

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

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for the NIH StrokeNet Telerehab Investigators

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Disclosures

Dr. Cramer serves as a consultant for MicroTransponder, Dart Neuroscience, Roche, Neuroolutions, Regenera, Abbvie, SanBio, and TRCare.

Unmet need: delivery of large doses of rehab therapy

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.

A Home-Based Telerehabilitation Program for Patients With Stroke

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In a pilot study of 12 patients with late subacute stroke and arm motor deficits, we provided 28 days of home-based telerehab:

- (1) Compliance was excellent (97.9%)
- (2) Good arm motor gains (Fugl-Meyer increase 4.8 points)
(879 arm repetitions/day)
- (3) Findings not dependent on computer skills

Dodakian et al, Neurorehab Neural Repair. 2017; 31:923-933

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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](https://clinicaltrials.gov/NCT02360488)



Primary outcome measure: change in arm motor Fugl-Meyer score from baseline to 30 days post-therapy.

- Primary analysis: Intent To Treat (ITT) group, i.e., all randomized subjects.
- Secondary analysis: Per Protocol (PP) group, i.e., those with ≥ 40 min therapy at 15 or more supervised sessions.

Analysis: hypothesized that telerehab has comparable efficacy based on a 30% non-inferiority margin:

If the lower bound of the 95% CI for the difference in ΔFM between groups exceeds 30% of ΔFM for In-Clinic group, then telerehabilitation would be considered non-inferior.

Sample size: Assumed In-Clinic group mean ΔFM of 6.85 points and $SD=4.0$, study needed 124 subjects for 80% 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



FDA: non-significant risk device study

[clinicaltrials.gov NCT02360488](https://clinicaltrials.gov/NCT02360488)



Telerehabilitation

Transfer Object

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

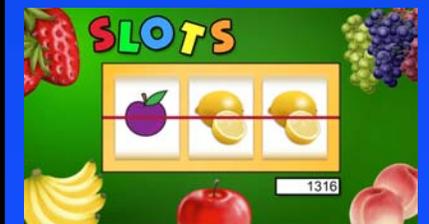
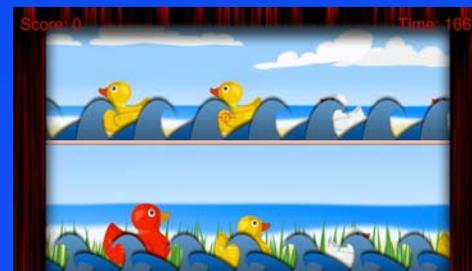
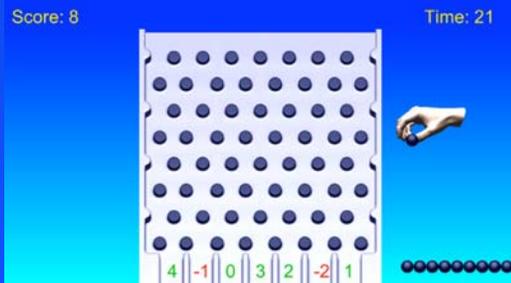
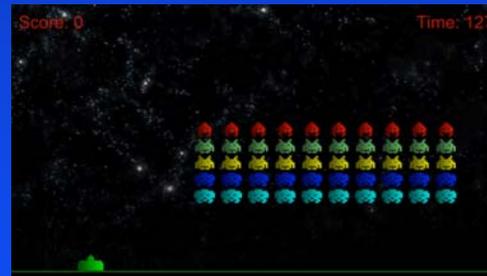


Diet	Stroke Facts	Stroke Risk Factors	Effects of Stroke	Exercise
\$1000	\$1000	\$1000	\$1000	\$1000
\$2000	\$2000	\$2000	\$2000	\$2000
\$3000	\$3000	\$3000	\$3000	\$3000
\$4000	\$4000	\$4000	\$4000	\$4000
\$5000	\$5000	\$5000	\$5000	\$5000

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:

Very displeasurable 1 2 3 4 5 6 7 Very pleasurable



Results

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

	Telerehab	In-Clinic	Overall
n	62	62	124
Age (years)	62 ± 14	60 ± 13	61 ± 13
Baseline arm motor Fugl-Meyer	42.8 ± 7.8	42.7 ± 8.7	42.8 ± 8.3
Time post-stroke (days)	132 ± 65	129 ± 59	131 ± 62
Stroke subtype n (%)			
Ischemic	54 (87.1)	52 (83.9)	106 (85.5)
Intracerebral hemorrhage	8 (12.9)	10 (16.1)	18 (14.5)
Gender (%F)	22.6%	32.3%	27.4%
Race			
Asian	9.7%	6.5%	8.1%
Black	24.2%	29.0%	26.6%
White	66.1%	62.9%	64.5%
Unknown	0	1.6%	0.8%
Ethnicity (% Hispanic)	4.8%	0	2.4%
Geriatric Depression Scale	3.4 ± 3.1	3.6 ± 2.7	3.5 ± 2.9
Montreal Cognitive Assessment	24.9 ± 4.1	24.4 ± 5.0	24.7 ± 4.6
Paretic side (%R)	43.5%	58.1%	50.1%
Baseline NIHSS score (median IQR)	3 [2-5]	3 [2-4]	3 [2-4]
Baseline modified Rankin Scale	2 [2-3]	2 [2-3]	2 [2-3]
Hypertension (% yes)	80.6%	85.5%	83.1%
Hypercholesterolemia (% yes)	64.5%	62.9%	63.7%
Diabetes mellitus (% yes)	22.6%	27.4%	25.0%
Atrial fibrillation (% yes)	16.1%	6.5%	11.3%

Results

Dropout

10 subjects dropped out before the 30 day post-therapy visit:

	<u>No Therapy</u>	<u>MD Withdrew</u>	<u>Lost to follow-up</u>	<u>Return to Work</u>
Telerehab	3	0	0	0
In-Clinic	1	2 (HTN, Fx)	2	2

Compliance

Most had ≥ 40 min therapy at 15 or more supervised sessions:

Telerehab--58 of 62 subjects (93.5 %)

In-Clinic--57 of 62 subjects (91.9 %)

Adverse events

	<u>SAE</u>	<u>Other adverse events</u>
Telerehab	3 (all unrelated)	16 (10 reasonably or definitely related)
In-Clinic	6 (all unrelated)	8 (6 reasonably or definitely related)

Results

	In-Clinic	Telerehab	Overall
Baseline Fugl-Meyer	42.7 ± 8.7	42.8 ± 7.8	42.8 ± 8.3
Fugl-Meyer change to d30	8.36 ± 7.0	7.86 ± 6.7	8.11 ± 6.8

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In-Clinic mean Δ FM is 8.36, 30% of which is 2.51.

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In-Clinic mean Δ FM is 8.36, 30% of which is 2.51.

The difference between groups in Δ FM is

0.5 points (unadjusted)

0.0 points (adjusted for covariates)—Is the 95% CI for this difference < 2.51?

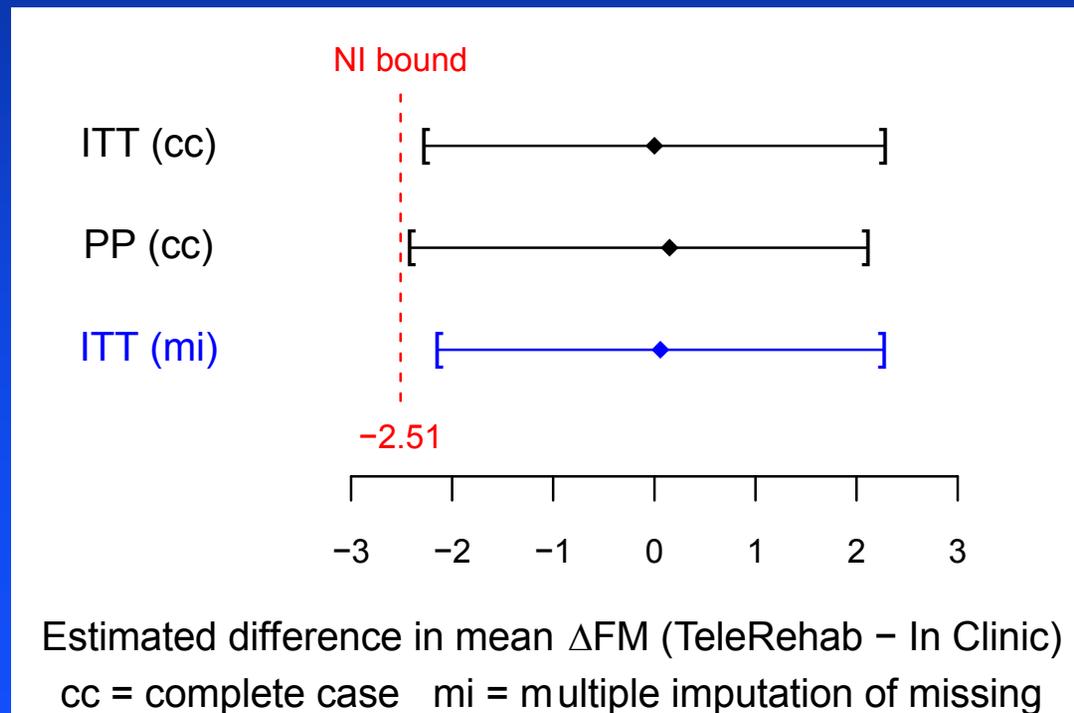
Adjusted for age, baseline FM, time post-stroke, enrollment site, and stroke subtype

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In-Clinic mean Δ FM is 8.36, 30% of which is 2.51.

The 95% CI for difference between groups in mean Δ FM <2.51

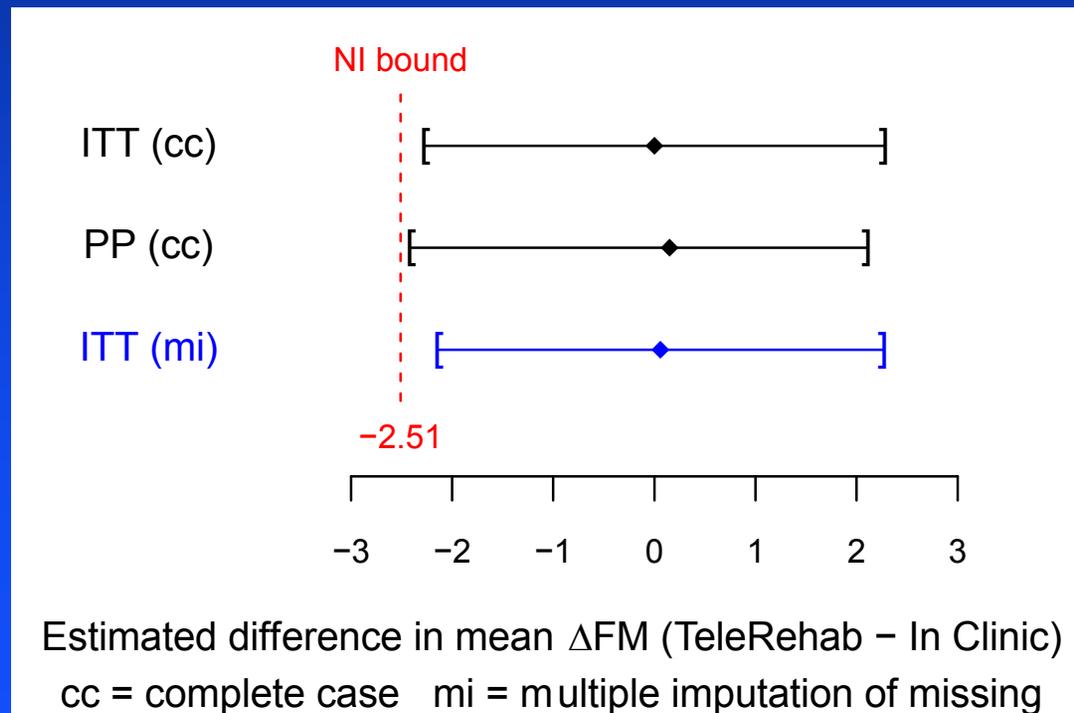


Adjusted for age, baseline FM, time post-stroke, enrollment site, and stroke subtype

Results

Data provide strong evidence that the difference between groups does not exceed a 30% reduction in efficacy.

- Intention To Treat and Per Protocol groups are in agreement.
- ITT, PP with multiple imputation of missing data: same finding
- Telerehabilitation is non-inferior.



Adjusted for age, baseline FM, time post-stroke, enrollment site, and stroke subtype

Conclusions

Mean gains (7.86-8.36 points) exceed minimal clinically important difference for arm motor Fugl-Meyer scale (4.25-7.25).

Very high compliance in the In-Clinic group suggests results might not reflect broad stroke population.

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

Telerehab is not inferior to In-Clinic therapy for improving arm motor status in patients with recent stroke.

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