Effects of Telerehabilitation on Physical Function and Disability for Stroke Patients
A Randomized, Controlled Trial

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Background and Purpose—To determine the effect of a multifaceted stroke telerehabilitation (STeleR) intervention on physical function, and secondarily on disability, in veterans poststroke.

Methods—We conducted a prospective, randomized, multisite, single-blinded trial in 52 veterans with stroke from 3 Veterans Affairs medical centers. Veterans with a stroke in the preceding 24 months were randomized to the STeleR intervention or usual care. The STeleR intervention consisted of 3 home visits, 5 telephone calls, and an in-home messaging device provided over 3 months to instruct patients in functionally based exercises and adaptive strategies. Usual care participants received routine rehabilitation care as prescribed by their physicians. The primary outcome measures were improvement in function at 6 months, measured by both the motor subscale of the Telephone Version of Functional Independence Measure and by the function scales of the Late-Life Function and Disability Instrument.

Results—The 2 complementary primary outcomes (Late-Life Function and Disability Instrument Function and Telephone Version of Functional Independence Measure) improved at 6 months for the STeleR group and declined for the usual care group, but the differences were not statistically significant (P = 0.25, Late-Life Function and Disability Instrument; P = 0.316). Several of secondary outcomes were statistically significant. At 6 months, compared with the usual care group, the STeleR group showed statistically significant improvements in 4 of the 5 Late-Life Function and Disability Instrument disability component subscales (P < 0.05), and approached significance in 1 of the 3 Function component subscales (P = 0.06).

Conclusions—The STeleR intervention significantly improved physical function, with improvements persisting up to 3 months after completing the intervention. STeleR could be a useful supplement to traditional poststroke rehabilitation given the limited resources available for in-home rehabilitation for stroke survivors.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00384748.

Key Words: stroke recovery rehabilitation telemedicine

Physical function reaches its peak at around 6 months poststroke and begins to decline as soon as 1 year after stroke; this suggests that increasing use of rehabilitation postdischarge is likely to result in better functional recovery. Indeed, supervised stroke rehabilitation in the community for up to 1 year postdischarge was associated with faster recovery and better functional status at 1 year than with unsupervised therapy. The main barriers cited by patients to participating in supervised rehabilitation postdischarge were getting to the rehabilitation clinic and inconvenience. Providing rehabilitation in the home is limited by high costs and rehabilitation provider availability, particularly in rural ar-
Home-based telerehabilitation (TR) is defined as use by a clinician of telecommunication devices (eg, telephone, videophone) to provide evaluation and distance support of disabled persons living at home. Many standardized instruments have been validated and recommended for use by occupational therapy/physical therapy via high-quality videoconferencing system when an in-person assessment is impractical. A 2011 systematic review of TR interventions in stroke care identified 9 studies; only 4 of these were randomized controlled trials (RCTs). The exercise component of the intervention included 3 to 4 exercises presented the exercise prescription, demonstrating each exercise before the participant performed for later review by the teletherapist. The exercise component of the intervention included 3 to 4 exercises that focused on strength and balance, selected by the therapist based on the physical performance measures. The IHMD also provided instant feedback to the participant in the form of positive encouragement to enhance exercise adherence.

Methods
A complete description of our methods has been published. In brief, the study was a 3-site, 2-arm, single-blinded RCT, with a fourth Veterans Affairs (VA) facility serving as the coordinating center. The institutional review boards at all 4 VA facilities reviewed and approved the research protocol, and written consent was obtained from all patients.

Settings and Participants
Participants were eligible for the study if they experienced an ischemic or hemorrhagic stroke within the previous 24 months. Other inclusion criteria included age 45 to 90 years, having been discharged to the community, not cognitively impaired (no more than 4 errors on the Short Portable Mental Status Questionnaire), able to follow a 3-step command, discharge motor Functional Independence Measure (FIM) score of 18 to 88 (ie, maximal assistance on no more than 4 motor activities of daily living as the most severe stroke included, and modified independence on at least 2 motor activities of daily living as the least severe), approval by the patient’s physician, and signed medical media release form. The FIM measures physical and cognitive disability with reference to burdens of care. It has been employed to check patient progress and to measure rehabilitation outcomes.

We employed 3 corresponding methods to identify potential study participants. First, we used the Functional Status Outcomes Database notification system, which utilizes administrative diagnoses to alert clinicians that a patient with an acute stroke was admitted to the VA facility. Second, prospective participants were identified by referrals made to study staff by clinicians on the acute medical/surgical wards, and stroke and/or rehabilitation units. Third, site-specific databases were queried by analysts who used an analogous algorithm to the Functional Status Outcomes Database automated search strategy. The IHMD was connected to a standard telephone line in the participant’s home. Participants answered questions consisting of a series of validated self-report measurement instruments regarding common poststroke complications of depression, self-care/mobility, and falls. The teletherapist viewed the participant’s answers. If any answers were of concern, the teletherapist called the participant. The IHMD used the Patient Health Questionnaire (PHQ-9) to screen for depression at baseline (week 1–2) and 3 months, the 16-item version of the Stroke Impact Scale (SIS-16) to assess self-care/mobility every 2 weeks, and once weekly to ask 3 questions related to falls. The IHMD also provided instant feedback to the participant in the form of positive encouragement to enhance exercise adherence.

Telephone Intervention
Five telephone calls were made from the teletherapist to the participant. Calls occurred approximately every 14 days, with the first occurring 7 to 10 days after Televisit 1. In the first call, the teletherapist established rapport and reviewed the participant’s current exercise regimen and current assistive technology. The teletherapist explored any potential barriers and identified solutions to overcome these barriers. Telephone calls 2 to 5 focused on reassessment and advancement of the exercise program, along with reviewing participant concerns relating to their functional mobility (eg, toilet and tub/shower transfers).
UC Group
Participants randomized to the UC group were not contacted by study personnel other than for the initial recruitment and consent, and to obtain baseline and outcome measures. The UC participants could receive any services provided as part of their usual VA or non-VA care, such as home health care.

Study Measures
Dependent variables were measured at baseline, 3 months, and 6 months (3 months after the completion of the intervention) through telephone interview by a research assistant blinded to randomization, and through the medical record.

Primary Outcome
The primary outcome focused on the aspects of physical function (ie, basic activities of daily living) most directly affected by the lower extremity exercise and adaptive strategies used in our study. We used 2 complementary primary outcome measures:

1. The motor subscale of the Telephone Version of the Functional Independence Measure (FONEFIM). The FONEFIM was developed as a telephonic alternative and yields good concordance to the in-person, performance-based FIM. The motor subscale of the FONEFIM (Motor FONEFIM) consists of 13 items encompassing 4 categories: self-care, sphincter control, transfers, and locomotion. Each item is scored on an ordinal scale from 1 being total dependence to 7 being total independence. Possible scores range from 13 to 91, with higher scores indicating greater independence. The scoring considers the use of adaptive equipment and/or the extent of personal assistance or supervision required to complete the task.

2. The Overall Function Component of the Late-Life Function and Disability Instrument (LLFDI). The LLFDI is a comprehensive measure of functioning and participation and includes 2 disablement constructs: function and disability. In contrast to the Motor FONEFIM, which measures independence in task performance, the LLFDI Function Component measures difficulty with task performance. For all components and subscales (domains), the LLFDI transforms raw scores into linear scaled scores (0–100), where a higher score represents better functioning.

Secondary Outcomes
Secondary outcomes included the 3 subscales of the LLFDI Function Component: upper extremity function (7 items reflecting ability to perform activities with the hands and arms, eg, holding a full glass of water), basic lower extremity function (14 items reflecting activities involving standing and use of the legs, eg, stepping up and down from a curb), and advanced lower extremity function (11 items reflecting activities that involve a high level of physical ability and endurance, eg, walking on a slippery surface outdoors).

Other secondary outcomes included the LLFDI Disability Component, which evaluates social roles (eg, visiting friends) and personal roles (eg, meal preparation), and evaluates difficulty with task performance and frequency of performance. The disability section provides an overall score and 5 subscores (frequency of social and personal roles, and difficulty with instrumental and management roles). All items are scored on a 5-point ordinal scale.

Covariates
The following demographic variables were collected by patient self-report: age, sex, race, marital status, and education. The Canadian Neurological Scale was employed to assess initial stroke severity, based on review of the medical record, using Goldstein and Chilukuri’s algorithm.

Statistical Analyses and Sample Size
All analyses were conducted using SAS version 9.2 (SAS Institute). Intention-to-treat analyses were used for all outcomes. Mean differences between variables at baseline were assessed using unpaired t tests and χ² tests. All outcome variables were analyzed using a mixed-model with a mixed-model analysis of variance procedure using maximum likelihood estimation. This model presumes that the groups have equal baseline means, which is appropriate for a RCT, and is comparable in efficiency to an analysis of covariance model. This method permits estimation in the presence of missing values, which means that all available data are used. All participants with at least 1 follow-up were included in the mixed-model analyses. Group, time (month of follow-up), the group-by-time interaction, participant age, stroke severity, and whether a participant was in a rehabilitation bed unit, were included as predictors in each model. (Because of the small sample size, we were not able to add other covariates to the model.) To adjust for type 1 error and assess the overall differences between the STeleR and UC groups during and at the end of the study, the statistical significance for group and the group-by-time interaction was assessed according to the change in log-likelihood. The overall effect of group (STeleR versus UC) was evaluated by comparing the maximum likelihood fit of the full (covariates plus group and group-by-time interaction) models. With reference to the total Function score of the LLFDI, with 20 subjects per group, we projected 80% power to detect an effect size of 0.50 (translating to an approximately 14.1% absolute difference in response rates between the groups) using a 2-sided χ² test with α=0.05. For the FIM, given the standard deviation in our population, this would equate to changing from using a tool or extra time rather than human help for ≥2 items. Significance was accepted at P<0.05. A Bonferroni correction was applied to all of the comparisons (ie, all of the primary and secondary outcomes), which would be P=0.025. All the probability values were for testing the interaction term only.

Results
Participants
Fifty-two participants met the inclusion criteria, gave written informed consent, and were randomized. Of those 52 participants, 48 participants completed baseline assessments. The 4 participants who failed to complete the baseline assessment (2 participants each in the STeleR and UC groups) could not be reached via telephone to complete the baseline assessment. Of the 48 participants who completed baseline assessments (25 STeleR and 23 UC), 44 participants (22 participants in each group) completed 3-month surveys (92% completion rate), and 43 participants (24 STeleR and 19 UC) completed 6-month surveys (90% completion rate). Five participants dropped out for the following reasons: lost to contact, reported being too busy to complete the final outcome assessment, or were unable to reach participant at the specified time point. One participant died before completing the follow-up interviews. There were no differences between dropouts and participants completing the trial. Intervention group membership was unrelated to loss to follow-up, and drop-outs did not differ for any of the participant characteristics in Table 1 at any of the follow-up time points. No serious study-related adverse events occurred.

There were no significant differences between the STeleR and UC groups at baseline (Table 1). With reference to race or ethnicity and marital status, participants were nearly evenly split between white (42%) and nonwhite (58%), and married (42%) and not-married (58%). Most nonwhite participants (79%) were black, and most not-married participants (50%) were divorced.

Change in Self-Reported Function and Disability
Primary Outcomes
At baseline, there were no differences between the 2 groups in Motor FONEFIM and LLFDI Function scores (statistical results not shown). The Motor FONEFIM increased some-
what over time (83.5–83.7) in the STeleR group, and it decreased slightly (81.5–80.9) in the UC group. This difference was not statistically significant. The LLFDI Function total score, which focuses on difficulty with basic activities of daily living tasks, increased from 49.5 to 54.6 in the STeleR group, and declined from 51.7 to 50.6 in the UC group (Table 1); this difference was not statistically significant. As can be seen in Figures 1 and 2, most of the improvement occurred during the 3-month intervention period, and essentially was maintained during the subsequent 3 months.

Secondary Outcomes
Examination of the LLFDI Function subscales showed an apparent treatment effect on all 3 domains, with ≥10% improvement in all subscales for the STeleR group, and a decline in function on all subscales for the UC group. One of the 3 domains approached significance. The Basic Lower Extremity score (items that involve the use of legs and standing) increased from 59.0 to 64.9 in the STeleR group and essentially remained unchanged from 61.3 to 61.1 in the UC group ($P=0.06)$. Four of the 6 LLFDI Disability subscales demonstrated a treatment effect and significantly improved over the 6-month study period. Table 2 shows that the STeleR intervention resulted in improvement in LLFDI Disability measures of all measures of task difficulty (ie, instrumental role domain, management role domain, and total role domain), and also in 1 of the 2 measures of task frequency (personal role frequencies). For instance, the total role domain that considers all elements of task difficulty increased from 53.9 to 68.0 in the STeleR group, and declined from 62.2 to 59.5 in the UC group ($P=0.025$). For all measures, most of the improvement occurred during the 3-month intervention period and was maintained during the subsequent 3 months.

Discussion
Motor weakness in the lower extremities adversely affects functional mobility, including sit-to-stand ability and the ability to walk,¹⁵ and thereby affects mobility-related daily tasks and social roles. Exercise and use of adaptive strategies, such as assistive technology (eg, gait aids, bathroom aids) and environmental modifications (eg, rails), have been found to improve physical functioning; these are the main focus of traditional physical rehabilitation. In fact, locomotor training, including the use of body-weight support in stepping on a treadmill, was not shown to be superior to physical therapist-supervised progressive exercise for stroke patients at home.²⁰ Thus, providing home-based, exercise-oriented interventions is very efficacious. Dovetailing with this literature, we demonstrated that a telehealth program that taught stroke patients how to perform functionally based exercises and improve the interface with their environment resulted in greater improvements in the ability to perform both self-care and social role tasks than did UC alone. To our knowledge, this is the largest RCT to date employing telehabilitation technology to improve functional outcomes for community-dwelling individuals who experienced a stroke within the past 2 years.

The LLFDI Function total score declined in the UC group, but improved 5.1 points between baseline to 6 months in the STeleR group. However, the time-by-treatment interaction was not statistically significant. In addition, the Motor FONEFIM did not significantly improve over time in the STeleR group compared with in the UC group.²¹ The LLFDI Function score measures some of the same basic functional skills as does the Motor FONEFIM (eg, climbing stairs). However, in contrast to the Motor FONEFIM, the LLFDI measures self-reported difficulty performing life tasks (instrumental and management roles), so it is an excellent complement to the Motor FONEFIM. Also, in contrast to performance-based functional measures like the Motor FONEFIM, the LLFDI is able to capture self-perceived changes in physical functioning ability.

Even though the primary outcomes were not supported by the data, the study offered substantial support for many of the secondary outcomes. An examination of the LLFDI Disability subscales demonstrated a significant treatment effect on all 3 task difficulty domains (total difficulty dimension, instrumental role difficulty, and management role difficulty), with ≥19% improvement in all of the LLFDI subscales in the STeleR group, and a decline in function on all of the subscales in the UC group. In other words, the STeleR intervention improved participants’ ability to perform life tasks, such as limitation in activities at home (instrumental role domain with an example item, such as take part in a regular fitness program) and management of social tasks that involve minimal mobility or physical activity (management role domain with an example item, such as take care of own health) more than did UC. These statistically significant improvements were similar to some of the findings from
Ouellette et al., who used the LLFDI to evaluate the efficacy of supervised, high-intensity progressive resistance training on function and disability for long-term stroke survivors. The changes in the intervention on the measures pertaining to task difficulty were not only statistically significant, but were clinically meaningful as well. The LLFDI change scores associated with minimal clinically important difference were 7.8 for Disability difficulty (limitation) domains; the study exceeded both for the total score and the subscales. We note that 1 of the 2 Disability frequency of performance scores (frequency for activities such as meal preparation and money management) significantly improved in the SteleR group compared with in the UC group, but the amount of change was modest and may not be clinically meaningful. There was no significant change seen in the Disability score of frequency of performance for social roles (eg, visiting friends). This is not surprising, as our intervention focused on physical skills and activities inside the home. Moreover, it seems self-evident that frequency of activities in general, and social and personal activities in particular, would be strongly influenced by factors other than physical ability alone (eg, routines for meal preparation, financial needs, personal preferences for social contact). Indeed, Keysor and Jette suggested that both psychosocial and environmental factors may drive the positive consequences of improved physical abilities on Disability outcomes.

Table 2. Study Outcomes Over Time By Group

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean SteleR Group ± SD</th>
<th>Usual Care Group ± SD</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Baseline 3 Months 6 Months</td>
<td>Baseline 3 Months 6 Months</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>25 22 24</td>
<td>23 22 19</td>
<td></td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>83.5±9.5 82.7±9.7 83.7±9.9</td>
<td>81.5±12.1 79.0±15.0 80.9±12.0</td>
<td>0.306</td>
</tr>
<tr>
<td>FONEFIM</td>
<td>49.5±10.1 54.6±13.6 54.6±12.0</td>
<td>51.7±12.8 49.6±12.0 50.6±11.7</td>
<td>0.248</td>
</tr>
<tr>
<td>Motor domain</td>
<td>64.7±21.2 70.1±19.4 72.2±20.6</td>
<td>65.6±17.2 64.1±17.8 64.3±19.3</td>
<td>0.426</td>
</tr>
<tr>
<td>LLFDI: function component</td>
<td>47.6±10.8 50.2±15.3 49.6±18.1</td>
<td>49.2±14.8 45.8±14.2 47.2±11.9</td>
<td>0.025</td>
</tr>
<tr>
<td>Overall function total†</td>
<td>45.9±8.0 45.7±9.0 46.9±8.6</td>
<td>46.1±9.2 44.8±9.5 45.0±7.8</td>
<td>0.248</td>
</tr>
<tr>
<td>Social role frequency†</td>
<td>42.0±12.9 43.1±10.6 42.1±9.7</td>
<td>43.0±8.0 41.7±11.3 41.4±10.3</td>
<td>0.224</td>
</tr>
<tr>
<td>Personal role frequency†</td>
<td>53.9±21.5 67.9±22.3 68.0±16.6</td>
<td>62.2±15.3 58.8±22.3 59.5±17.7</td>
<td>0.025</td>
</tr>
<tr>
<td>Difficulty dimension total†</td>
<td>52.5±21.5 66.6±24.0 68.1±13.2</td>
<td>61.2±15.9 56.0±20.0 58.0±18.7</td>
<td>0.031</td>
</tr>
<tr>
<td>Instrumental role difficulty†</td>
<td>64.1±24.4 76.4±21.1 79.3±19.1</td>
<td>73.3±22.6 74.3±25.8 69.4±19.9</td>
<td>0.024</td>
</tr>
<tr>
<td>Management role difficulty†</td>
<td>64.1±24.4 76.4±21.1 79.3±19.1</td>
<td>73.3±22.6 74.3±25.8 69.4±19.9</td>
<td>0.024</td>
</tr>
</tbody>
</table>

FONEFIM indicates Telephone Version of Functional Independence Measure; LLFDI, Late-Life Function and Disability Instrument.

*Omnibus P Value provides the overall differences between groups at the end of the study for group and group-by-time interaction assessed according to the change in log-likelihood on 2 degrees of freedom. The intercepts were the random effects in the mixed model. The baseline values were not added to the models and the likelihood ratio test includes only the interaction term. The P values are corrected with the Bonferroni criterion.

†Higher scores indicate higher levels of functioning and/or fewer limitations.

Ouellette et al., who used the LLFDI to evaluate the efficacy of supervised, high-intensity progressive resistance training on function and disability for long-term stroke survivors. The changes in the intervention on the measures pertaining to task difficulty were not only statistically significant, but were clinically meaningful as well. The LLFDI change scores associated with minimal clinically important difference were 7.8 for Disability difficulty (limitation) domains; the study exceeded both for the total score and the subscales. We note that 1 of the 2 Disability frequency of performance scores (frequency for activities such as meal preparation and money management) significantly improved in the SteleR group compared with in the UC group, but the amount of change was modest and may not be clinically meaningful. There was no significant change seen in the Disability score of frequency of performance for social roles (eg, visiting friends). This is not surprising, as our intervention focused on physical skills and activities inside the home. Moreover, it seems self-evident that frequency of activities in general, and social and personal activities in particular, would be strongly influenced by factors other than physical ability alone (eg, routines for meal preparation, financial needs, personal preferences for social contact). Indeed, Keysor and Jette suggested that both psychosocial and environmental factors may drive the positive consequences of improved physical abilities on Disability outcomes.

![Figure 1. Change in Motor FONEFIM Score over time. FONEFIM indicates Telephone Version of Functional Independence Measure; SteleR, stroke telerehabilitation.](http://stroke.ahajournals.org/Downloaded from)
The present study had some limitations. First, our study was conducted at 3 VA medical centers. Given that VA patients are mainly men, older, and have more comorbid conditions than does the general US population, our findings may not be generalizable. For instance, women have frequently more difficult social circumstances after a stroke because they are more likely to be living alone. However, the present study did include a sizable proportion of unmarried men that could help balance this potential sex bias. All study participants had to be deemed competent to provide informed consent, and we excluded stroke survivors who could not successfully follow a 3-step command; this, in effect, excluded patients with significant receptive aphasia. Thus, we do not know what added challenges might be present in applying the intervention to stroke survivors with receptive aphasia or other cognitive deficits. Although stroke rehabilitation services provided by the Veterans Health Administration are similar to those supported by Medicare, translation to a non-VA medical center setting may present new challenges for successful implementation, given the VA medical center’s strong telehealth infrastructure and presence of a seamless medical care continuum; this is well-supported by electronic medical records. Some of the challenges related to the implementation of this intervention pertained to variable infrastructure of technology in the home (eg, availability of high-speed internet), issues pertaining to information security when using the internet for telecommunication, and technological needs for accurate real-time televideo imaging of movement. These challenges are directions for future research. To compensate for some of these issues, we employed a combination of store & forward technology (ie, videotaping all encounters) in the event of technological issues affecting the accuracy with the live 2-way video. This approach ensures patient confidentiality and can be employed irrespective of the technology infrastructure.23

In sum, with reference to this group of predominantly older, veteran stroke survivors who were men, the STeleR intervention significantly improved physical function. Most of the improvement on the measures occurred during the 3-month intervention window and essentially were maintained during the subsequent 3 months. STeleR has potential to be a useful supplement to traditional poststroke rehabilitation, given the limited resources available for in-home rehabilitation for stroke survivors. Many individuals with stroke have serious challenges traveling to a facility for their care because either they cannot drive or their informal caregiver cannot take extended time off work to travel to the main hospital.24 Telehealth-based programs similar to STeleR could be an important way to overcome these access barriers and may be particularly useful for reaching vulnerable patient groups, such as individuals from a lower socioeconomic status and those who live in a rural area. STeleR may also be more readily integrated into clinical practice than are face-to-face programs. Findings from this study could lead to improved methods for functional assessment and more effective and efficient rehabilitation strategies, and could support the implementation of more efficient and effective approaches to coordination of care when transitioning from hospital to home. Even though our novel intervention employed research staff for the home visits, we believe that it has ready application to real-world scenarios. For example, home health personnel already in the home, such as skilled nurses or even certified nurse aids, might use the technology to communicate efficiently with centrally located rehabilitation personnel. Within the Veterans Health Administration, telehealth technologists are now employed in peripheral clinics to facilitate telehealth clinics. In addition, the telehealth technologists may be able to facilitate home telehealth visits.

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