Telerehabilitation Early After Stroke
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Brief summary

Stroke is a major cause of disability. Loss of movement is a major part of this. Studies show that high doses of rehabilitation therapy can reduce disability, but many patients do not receive this, e.g., due to obstacles such as difficulty accessing care. We have previously found that telerehabilitation is an effective way to deliver care and improve outcomes. These prior studies were performed after hospital discharge, when patients were already back at home. The current study aims to extend this work by introducing telerehabilitation to the bedside of patients admitted to an inpatient rehabilitation facility (California Rehabilitation Institute or MossRehab). In this study, we will measure issues and effects of telerehabilitation that is started during the rehab admission and is continued after discharge in the patient's home.

Specific Aims

There are 3 Specific Aims to be addressed by this study:

1. Assess the feasibility of initiating telerehabilitation during admission to an inpatient rehabilitation facility
2. Evaluate the patient experience
3. Measure patient outcomes at the end of a 6-week course of telerehabilitation, particularly with respect to motor outcome, functional outcome, and mood outcome.

Background and Significance

Patients need higher doses of high-quality rehabilitation therapy: Stroke remains a leading cause of human disability. Motor deficits are a substantial contributor to this, particularly in the arm: few patients fully recover from arm weakness after a stroke, with the remainder demonstrating persistent arm impairments that are directly linked to larger activity limitations and participation restrictions, lower quality of life, and decreased well-being[1-3]. Increasing evidence suggests that intensive activity-dependent therapy can improve outcomes. Hundreds of repetitions of task-specific practice may be required to optimize function post stroke." However, most patients do not receive such therapy for reasons that include difficulty traveling to a provider, shortage of regional rehabilitation care, and poor compliance with assignments. Furthermore, even when patients can access stroke rehabilitation, the amount of therapy provided in standard of care is limited [4-8], averaging just 32 arm movements/session[4].

The quality of rehabilitation therapy is also important and can increase the extent to which clinical neuroplasticity is harnessed[9]. Effects are increased when therapy is challenging, motivating, and engaging[10-13].

The promise of a telehealth approach for increasing rehabilitation therapy: Telehealth approaches have the potential to address these issues by increasing access and by boosting motivation. Telerehabilitation is the delivery of rehabilitation services via communication technologies[14]. Telerehabilitation therapy is delivered by a licensed therapist via a computer and over the internet, often asynchronously, but follows the same principles of traditional, person-to-person, individualized rehabilitation care. Such telehealth therapy provides a powerful supplemental option to brick-and-mortar delivery of rehabilitation services[15-18], reducing the need for impaired patients to travel and increasing access to care by clinicians familiar with stroke rehabilitation, especially in regions with a shortage of providers. These points are underscored in times of quarantine.

The rationale for using this 6-week (42-hour) program of therapist-supervised, home-based TR: This is an effective dose of an effective therapy and so treatment dose and content will not be modified when addressing current hypotheses. The prior national trial[19] found that 6 weeks of TR was safe and associated with substantial gains in UE-FM, Box & Blocks, and mRS scores, among all patients as well as among patients enrolled >90 days post-stroke. Thus, current goals do not aim to change the intervention but instead to examine effects in a new population, who are at an earlier time after stroke onset.

Research Design and Methods

Study Procedures

Patients who are potentially eligible will be identified from review of daily admissions. Those who have a diagnosis of stroke will be pre-screened through chart review. Those who are deemed potentially eligible will

be approached. The study will be explained and all questions answered. Patients will then be asked to sign informed consent, as well as the HIPAA Authorization form (which is used to acquire outside medical records).

For patients who sign consent, Visit 1 testing will ensue, the initial purpose of which is to fully confirm study eligibility. Patients who meet all entry criteria, and no exclusionary criteria, will then complete Visit 1 testing.

Each patient's telerehabilitation therapy program is designed, administered, and supervised by a licensed occupational therapist (OT) or physical therapy (PT). The therapist then uses the therapist-facing study software to design an initial 70-minute treatment session.

Using the therapist-facing study software, the therapist is able to monitor usage and game performance statistics and create successive day's therapy programs. The therapist has a 30-minute videoconference with the patient three times/week.

Once the patient has reached home, our team delivers the telerehabilitation system to the patient's home, sets it up, and connects it to the internet.

The patient then completes 36 treatment sessions over 6 weeks, consisting of 3 sessions/week that are supervised rehab therapy sessions (begin with a 30-minute videoconference with the licensed OT or PT) alternating with 3 sessions/week of unsupervised rehab therapy sessions whereby the patient follows the instructions on the screen to engage in rehab therapy. Because patients sometimes miss a session, e.g., due to a conflict, we allow up to 8 weeks for patients to complete their 36 rehab therapy sessions. In some cases, initial session(s) will occur prior to discharge from the inpatient rehabilitation facility.

After the 36 sessions are completed, or at 8 weeks after the first session, the team will return to the patient's house, perform Visit 2 assessments, and remove the telerehabilitation system. The telerehabilitation system will be brought back to the study site, where it will be carefully cleaned, and then made available to the next study enrollee.

Further details of the Telerehabilitation intervention:

Telerehabilitation is delivered over 36 sessions, each of 70-minutes duration. Half of the sessions are supervised by a licensed OT or PT (the goal is to work with the same therapist for 6 weeks) and half of which are unsupervised. To account for possible extrinsic events (e.g., illness or vacation), patients are permitted up to 8 weeks to complete these 36 treatment sessions.

Videoconferences: Supervised sessions begin with a patient-therapist videoconference, during which therapists supervise therapy, answer questions, review treatment plans, and perform selected study assessments. Therapists are also encouraged to discuss use of the UE in home.

Each daily 70-minute treatment session is created by a licensed OT or PT and includes:

(1) At least 15 min/day of arm exercises.

(2) At least 15 min/day of functional training through games. Numerous input devices are available for use to drive game play. A total of 25 functional games are available. Games stress various motor control features, e.g., varying movement speed, range of motion, target size, extent of visuomotor tracking, or level of cognitive demand, which are selected and adjusted by the therapist. For

(3) Five minutes/day of stroke education. The education content targets 5 categories (Stroke Risk Factors, Stroke Prevention, Effects of Stroke, Diet, and Exercise) and corresponds to the Stroke Knowledge Exam. At the start of unsupervised sessions, subjects answer multiple-choice questions, delivered via a video Jeopardy[20, 21] game format, then receive feedback.

The remaining 35 minutes consist of additional exercises and games, per the judgment of the licensed OT or PT.

Hardware: The telerehabilitation system hardware consists of an internet-enabled computer with table, chair, and multiple gaming input devices--but no keyboard, as no computer operations are required by subjects.

Eligibility criteria:

Inclusion Criteria for patients with stroke

1. Age 18 years or older
2. Stroke that has been radiologically verified
3. Arm motor FM score <56 (out of 66) at Visit 1
4. Box & Block Test score with affected arm is at least 3 blocks in 60 seconds at Visit 1
5. Informed consent and behavioral contract signed by the subject (i.e., no surrogate consent)
6. Admitted to California Rehabilitation Institute or MossRehab for stroke rehabilitation

Exclusion Criteria for patients with stroke

1. A major, active, coexistent neurological or psychiatric disease, e.g., alcoholism or dementia
2. A major medical disorder that substantially reduces the likelihood that a subject will be able to comply with all study procedures
3. Severe depression, defined as Geriatric Depression Scale Score >10 at Baseline Visit
4. Significant cognitive impairment, defined as Montreal Cognitive Assessment score < 22 (a lower score is permitted if due to aphasia and if the patient is specifically allowed by Dr. Cramer)
5. Deficits in communication that interfere with reasonable study participation
6. Lacking visual acuity, with or without corrective lens, of 20/40 or better in at least one eye
7. Life expectancy < 6 months
8. Pregnant
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 within 3 months of study enrollment
10. Unable to successfully perform all 3 of the rehabilitation exercise test examples
11. Unable or unwilling to perform study procedures/therapy or attend study visits, or expectation of noncompliance with study procedures/therapy
12. Non-English speaking, such that subject does not speak sufficient English to comply with study procedures
13. Expectation that subject will not have a single domicile address during the 6 weeks of therapy that has either Verizon wireless reception or a home WiFi network and that has space for the telerehabilitation system.

Statistics and Data Analysis

This is a feasibility study. The purpose is to understand feasibility of this established therapy in a population admitted to an inpatient rehabilitation facility, to understand the experience from the point of view of the patient, and to document changes in motor outcome. Results will be tabulated. Statistical moments will be calculated. The sample size was selected to insure that a representative experience is obtained across the very heterogeneous population that is subacute stroke, and is intended to approximate half the study size of the recent national trial.

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