Upper Extremity Robotic Therapy is Effective in Post-stroke Hemiplegia: a Randomized Controlled Trial

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Disclosure Information

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Background

- In subacute treatments for post-stroke hemiplegia, repetitive movements at a constant level of assistance have been used and shown to effectively help recover upper extremity (UE) function.
- Self-training is a way to enhance repetitive movements of UE, but difficult to maintain enough amount of exercise.
- Recently, training assistant robots have been developed as a clinical tool for this purpose.
**Reo™ Therapy System**
(Motorika Ltd., Israel)

- Assist repetitive movements of the forearm in multiple directions at a constant level of assistance.
- 5 pre-programmed movements (i.e. Forward reach, Horizontal reach)
- 5 levels of robotic assistance (from robot-assisted to robot-unassisted movements)

- Few researches in subacute rehabilitation
- Who may benefit is unclear
Purpose

- To examine whether robotic therapy in addition to standard UE training improves UE function in subacute post-stroke hemiplegia more than self-training in addition to standard training.
- To examine which severity level of hemiplegia could benefit from the robotic therapy.

Research Design

Multicenter clinical trial
Prospective, Randomized, Open, Blinded-Endpoint

Inclusion Criteria:
- Patients with stroke in the previous 4 to 8 weeks,
- Hemiplegia with UE Brunnstrom stage 3 to 4
Participants

Assessed for eligibility  n=715

Excluded  n=655
650 did not meet inclusion criteria
5 refused to participate

Baseline assessment/ randomization  n=60

Robotic therapy group
Standard therapy + Robotic therapy  n=30

Completed treatment/assessment  n=30
Included for data analysis  n=30

Control group
Standard therapy + Self-training  n=30

Completed treatment/assessment  n=26
Included for data analysis  n=26

Discontinued  n=4
1 adverse event
3 refused
## Participant Demographics

<table>
<thead>
<tr>
<th></th>
<th>Robotic Therapy (N=30)</th>
<th>Control (N=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>21 (70.0)</td>
<td>18 (69.2)</td>
<td>p=0.950</td>
</tr>
<tr>
<td>Female (%)</td>
<td>9 (30.0)</td>
<td>8 (30.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Age (yr; SD)</strong></td>
<td>65.2 (10.9)</td>
<td>64.5 (11.5)</td>
<td>p=0.846</td>
</tr>
<tr>
<td><strong>Affected side</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right (%)</td>
<td>10 (33.3)</td>
<td>14 (53.8)</td>
<td>p=0.122</td>
</tr>
<tr>
<td>Left (%)</td>
<td>20 (66.7)</td>
<td>12 (46.2)</td>
<td></td>
</tr>
<tr>
<td><strong>OCSP classification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LACI</td>
<td>7 (23.3)</td>
<td>6 (23.1)</td>
<td>p=0.953</td>
</tr>
<tr>
<td>TACI</td>
<td>3 (10.0)</td>
<td>2 (7.7)</td>
<td></td>
</tr>
<tr>
<td>PACI</td>
<td>20 (66.7)</td>
<td>18 (69.2)</td>
<td></td>
</tr>
<tr>
<td>POCI</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Time after the onset (Day; SD)</strong></td>
<td>47.8 (7.0)</td>
<td>46.9 (8.1)</td>
<td>p=0.677</td>
</tr>
<tr>
<td><strong>Baseline Fugl-Meyer Assessment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper extremity total score</td>
<td>29.1 (16.3)</td>
<td>31.8 (15.4)</td>
<td>p=0.526</td>
</tr>
<tr>
<td>Shoulder/elbow/forearm score</td>
<td>18.7 (9.0)</td>
<td>20.5 (8.2)</td>
<td>p=0.414</td>
</tr>
<tr>
<td>Flexor synergy score</td>
<td>6.7 (3.9)</td>
<td>8.1 (3.0)</td>
<td>p=0.035</td>
</tr>
</tbody>
</table>
Intervention

- Interventions for six weeks (7 days a week)
  
  Robotic Therapy Group:
  - Standard UE Rehabilitation (40 min) + Robotic Therapy (40 min)

  Control Group:
  - Standard UE Rehabilitation (40 min) + Self-training (40 min)

Outcome Measures

- UE function: Fugl-Meyer Assessment (FMA)
  - UE total score: 66 points
  - Shoulder/Elbow/Forearm score: 36 points
  - Flexor Synergy score: 12 points
Effect on Proximal UE Movement

Change in score on FMA:
Shoulder/Elbow/Forearm score

Pre
Post

Robotic therapy group
Control group

p<0.001
p<0.05
n.s.
Effect on UE Synergy Movement

Change in the score on FMA:
Flexor Synergy score

Pre  Post

-1  6  p<0.01
-1  3  p<0.001
0  5  n.s.

Robotic therapy group
Control group
Baseline UE Function and FMA Improvement

Higher Class
Baseline FMA total score \( \geq 30 \)

Lower Class
Baseline FMA total score \( < 30 \)

Pre vs. Post change in score on FMA

- Robotic therapy group
- Control group

Higher Class
- Baseline FMA total score \( > 30 \)
- Pre vs. Post change in score:
  - \( p < 0.001 \)
  - \( n.s. \)

Lower Class
- Baseline FMA total score \( < 30 \)
- Pre vs. Post change in score:
  - \( p < 0.05 \)
  - \( n.s. \)

Graphs showing change in score on FMA before and after treatment, comparing robotic therapy group and control group.
Discussion

- People with moderately severe hemiplegia may benefit the most from this robotic therapy.
- The patients with lower function have a difficulty performing self-training correctly.
- They are more likely to benefit from the robot
  - repetitive movement exercise
  - right movement pattern
  - constant amount of assistant
Limitation

- The program of Robotic Therapy was selected by each therapist to fit each patient’s function.
  - Guideline of program selection need to be developed.
- Patients with more severe hemiplegia were not recruited in this study.
  - Patients with more severe hemiplegic need to be investigated.
Conclusion

- Robotic therapy, as compared with usual self-training, increase voluntary movement and function of UE in post-stroke patients
- These effects are more remarkable in moderately severe hemiplegia
- Robotic therapy can be an effective clinical tool for improving UE function during subacute rehabilitation