

Telerehabilitation in the Home Versus Therapy In-Clinic for Patients With Stroke

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



Patients often do not receive highest dose of rehab

Observation of Amounts of Movement Practice Provided During Stroke Rehabilitation

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During inpatient or outpatient stroke rehabilitation, the mean # functional UE repetitions per session was 32.

Patients often do not receive highest dose of rehab

Reasons include

- financial constraints
- patient can't travel to a rehab therapy provider
- shortage of rehabilitation care in some regions, e.g., rural
- poor compliance

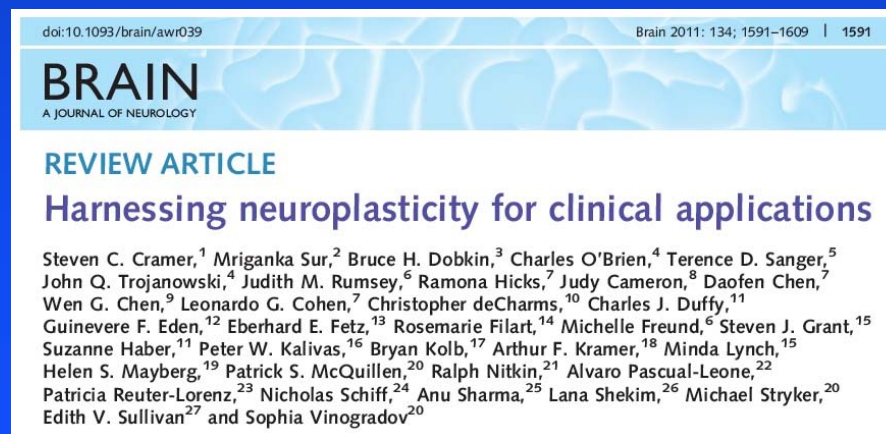
Yet gains are often greater when provide rehab of higher

- duration
- intensity

Quality of rehab therapy: key factors

Brain plasticity is greatest when the task is

- challenging
- repeated many times
- motivating
- interesting
- intensive
- accompanied by feedback



Telerehabilitation: well suited to address these issues

Advances in telemedicine suggest capacity to provide larger therapy doses, individualized, cost-efficient

Telehealth is a tool that enables therapists, RNs, and MDs—does not replace them.

We reasoned that telehealth methods could be applied to stroke rehab to meet this unmet need and performed a pilot study.

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- 124 subjects with arm motor deficits 4-36 weeks after stroke, randomized to intensive arm motor therapy
 - (a) traditional in-clinic, versus
 - (b) in-home telerehabilitation
- 36 sessions (18 supervised + 18 unsupervised), 80 min each, over 6 weeks; intensity, duration, and frequency matched across groups
- Assessor-blind, randomized, non-inferiority design

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Main Study Aims

- **Aim 1.** Subjects randomized to receive telerehabilitation will show arm motor gains that are not inferior to subjects treated in-clinic.

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- Arm movement the focus here because it is
 - central to human function
 - commonly affected after stroke
 - strongly linked to disability level and well-being after stroke

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- **Aim 2.** Targeted education for 6 weeks will significantly increase patient knowledge related to stroke prevention and stroke risk factor control.
- **Aim 3.** Subjects in the telerehabilitation arm will show comparable or better
 - compliance with therapy and
 - activity-inherent motivation (how much a patient enjoys therapy).

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Parent RCC	Study Site
Los Angeles Southern California	University of California, Irvine
Northwest Stroke Trials Network	Harborview Medical Center
Chicago Stroke Trials Consortium	Rehabilitation Institute of Chicago
Cleveland Regional Coordinating Center	MetroHealth Rehabilitation Institute of Ohio
Georgia StrokeNet	Emory Rehabilitation Hospital
South Carolina Collaborative Alliance for Stroke Trials	MUSC Center for Rehabilitation Research in Neurological Conditions
Stroke Trials Network of Columbia and Cornell	Burke Rehabilitation Hospital
New England Regional Coordinating Center	Spaulding Rehabilitation Hospital
Miami Regional Coordinating Center	Brooks Rehabilitation

Adding Kessler, Mt. Sinai, Kaiser Vallejo



Telerehabilitation: assess, monitor, educate, and treat

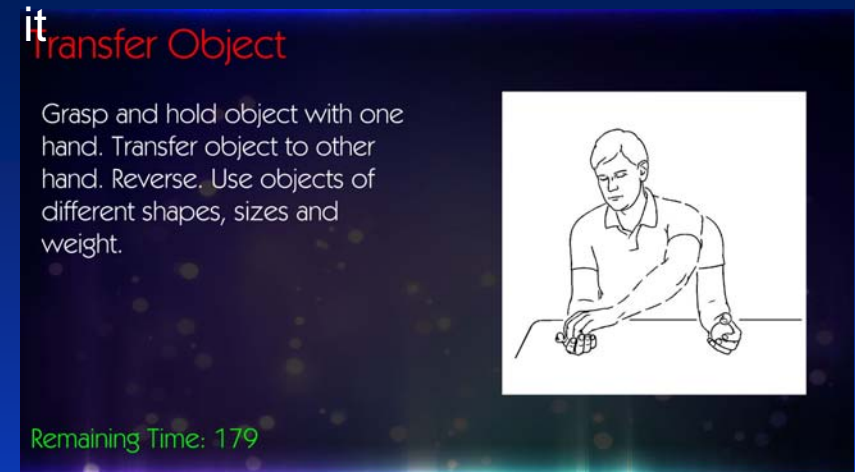


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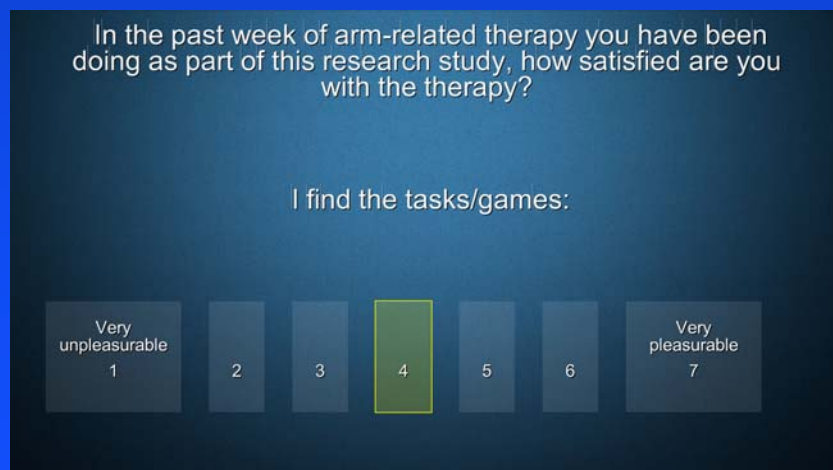
System prompts subjects at home to begin



Includes exercises--the system doesn't replace traditional therapy, it builds on



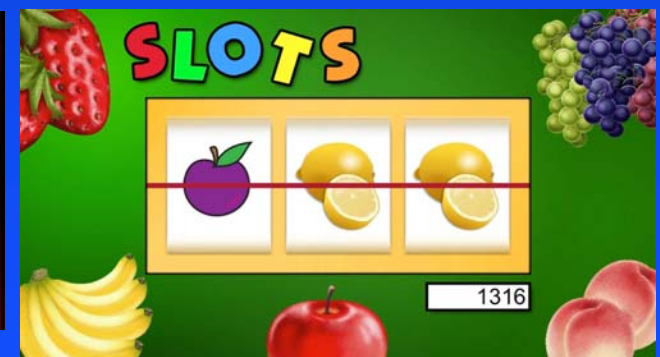
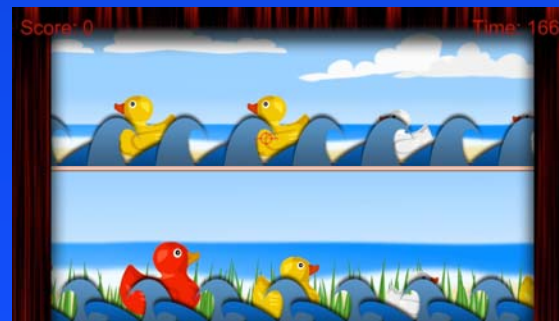
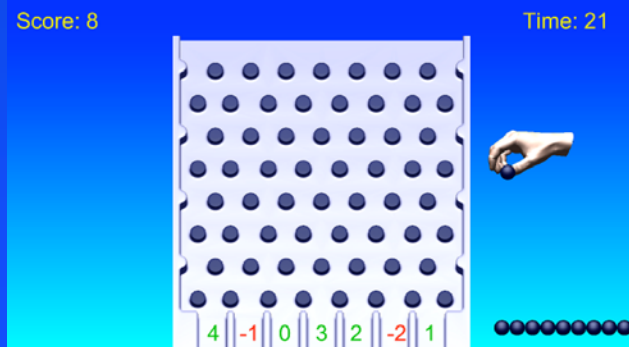
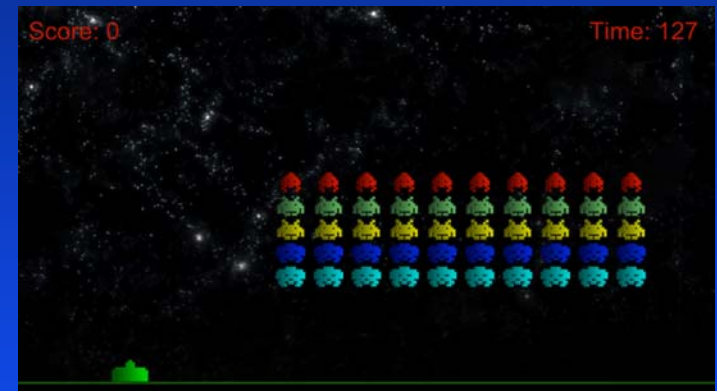
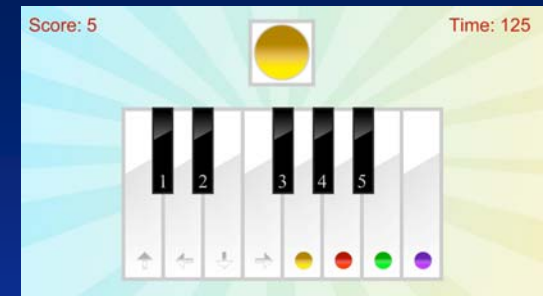
Patients assessed using the system



Stroke education using the system



Most aspects of telerehabilitation are game-ified



A second part of the system is the web-based interface used by therapists, remotely, to create treatment sessions, monitor usage and scores, videoconference, etc



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Study-related communication with enrollment sites

- Investigator Meeting at UC Irvine
- Monthly conference calls with all sites
- Monthly newsletters
- Calls with Treatment Therapists every other month
- UC Irvine website, where therapists can provide feedback
- 24 hour emergency phone number
- Email: telerehab@uci.edu

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Key issues in developing/running the trial

Challenges for standardizing assessments in a multi-site recovery/rehab trial: FM cert and re-cert every 4 mo online

Limited experience in the field to guide this (appreciate assistance provided by Steve Wolf and Carolee Winstein !)

Challenges for consistency of internet connectivity; across the U.S.; urban and rural

Used Verizon modem only; in future might allow a person's own home wireless network if passes certain tests at baseline

Balance between [1] require patients to plug in game devices versus [2] game devices are always on, powered, and ready

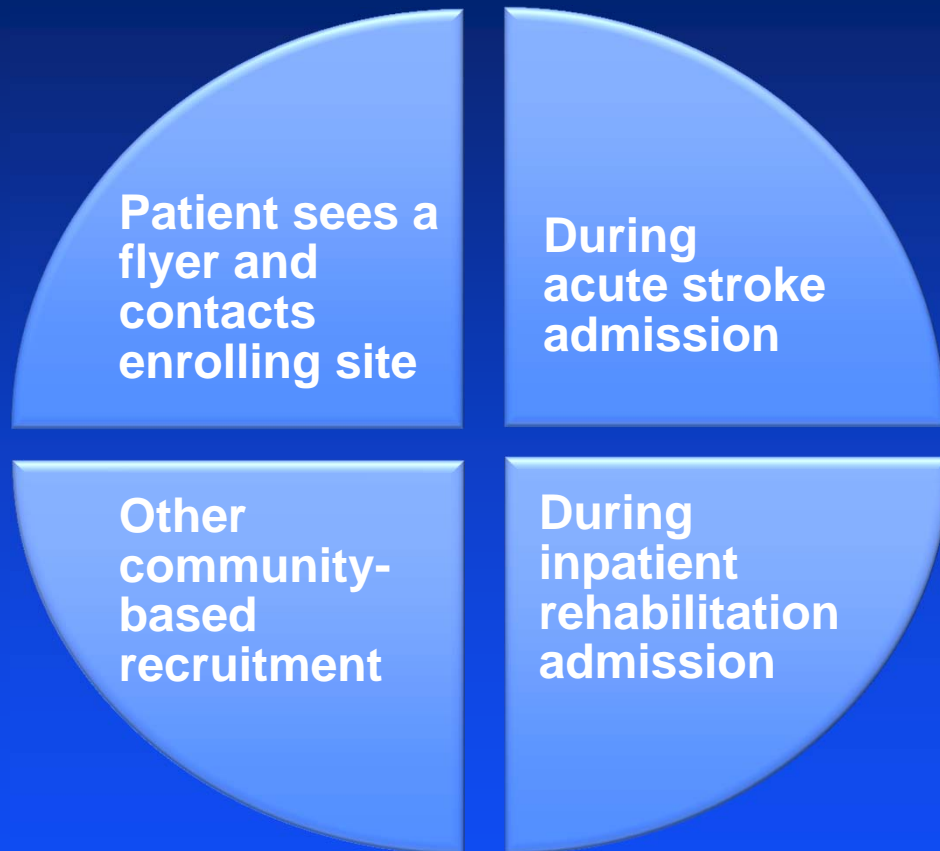
Designed study towards [2] but this is not ideal for some devices; in future will allow more of [1] if OK'd by therapist.

Recruitment

Although can recruit through many routes, most sites not achieving 0.67 patients/mo

To improve enrollment:

- adjusted entry criteria (without affecting scientific hypotheses)
- increased \$\$/patient
- adding more study sites
- surveyed sites; best methods disseminated



***** A better system is needed to identify and/or recruit patients into stroke recovery/rehab studies during the acute**

phase of stroke ***

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