Telerehabilitation In The Home Versus Therapy In-Clinic For Patients With Stroke


*Professor, Depts. Neurology, Anatomy & Neurobiology, and PM&R

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Dr. Cramer serves as a consultant for Abbvie, Constant Pharmaceutical, MicroTransponder, Neurolutions, Regenera, SanBio, Stemedica, and TRCare.
Motor deficits are a major contributor to post-stroke disability.

Animal studies with favorable plasticity use high rehab doses. (600 repetitions of pellet retrieval/day, Nudo 1996)

In humans, higher rehab therapy doses may improve outcomes.

Quantity of rehab therapy often low in humans, however:
   (1) financial constraints
   (2) patient can’t travel to a rehab therapy provider
   (3) shortage of rehabilitation care in some regions
   (4) poor patient compliance with assignments
   (5) limited dose during stroke rehabilitation
       (mean of 32 arm repetitions/session, Lang 2009)
Quality of rehab also important; greater plasticity when a task is
(1) challenging and varied
(2) accompanied by appropriate feedback
(3) motivating and goal-oriented
(4) interesting
(5) environmentally and ecologically relevant

We reasoned that telerehabilitation is ideally suited to efficiently provide a large dose of useful rehab therapy after stroke.
Telerehabilitation in the Home Versus Therapy In-Clinic for Patients With Stroke

124 subjects with stroke 4-36 weeks prior and arm motor deficits

Randomized at 11 US sites to intensive arm motor therapy
(a) traditional In-Clinic, versus
(b) in-home Telerehabilitation

Treatment
36 sessions (18 superv’d, 18 unsuperv’d), 70 min, over 6-8 wk
Intensity, duration, and frequency of therapy matched

Assessor-blind, randomized, non-inferiority design

clinicaltrials.gov NCT02360488
Primary outcome measure: change in arm motor Fugl-Meyer score from baseline to 30 days post-therapy
  Intent To Treat (all randomized subjects), multiple imputation for missing data

Secondary outcome measures:
  [1] Gains in stroke knowledge
  [2] Change in motivation over time

Analysis: If the non-inferiority margin (30% of ΔFM for In-Clinic group) falls outside the 95% CI for the difference in ΔFM between groups, then telerehabilitation would be considered non-inferior.

Sample size: Assumed In-Clinic group mean ΔFM of 6.85 points and SD=3.8, study needed 124 subjects for 85% power.
Key Inclusion criteria
1. Age ≥18 years
2. Stroke (ischemic or ICH) onset 4-36 weeks prior
3. Arm motor Fugl-Meyer score = 22-56 (out of 66)

Key Exclusion criteria
1. Major, active, coexistent neurological or psychiatric disease
2. Other diagnosis substantially affecting paretic arm
3. Severe depression (GDS Score >10)
4. Significant cognitive impairment (MoCA <22)
5. Communication deficits interfering with participation
6. Life expectancy <6 months
7. Non-English speaking
8. Unable to perform the 3 rehabilitation exercise test examples
9. Subject will not have a single address during the 6 weeks of therapy within 25 miles* of study site, with Verizon reception
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Details of study treatment

Treatment based on

[1] The Accelerated Skill Acquisition Program, which is “principle based, impairment focused, task specific, intense, engaging, collaborative, self-directed, and patient centered”


For both groups, all 70-minute sessions included:

[1] **Arm exercises** (88 available): at least 15 min/day

[2] **Functional training**: at least 15 min/day
   - In-Clinic used functional tasks
   - Telerehab used functional games

[3] **Stroke education**: 5 min/day, during unsupervised sessions
   - Focused on stroke prevention, risk factors, recognition, and treatment
In-Clinic Group

- **18 supervised treatment sessions** (70 minutes)
  - At the research center, with a therapist
- **18 unsupervised treatment sessions** (70 minutes)
  - In the home, using an individualized booklet
In-Clinic Group
• **18 supervised treatment sessions** (70 minutes)
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Telerehabilitation
• Study team delivered a telerehabilitation system to the home
• **18 supervised treatment sessions** (70 minutes)
  --In the home, 30 min therapist videoconference at start
• **18 unsupervised treatment sessions** (70 minutes)
  --In the home, using telerehab system (no therapist contact)
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Games could be adjusted in relation to motor control, e.g., movement speed, timing, planning, range of motion, target size, cognitive demand, hemifield bias, bimanual, sustained, proximal vs. distal, and 1\textsuperscript{st} person vs. 3\textsuperscript{rd} person perspective
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Input device used to play games could also be adjusted
FDA: non-significant risk device study

clinicaltrials.gov NCT02360488
Telerehabilitation

<table>
<thead>
<tr>
<th>Diet</th>
<th>Stroke Facts</th>
<th>Stroke Risk Factors</th>
<th>Effects of Stroke</th>
<th>Exercise</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1000</td>
<td>$1000</td>
<td>$1000</td>
<td>$1000</td>
<td>$1000</td>
</tr>
<tr>
<td>$3000</td>
<td>$3000</td>
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</tbody>
</table>

**Transfer Object**

Grasp and hold object with one hand. Transfer object to other hand. Reverse. Use objects of different shapes, sizes and weight.

In the past week of arm-related therapy you have been doing as part of this research study, how satisfied are you with the therapy?

I find the tasks/games:

<table>
<thead>
<tr>
<th>Very unsatisfactory</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Very satisfying</th>
</tr>
</thead>
</table>

Score: 5
Time: 125

Score: 0
Time: 127

Score: 8
Time: 21

Score: 0
Time: 106

Current total: 12. Press ↓ to hit or ↑ to stay

Score: 0
Time: 127

Slot Machine
## Results

124 subjects randomized between 9/23/15 and 1/3/18

<table>
<thead>
<tr>
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<th>Telerehab</th>
<th>In-Clinic</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>62</td>
<td>62</td>
<td>124</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62 ± 14</td>
<td>60 ± 13</td>
<td>61 ± 13</td>
</tr>
<tr>
<td>Baseline arm motor Fugl-Meyer</td>
<td>42.8 ± 7.8</td>
<td>42.7 ± 8.7</td>
<td>42.8 ± 8.3</td>
</tr>
<tr>
<td>Time post-stroke (days)</td>
<td>132 ± 65</td>
<td>129 ± 59</td>
<td>131 ± 62</td>
</tr>
<tr>
<td>Stroke subtype n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>54 (87.1)</td>
<td>52 (83.9)</td>
<td>106 (85.5)</td>
</tr>
<tr>
<td>Intracerebral hemorrhage</td>
<td>8 (12.9)</td>
<td>10 (16.1)</td>
<td>18 (14.5)</td>
</tr>
<tr>
<td>Gender (%F)</td>
<td>22.6%</td>
<td>32.3%</td>
<td>27.4%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>9.7%</td>
<td>6.5%</td>
<td>8.1%</td>
</tr>
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<td>Black</td>
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<tr>
<td>White</td>
<td>66.1%</td>
<td>62.9%</td>
<td>64.5%</td>
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<tr>
<td>Unknown</td>
<td>0</td>
<td>1.6%</td>
<td>0.8%</td>
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<tr>
<td>Ethnicity (% Hispanic)</td>
<td>4.8%</td>
<td>0</td>
<td>2.4%</td>
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<tr>
<td>Geriatric Depression Scale</td>
<td>3.4 ± 3.1</td>
<td>3.6 ± 2.7</td>
<td>3.5 ± 2.9</td>
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<tr>
<td>Montreal Cognitive Assessment</td>
<td>24.9 ± 4.1</td>
<td>24.4 ± 5.0</td>
<td>24.7 ± 4.6</td>
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<td>Paretic side (%R)</td>
<td>43.5%</td>
<td>58.1%</td>
<td>50.1%</td>
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<td>Hypertension (% yes)</td>
<td>80.6%</td>
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Dropout
10 subjects (8.1%) dropped out before the final visit:

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<th>No Therapy</th>
<th>MD Withdrew</th>
<th>Lost to follow-up</th>
<th>Return to Work</th>
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<tr>
<td>Telerehab</td>
<td>3</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>In-Clinic</td>
<td>1</td>
<td>2 (HTN, Fx)</td>
<td>2</td>
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Compliance
Telerehab—58/62 (98.3 %) subjects compliant with 36 sessions
In-Clinic—57/62 (93.4 %) subjects compliant with 36 sessions

Adverse events

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The adjusted difference* between groups in ΔFM is 0.06 points:
Does the non-inferiority margin of 2.47 points fall outside of the 95% CI for this difference?

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Results

The non-inferiority margin (2.47 points) fell outside of the 95% CI for 0.06 points (adjusted* group difference in ΔFM)

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**Telerehabilitation is non-inferior.**

FM arm motor gains did not differ among subjects with (n=39) vs. without (n=75) aphasia.
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The number of TR arm movement repetitions averaged 1,031/day.
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Gains in activity-inherent motivation to end of therapy were 0.47 points higher in IC > TR group (p=0.008) on 7 point PACES scale.
Arms improved, as Fugl-Meyer score gains (7.86-8.36 points) exceed minimal clinically important difference (4.25-7.25).
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Therapist-guided, home-based, effective telerehab might
  --be paired with a drug (experience-dependent plasticity)
  --facilitate detailed remote measurements
  --extend to other neurological domains (language, leg, etc.)
  --enable stroke smart home
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