Protocol

Study Title: Long-term Telerehabilitation for Patients With Stroke

ClinicalTrials.gov Identifier: NCT03460587

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Study overview: In this prospective, single-group, therapeutic feasibility trial, patients underwent live assessment at the UC Irvine clinic twice at baseline, after which a telehealth system was delivered to the patient's home. Patients then received 12 weeks of TR therapy, 6 days/week, with a live clinic assessment at the end of week 6 and week 12. Patients were free to call the lab with questions. This study was approved by the UC Irvine IRB, and was registered as clinicaltrials.gov ID # NCT03460587.

Participants: Patients were recruited from the community through local advertisements. In sum, enrollees were adults with arm paresis due to stroke and no limiting cognitive deficits. Full entry criteria appear below. Patients signed informed consent (no surrogate consent) and were evaluated for eligibility at the first 2 visits.

Inclusion criteria

1. Age ≥18 years at the time of randomization
2. Stroke that is radiologically verified, with any time of stroke onset prior to randomization
3. Upper extremity motor Fugl Meyer (UE-FM) score of 28-66 out of 66; to insure some deficit is present, if UE-FM >59, must also have Box & Blocks (B&B) score on affected side >25% lower than on non-affected side
4. Box & Block Test score with affected arm is at least 3 blocks in 60 seconds at the first visit
5. Informed consent and behavioral contract signed by the subject

Exclusion criteria

1. A major, active, coexistent neurological or psychiatric disease, including alcoholism or dementia
2. A diagnosis (apart from the index stroke) that substantially affects paretic arm function
3. A major medical disorder that substantially reduces the likelihood that a subject will be able to comply with all study procedures
4. Severe depression, defined as Geriatric Depression Scale Score >11 out of 15
5. Significant cognitive impairment, defined as Montreal Cognitive Assessment score < 22; this can be waived at the discretion of the study PI, e.g., for aphasia
6. Deficits in communication that interfere with reasonable study participation
7. Lacking visual acuity, with or without corrective lens, of 20/40 or better in at least one eye
8. Life expectancy < 6 months
9. Receipt of Botox to arms, legs, or trunk in the preceding 6 months, or expectation that Botox will be administered to the arm, leg, or trunk prior to completion of participation in this study
10. Unable to successfully perform all 3 of the rehabilitation exercise test examples
11. Unable or unwilling to perform study procedures/therapy, or expectation of non-compliance with study procedures/therapy, or expectation that subject will be unable to participate in study visits
12. Concurrent enrollment in another investigational study
13. Subject does not speak sufficient English to comply with study procedures
14. Expectation that subject will not have a single domicile address during the 12 weeks of therapy, within 75 miles of the central study site

Study intervention: After all eligibility criteria were confirmed, the patient signed a behavioral contract that listed a personal treatment goal and the time when therapy would begin each day. An initial treatment plan was created by a licensed occupational therapist (OT) or physical therapist (PT), standardized by use of an algorithm that uses the 33 UE-FM sub-scores to identify the 3 greatest UE impairments. The algorithm suggests games and exercises that are matched to these 3 impairments and so calibrates initial TR games and exercises to each patient's impairment level.

Patients were provided 72 treatment sessions, 6/week for 12 weeks. Each session was 60 minutes in duration and consisted of least 15 minutes of functional games, at least 15 minutes of exercises, and 5 minutes of stroke education using a Jeopardy style game.

There were 12 input devices used by patients to interact with the TR system: a PlayStation Eye camera, motion game controller (PlayStation Move, Sony; Tokyo, Japan), joystick, small buttons (10), large buttons (4), toy pistol holding a Wii remote (Nintendo; Kyoto, Japan) with corresponding IR sensor bar, trackpad (Logitech; Newark, CA), grip force cylinder, pinch force cube, rotating shuttle wheel (Powermate, Griffin Technology; Nashville, TN), steering wheel with gas/brake, and a 9-DOF IMU containing a 3-axis accelerometer, gyroscope, and magnetometer.

A total of 114 exercises were available, targeting UE, LE, and trunk. Each was 1-5 min long and consisted of a video showing the assigned movement. Patients were instructed to move as in the video. Therapists had the option to incorporate standard equipment (e.g., resistance bands; Theraband; Akron OH) provided to patients at the time the TR system was delivered to the home, to be used while watching the exercise videos.

A total of 33 functional games were also available, each 1-5 min long. These stress motor control features, e.g., varying movement speed, range of motion, target size, extent of visuomotor tracking, or level of cognitive demand. Game features were selected and adjusted by the therapist. For example, during the whack-a-mole game, higher difficulty level means a broader area where targets can appear on the tabletop and less time to successfully hit the target. Therapists also select which input device the patient will use for game play, based on UE status, e.g., the flappy-bird game can be played using the grip force cylinder, pinch force cube, or trackpad.

Therapists also decided whether 5 photographs would be taken at random time points during a given game, to gain insights into how the patient was playing the game. After the day's 1-hour of assignments were completed, patients were allowed to free play, i.e., to use the system to play functional games *ad libitum*.

Stroke education targeted 5 categories (Stroke Risk Factors, Stroke Prevention, Effects of Stroke, Diet, and Exercise) focused on secondary prevention. Patients made arm movements to enter their answers to multiple-choice questions, delivered via a video Jeopardy game format (an approach known to foster learning), and then received feedback on their answers.

To build each day's treatment session, therapists use a graphical interface to drag treatment elements into a 60-min planner for each day's session; they then adjusted the challenge level (games) and the duration (games and exercises), and selected which input device would be used to drive gameplay (games). The daily treatment plan was regularly updated by a therapist based on findings from videoconferences and from review of TR-based data. Four types of TR-based patient data were automatically transmitted from home to lab, in real time: system usage (time TR was used), patient performance (game scores), behavioral status (assessment scores), and photographs (during games and pill consumption).

Patients had 18 HIPAA-compliant videoconferences (VSee software; VSee; Sunnyvale, CA) with a licensed therapist: three times/week during weeks 1-2, two times/week during weeks 3-4, and one time/week during weeks 5-12. During videoconferences, questions were answered, feedback was provided, progress was reviewed, and on some days remote assessments were made.

During the 30 min prior to the TR session, the computer alerted the subject that the start time was coming soon. The subject hit a large tabletop button to begin the day's session and to start subsequent games/exercises after each one is completed. In this way, patients could take a break between games/exercises. Unsupervised sessions had the same treatment content as supervised sessions, but no therapist contact.

Study assessments: The primary endpoint was the Upper Extremity Fugl-Meyer scale, which ranges from 0-66, with higher scores indicating less UE impairment. The two main secondary endpoints for the lower extremity was the Lower Extremity Fugl-Meyer motor scale, which ranges from 0-34, which higher scores indicating less LE impairment.