic

and conventional occupational exercises. In each session the patients underwent a stretching stage involving passive movements (300 repetitions), a warming up stage with strengthening exercises, and a final training active stage ensemble to promote palmar grasps, and personalized activities with marbles and screw for fine pinching (lateral and pulp) control.

The intervention group was administered robotic assisted therapy (robot Amadeus Tyromotion, Austria, http://tyromotion.com/en/products/amadeo). In each session, the robot based treatment involved two stages; first passive activities (300 repetitions), followed with partial assistance or resistance (300 repetitions) which provides a variable challenge for the patients. From the fourth session onwards active movements were included (100 repetitions) for a total of 700 repetitions per session. Approximately 28,000 repetitions were made throughout the experiment. Further specific details of the trial protocol can be found in.[36] The trial was registered only internally at INNN (Registration Number 92/13).

Outcomes

Initial (before therapy onset – pre) and final (after treatment end – post) assessments were performed by an experienced rehabilitation physician – LP. Primary outcomes were the sensorimotor recovery of hand and wrist, and the motor recovery rate for the hand. Sensorimotor recovery of patients was evaluated with the Fugl-Meyer assessment (FMA) scale[37] with particular attention to the hand and wrist section (maximum score = 24) to assess the functional capacity of the affected hand. The Motricity Index (MI)[38] scale was used to assess the motor recovery rate of the patients (100% = maximum IM). Progress was monitored using both scales before and after the treatment.

Statistical methods

Statistical analysis was performed with statistical package R (v 3.2.2, The R foundation). Sample size was not precalculated with power analysis; instead the recruiting period was fixed to 8 calendar months. Following extraction of distribution descriptive statistics, including effect sizes; confirmation of matching in initial conditions in co-factors among control and intervention groups was made using Wilcoxon Rank Sum (WRS) tests with continuity correction or Fisher's exact test (FET), depending on the nature of the variables (categorical, interval or ratio). Univariate and bivariate relations between factors and co-factors with endpoints were descriptively explored. Finally, specific statistical questions were made. For each group, improvements in dexterity performance were evaluated using Wilcoxon Sign Rank (WSR) test with continuity correction for paired samples. Comparative differences between control and intervention in these improvements were established using Wilcoxon Rank Sum tests with continuity correction. Cohen's d effect sizes and the 95% confidence interval for the contrast (continuous data) were further calculated. In all cases, statistical significance threshold was kept at $\alpha = 5\%$. The described analytical procedure was repeated for both Fugl-Meyer and Motricity Index scales.

Sources of funding

The robot was kindly lent by Tecno Lógica Mexicana (TLM) S.A. de C.V. but they gave no further funding and they had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. We do not have any relation commercial or academic with the robot maker Tyromotion (Graz, Austria), or its distributor in Mexico, Tecno Lógica Mexicana (TLM) S.A. de C.V. (Mexico City, Mexico).

Results

The recruiting period was fixed to 8 calendar months from 1st May 2013 to 28th Dec 2013. In total, 17 subjects completed the experiment with 9 allocated to the intervention group and 8 to the control group as illustrated in Fig. 1. None were excluded or lost after randomization. Treatment duration was (mean ± std) 2.18 ± 1.25 months for the control group and 2.44 ± 0.88 months for the intervention group, a difference which is not significant (two-sample $t(15) = -0.5007$; $p = 0.623$; 95% C.I.). The primary analysis was intention-to-treat and involved all patients who were randomly assigned.

Matching in initial conditions between the groups was confirmed with differences in tested co-factors failing to show significant differences; age (WRS: $W = 34$, p-value $= 0.885$), time since stroke (WRS: $W = 32$, p-value $= 0.726$), gender (FET: p-value $= 0.620$), hemiparetic side (FET: p-value $= 1$), hand FMA at start (WRS: $W = 50.5$, p-value $= 0.173$) and prehension MI at start

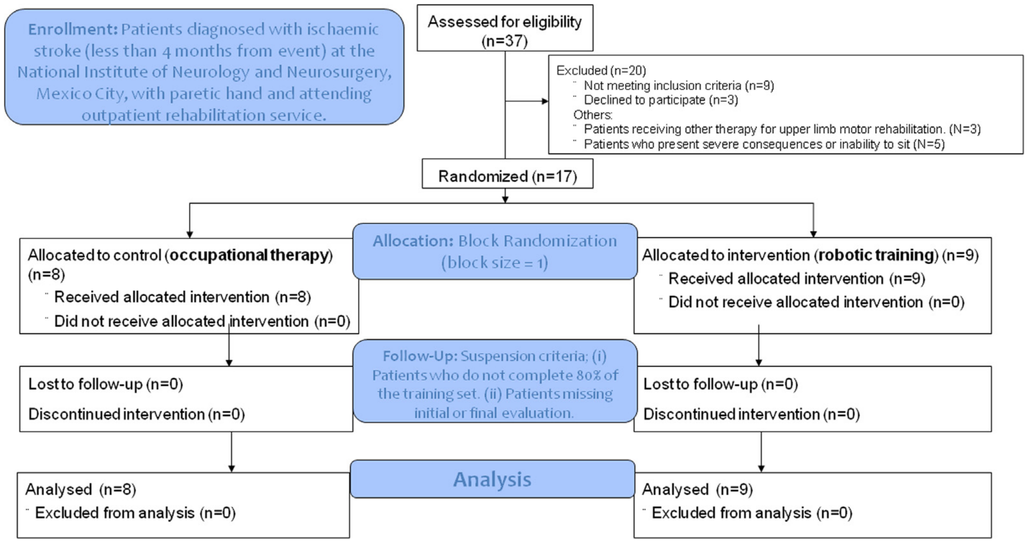

Fig. 1. Flow chart, following the CONSORT guidelines, through the phases (enrollment, intervention allocation, follow-up, and data analysis) of the parallel randomized trial of the two groups.

(WRS: $W = 45.5$, p-value $= 0.358$). Note that in this experiment all patients had ischemic strokes.

Statistically significant better improvement in performance was found for the FMA for robotic intervention control hand FMA (WSR: p-value $= 0.097$); for the robotic intervention group hand FMA (WSR: $p < 0.001$). However, the MI did not exhibit the same statistical difference. For control: prehension MI (WSR: $p = 0.097$). For intervention: prehension MI (WSR: $p = 0.009$).

FMA changes are shown in Fig. 2. Analogously, MI changes are shown in Fig. 3. Differences for the hand, were as follows: Fugl-Meyer improvements in the motor dexterity for the hand achieved with the intervention therapy was significantly greater than improvement obtained with the control therapy, but the Motricity Index, despite the bigger effect size induced by the intervention therapy, did not show such significant difference for prehension (FMA hand: WRS: $W = 8$, $p < 0.01$; MI prehension: $W = 17.5$, $p = 0.080$). Contrast estimated effect sizes and the related confidence intervals are presented in Table 2.

Harms

There were no reported injuries or complications from treatment with the robot.

Discussion

The complexity of hand function has been a limiting factor in the development of devices that allow training the whole upper limb including the hand. Enhancing robots with capabilities to train the hand would be of major benefit to the patient. In this sense, most robots currently attempting to provide any kind of support for hand training are designed to train the pressure of the hand without favoring training finger extension. The Amadeo Tyromotion robot is one of the few capable of training finger extension, but evidence of hand rehabilitation accumulated thus far specifically using this robot is still limited. The number of randomized control studies carried out thus far in stroke rehabilitation is almost 1000, however this number is dramatically reduced to one when it comes to testing robotics in subacute stroke patients and demonstrating good quality (PEDro > 5).[32] Specifically for the Amadeo, two studies have been identified, but neither is an RCT. The study by Stein et al[39] carried out with chronic patients ($n = 12$), was only a feasibility study to demonstrate safety and feasibility. The study of Sale et al[40] on subacute patients found a longitudinal improvement on hand function, but it only included 7 patients and was not controlled; so it is difficult to know whether the robot provides an advantage.

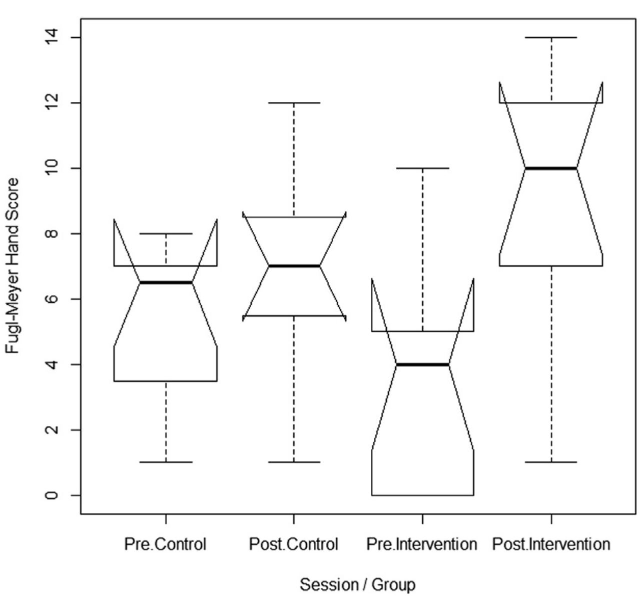

Fig. 2. Fugl-Meyer hand assessment score for the subacute patients for both groups, control and intervention, along the two longitudinal time points, at study onset and at study offset.

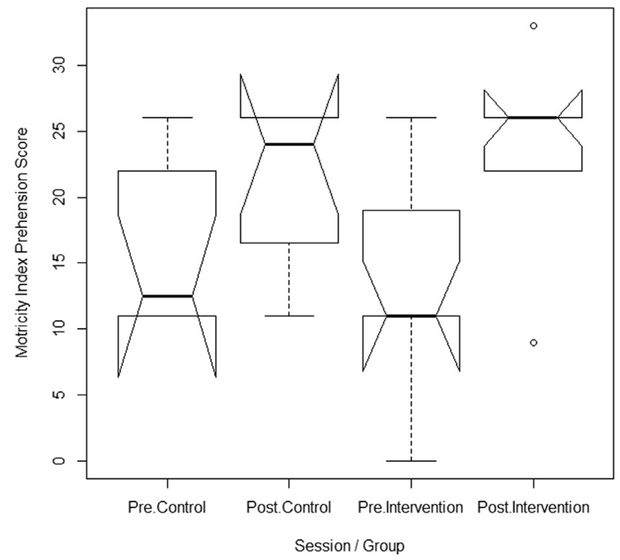

Fig. 3. The Motricity Index prehension score for the subacute patients for both groups, control and intervention, along the two longitudinal time points, at study onset and at study end.

The early extension of fingers is a critical element to establish prognosis of motor recovery, and knowledge of this capacity can be harnessed to direct the therapy to those who will benefit the most from it.[41–44] All intensive training regardless of the stage is almost certain to result in some improvement or reduction in impairment; e.g. patients will improve their Fugl-Meyer score, but this does not mean an improvement in function. An early intensive treatment can better harness plasticity and favor cortical reorganization. Unfortunately, rehabilitation in existing studies in humans, with few exceptions, has not been intense and early.[45] Based on this information an hypothesis was formulated that a robotic intervention was expected to be more effective in the subacute stage than the classical therapy, and thus early robot-based intervention should be favored.

Considering the results, and specifically the observation that hand recovery is more pronounced with robotic therapy than with occupational therapy, it appears that early robotic intervention is beneficial. However, although the results suggest that hand recovery is larger with robotic therapy than with occupational therapy during this subacute stage, the subtleties revealed by the analysis suggest that this difference might not be clear enough for closing the debate.

Although these results were to an extent expected considering current understanding of neurorehabilitation principles,[46] this study adds experimental evidence to what, in our opinion, is still insufficient evidence. Stroke survivors complete almost all recovery from impairment by 3 months; and, further observable improvement is the result of compensatory strategies.[45] According to the results of this study, during the subacute stage, the patients treated with the robotic therapy show an important change in finger movement which was not observable in those patients treated with classical occupational therapy. In this sense, the extra benefit given by the robot assistance is that it may be giving patients an opportunity to recover physical abilities they may not have otherwise regained. As pointed out by Krakauer, the development of methods

Table 2
Summary of primary outcomes results and effect size in improvements

	Occupational therapy ($n = 8$)			Robotic therapy ($n = 9$)			Difference in improvement (95% CI)
	Pre (mean [SD])	Post (mean [SD])	Improvement (mean [SD])	Pre (mean [SD])	Post (mean [SD])	Improvement (mean [SD])	
FMA hand	5.37 [2.77]	6.87 [3.18]	1.50 [2.26]	3.44 [3.77]	9.11 [4.07]	5.66 [2.73]	4.17 [2.32 to 6.01]
MI prehension	16.00 [6.27]	21.25 [6.01]	5.25 [6.64]	12.33 [8.91]	24.33 [7.15]	12.00 [7.79]	6.75 [4.07 to 9.43]

that take advantage of the regional poststroke plasticity identified in animal models may help optimize that training, and such methods may include combinations of cortical stimulation, robotic training, CIMT, and other interventions.[45] The fact that patients treated with the robot were more likely to move their fingers during the subacute stage represents an opportunity to improve the early stage, perhaps boosting their response to therapy. The results are expected to generalize well to both genders and adults above 30 years old. Generalizability to patients of hemorrhagic stroke is however, uncertain. Although inclusion and exclusion criteria allowed these patients, only patients of ischemic stroke were enrolled.

The findings of this study are important for decision making in therapy administration and both treatment benefits and resource allocation would need to be considered when making decisions about implementation. The cost of robotic devices may not be feasible in all clinical contexts, and the strength of this study alone is insufficient to support their use as standard practice.

Limitations

To restrict experimental conditions this research evaluated the effectiveness of one single robot, the Amadeus Tyromotion – the potential confounder arising from using different robotic solutions was eliminated. For this particular robot, and regardless of the stage of the patient, we observed the following advantages. First, the robot is adaptable to any type of physical deformity permitting ergonomic support of the hand and gives proper grip and comfort during the therapy. Second, management of the robotic treatment programs are simple and customizable to the individual needs, promoting adequate patient interaction with the device. Third, the finger movement mechanism allows the training to be passive, assisted or active. Fourth, the robot further allow training of a single finger or complex functions such as opposition, in coarse and in fine pinching function as well as finger extension. The experimental design did not consider a third group with an alternative rehabilitation robotic device. Although a group with an alternative robotic treatment would have facilitated generalization of any finding related to robot-assisted therapy, clarification of the specific advantages of the devices, and better discrimination of robot-assisted generic benefits versus device-specific benefits, the experimental compromise would have been in statistical power. An effort was made to ensure comparable number of repetitions across groups (therapy intensity), but the different nature of the exercises makes equal counting troublesome. Despite finding statistical differences on one outcome measure, the groups sizes in our study were very small for a clinical trial and preclude confidence in the size or generalizability of the treatment effects we observed. This small sample was not sufficient to provide definitive conclusions on both study outcome measures. Finally, having a single assessor may introduce statistical bias which is not accounted for.

Conclusions

This research has explored the benefits of administering active assisted robot therapies compared to a classical occupational therapy for the hand at equal dose during the subacute stage in stroke patients. We expected the robotic therapy to surpass the effects of the occupational therapy more obviously capitalizing on better exploiting the increase in cortical excitability at this stage. Instead, the results exhibit the right trend but failed to reach significance across endpoints. Notwithstanding, based on the results that the robotic therapy makes a difference over classical occupational therapies when it comes to hand function recovery on the subacute stage, early intervention with a robotic device is recommended. We conclude that this type of intervention may induce a change, perhaps at cortical level (although not measured here) which may be giving patients an opportunity to achieve a better recovery.

Clinical relevance

- Robotic intervention in subacute stage leads to significant improvements in hand motor dexterity.
- Superiority over classical occupational therapy is suggested by data.
- Robotic intervention may be inducing a supplementary change giving patients an additional opportunity to recover.

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Quiz: #404

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#1. The study design was
  a. retrospective
  b. systematic review
  c. RCT
  d. case study

#2. Sensorymotor recovery was evaluated with the
  a. Fugl-Meyer assessment scale
  b. DASH
  c. Purdue Peg Board
  d. 9 Hole Peg Test

#3. Assessments were performed by
  a. a CHT
  b. an OTR/L
  c. a PT, PhD
  d. an experienced physician

#4. The robotic protocol is
  a. clearly detailed in the intervention section of the article
  b. shown in photos
  c. referenced in footnote #36 which refers to an article in Spanish, and therefore English speaking readers really have no good picture of what the robotic intervention was
  d. readily available for clinical use in Mexico, the UK, and the US

#5. The results are sufficiently strong to allow cross diagnostic application
  a. true
  b. false

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