NCT05616832

PROTOCOL TITLE:
Examining the association between psychosocial factors and adherence to a home exercise program for upper extremity recovery in Veteran stroke survivors

PRINCIPAL INVESTIGATOR:
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1.0 Objectives / Specific Aims

The objective of this study is to explain how modifiable psychosocial factors manifest themselves in terms of barriers and facilitators for HEP adherence among Veteran stroke survivors.

2.0 Background

Stroke affects nearly 800,000 people in the United States annually.[1] Around 15,000 Veterans are admitted to Veterans Affairs (VA) facilities per year with stroke,[2] and Veterans attend approximately 60,000 outpatient visits for stroke each year.[3] Upper extremity (UE) impairment is a common consequence of stroke[4,5] that requires ongoing outpatient visits for treatment. UE impairment reduces individuals' ability to perform activities for self-care, employment, and recreation, thereby diminishing independence and quality of life.[6,7]
Extensive repetitions of UE activity improve functional recovery of the UE post-stroke,[8–11] and are strongly recommended by the VA/Department of Defense Clinical Practice Guideline for the Management of Stroke Rehabilitation.[12] However, the high amount of UE activity[8] necessary for neuroplasticity and functional recovery is not achieved within typical therapy sessions.[11,13–15] To circumvent limited time with a therapist, a home exercise program (HEP) is commonly prescribed.[16] Unfortunately, patient adherence to HEP is known to be low,[16–19] resulting in poor motor recovery.[16,17,20,21]
Behavioral interventions are effective in improving adherence to medication regimes for people with diabetes[22] and hypertension[23], as well as for physical activity among older adults.[24] Thus, there is a growing call to provide behavioral interventions within rehabilitation to increase adherence.[25] However, there is no evidence for efficacy of such interventions in stroke rehabilitation, let alone specifically for Veterans. Only one systematic review exists[26] to find that 4 out of 5 randomized controlled trials failed to show statistically significant differences for a behavioral intervention over control in increasing physical activity adherence for stroke survivors among the general population.[27] This result indicates that conventional behavioral interventions are inadequate to address adherence to HEP post-stroke. This is likely because practicing HEP after stroke is more difficult than taking medication, and promoting adherence to HEP post-stroke requires more consideration of individual survivors' psychosocial factors than is needed for medication adherence.[16,28] Therefore, understanding Veteran stroke survivors' psychosocial factors is the key to developing a behavioral intervention that adequately addresses barriers to increase adherence to HEP and promote recovery.

3.0 Inclusion and Exclusion Criteria/ Study Population

Inclusion Criteria

- U.S. Veteran
- 18 years old or older
- History of stroke
- Stroke-related hand impairment requiring concurrent standard rehabilitation therapy or for which participant indicates interest in obtaining rehabilitation therapy
- Ability to engage in therapeutic tasks, demonstrated by grasping and moving a small, everyday object such as keys or phone with affected hand
- Can put on a wrist-worn device like a watch on the paretic wrist every day, either using the nonparetic hand or with assistance from a caregiver
- Can read and understand words and numbers on a smart phone screen

Exclusion Criteria

- No volitional movement of the affected UE
- Language barrier or cognitive impairment that precludes following commands and/or providing consent

Screening: Eligibility will be determined based on the potential participant's verbal confirmation of all inclusion criteria, by verbally confirming that they do have volitional movement of the affected UE, and by demonstrating cognitive ability sufficient for participation based on a correct answer to both of the following questions: 1. *Can you tell me what day of the week it is?* and 2. *Can you tell me what year it is?*

Plan to include a diverse population: We will include chronic stroke survivors of all genders and all racial and/or ethnic groups, since stroke occurs in persons of all genders and all racial and/or ethnic backgrounds. We will not exclude people based on sex/gender, racial or ethnic group. Our goal is to construct a participant pool that matches post-stroke survivor distributions in South Carolina, based on the stroke prevalence data in each sex, racial and ethnic group together with the sex, racial and ethnic distribution of the population in South Carolina. Recruitment of diverse groups is possible based on evidence from a current database of local stroke survivors interested in research, the RESTORE stroke registry, which currently has 48% female, 41% African-American, and 1% Hispanic.

Children: Children under the age of 18 years will be excluded. The rationale for exclusion of children is that stroke predominantly occurs in adults, and stroke is very rare in children. Importantly, these rare cases may differ in their etiology from the individuals we propose to study.

4.0 Number of Subjects

A total of 35 subjects will be recruited to participate in this study.

5.0 Setting

All research activities will take place at the Ralph H. Johnson VA Health Care System.

6.0 Recruitment Methods

All 35 Veteran participants will be recruited through the following methods:

a. We will recruit Veterans from the IRB-approved Registry of Stroke Recovery (IRB number: 0037803). This registry has 188 Veteran stroke survivors who are interested in participating in rehabilitation research. These individuals will be contacted by phone and/or email, depending on their contact preference indicated in the Registry.
b. In addition, we will use the VA Informatics and Computing Infrastructure (VINCI) service and contact all Veterans who had a stroke and were treated at Ralph H. Johnson VA Health Care System. The initial contacts will be made via letter per VA policy.
c. Study flyers will be posted in research/hospital buildings.
d. Patients at the VA Charleston Stroke Clinic who are identified by their providers as potentially eligible will be given a study flyer so that they may choose to call if they are interested in learning more about the study.

7.0 Consent Process

Consent will be obtained by the Principal Investigator. The consent process will take place in a private room when the potential participant comes to the Ralph H. Johnson VA Health Care System at a scheduled time agreed upon between the study personnel and the participant. The content of the consent will be verbally explained to the participant and the participant will be given time to read and ask questions. If the person requests a waiting period, then one will be given. If the person desires to consent immediately, then the person will provide consent immediately. A copy of the completed signed consent will be provided.

8.0 Study Design / Methods

Study design: The study will be an observational pilot study using a single group of Veteran stroke survivors.

Home exercise program: Participants will be asked to complete a home exercise program consisting of upper extremity movement to meet a daily activity goal measured by a wrist-worn tracker (like a smartwatch). The tracker, ARYS™ (Tyromotion, Graz, Austria), will objectively measure UE activity in acceleration magnitude after filtering out influence from non-UE movements such as walking or being in a moving vehicle.[29,30] A smartphone connected to the sensor visually displays cumulative UE activity level for each day, relative to the daily goal (in the total acceleration magnitude) for the user.[30] The daily UE activity goals are set at 3% higher than the patient's UE activity levels from previous days, until a comparable activity level between the paretic and nonparetic UE is

reached.[30] Activity level is known to be similar between the dominant and nondominant hand in healthy adults,[31] thus the activity goal does not depend on handedness. Participants will be instructed to charge the sensor every night during sleep and put on the sensor on the paretic wrist in the morning, just like wearing a watch. This process of wearing a wrist-worn device after overnight charge every day is feasible, since our previous study demonstrated 99.5% adherence to such a process in chronic stroke survivors every day for 2 months.[32] At the first study visit, Veterans will be instructed in how to use the wearable sensor and associated mobile application, which will be ready for use on the provided smartphone.

Evaluations: Outcome measures will be administered using conventional clinical assessments and questionnaires in-person prior to the home exercise program. Completing clinical assessments and questionnaires will take about 3-5 hours and can occur over 1-2 visits, depending on the participant's preference.

Clinical assessments will be used to measure functional status of the upper extremity. Box and Blocks Test (BBT)[33] measures functional status in a test in which participants are asked to move 1-inch blocks from one box to another as quickly as possible for 1 minute. Participants will complete this test using their unaffected and then affected upper extremity. The Fugl-Meyer UE Assessment[34] is a measure of upper extremity impairment and recovery. In this test, participants are asked to move their affected UE to in certain ways to demonstrate shoulder, elbow, wrist, and finger movement. These 2 clinical assessments will be videotaped for scoring.

The Montreal Cognitive Assessment (MoCA)[35] will be administered to quantify participants' cognitive function. In this assessment, participants are asked to complete written, verbal, and recall tasks. This assessment will not be videotaped.

Table 1, below, includes a list of pen-and-paper questionnaires that participants will be asked to complete. These questionnaires will not be videotaped. Participants will be able to read the questions on the questionnaires, and the PI will also read the questions aloud to participants. The PI will see participants' answers at the time of completion. Demographics and Pittsburgh Sleep Quality Index require some free-form answers, such as age, household income, current and/or previous occupation, stroke and medical history, and times related to sleep. All other questionnaires require answers on a scale. The Pain level questionnaire asks for the participant's current pain level on a scale from 0-10. All other questionnaires utilize Likert scales. In Table 1, the questionnaire listed asks questions related to the domain listed.

Table 1: Questionnaires

Domain	Questionnaire Name and/or Description
Demographics	Age, race, gender, socioeconomic status (SES) indicated by household income and employment status,[36,37] education level, stroke and medical history, and home environment.
Pain level	Visual analog scale from 0-10
Self-perceived stroke impact	Stroke Impact Scale:[38] Physical strength, memory, mood, communication, ADLs and instrumental ADLs, mobility, hand function, meaningful activities, and recovery domains
Self-efficacy	Spinal Cord Injury (SCI) Exercise Self-Efficacy Scale[39,40] *Validated for people with SCI and regularly used for stroke survivors*[40]
Mood	Patient Health Questionnaire (PHQ-9)[41] Generalized Anxiety Disorder scale (GAD-7)[42]
Sleep	Pittsburgh Sleep Quality Index (PSQI)[43]
Health literacy	Health Literacy Assessment Using Talking Touchscreen Technology (Health LiTT)[44]
Behavioral activation	Behavioral Activation for Depression Scale (BADS)[45]
Physical activity level	Rapid Assessment of Physical Activity (RAPA)[46,47]
Communication ability	Communication Outcome After Stroke scale (COAST)[48]

Digital health literacy	Digital Health Literacy Instrument (DHLI)[49]
Social support	Multidimensional Scale of Perceived Social Support (MSPSS)[50]
Psychosocial functioning	Brief Inventory of Psychosocial Functioning (BIPF)[51,52]

Interview: Participants will be interviewed at an in-person visit after the completion of the home exercise program in a semi-structured interview format, to discuss their perspectives on barriers and facilitators to completing a home exercise program for the upper extremity. The interview will be audio-recorded for transcription. The interview will last approximately 30 minutes.

Summary of data collected: The table below (Table 2) summarizes the data and sources of data to be collected in this study.

Table 2: Data sources

Source	Type of Data
Participant disclosure	Screening eligibility
Clinical assessment of participant's upper extremity	Scores from BBT and Fugl-Meyer UE Assessment collected by the PI
Clinical assessment of participant's cognitive function	(For screen): Answer to the questions, *1.* Can you tell me what day of the week it is? *and 2.* Can you tell me what year it is? (For analyses): Score from MoCA collected by the PI
Participant subjective report	Information about demographics and psychosocial factors collected by the PI through questionnaires (see Table 1)
Upper extremity movement (in acceleration magnitude)	ARYS^{TM} tracker
Interview	One-on-one, semi-structured interview in which PI will ask the participants questions about barriers and facilitators to completing a home exercise program for the UE

9.0 Data Management

Statistical analysis: The primary analysis for primary outcome measures will be examined using regression. Initially, the relationships will be visually examined through scatterplots. Nonlinear regressions may be applied if necessary. Factors that are deemed relevant from the univariate analyses will then be used in multivariable regression to identify predictors of adherence. Secondary analyses will include regression between adherence and demographic information, physical functional status, secondary psychosocial factors, and demographics.

Qualitative analysis: All interview audio recordings will be transcribed by the VA's Centralized Transcription Service Program (CTSP). CTSP transcribers are not part of the study team. Interviews will be analyzed by study personnel using inductive content analysis.[53]

Mixed methods: We will use a convergent design with an interactive approach to integrate quantitative and qualitative data. Qualitative data collected via a semi-structured interview will include a review of the participant's responses to psychosocial measures taken at the initial evaluation so that participants can provide an explanation into their selections. In other words, a component of the semi-structured interview will involve parallel questions to those from the measures to provide qualitative explanation on the quantitative relationship determined initially. Integration of quantitative and qualitative data will occur at the methods level by merging results of the regression analysis with interview results.[54] At the reporting level, data will be integrated through narrative using the weaving approach so that measures associated with specific barriers and facilitators for adherence can be grouped.[54] Using these methods, the end result of this study will be a clearer understanding of the relationship among psychosocial factors, barriers and facilitators for adherence, and HEP adherence. These findings will inform future intervention development to increase HEP adherence and improve recovery post-stroke.

Sample size justification: In a preliminary study, a correlation of 0.57 between self-efficacy and HEP adherence was observed in a sample of 12 stroke survivors. With a correlation of 0.57 and a sample size of 30, a margin of error of 0.26 is expected (Power Analysis & Sample Size statistical software, NCSS LLC, Kaysville, Utah),[55] which is deemed sufficient for this study to reveal the relationship between modifiable psychosocial factors and HEP adherence. Accounting for 16.7% attrition rate, we will recruit 35 Veteran stroke survivors. This attrition rate of 16.7% is very conservative for the proposed study. This prudent plan to recruit 35 Veterans will ensure sufficient data collection of at least 30 Veterans.

Confidentiality: All data except for the consent forms and HIPAA forms will be coded at the time of data recording in accordance with VHA Directive 1605.01 such that personally identifiable information is not used in the data recording. Qualitative interviews will not have identifiable information such as participant names. Videos of the clinical assessments will be recorded such that the hand, arm, and object being grasped will be in the video but not the participant face. All electronic data will be stored in a password-protected server that is accessible to study personnel only. All paper data with personally identifiable information including the consent forms and HIPAA forms will be stored in a key-locked cabinet in a key-locked room that is accessible to study personnel only. Other paper data without personally identifiable information including testing sheets documenting testing sequences and notes will also be stored in a cabinet in a key-locked room that is accessible to study personnel only.

De-identification method: All identifying information will be removed from the data in accordance with VHA Directive 1605.01 Appendix A. Any data with identifiable information including the consent, HIPAA, and videos are not considered de-identified data and will not be shared. Other data will be de-identified by using a participant code instead of identifiable information to label the data at the time of data collection. We will ensure that custody and disposition of VA Federal Records are maintained in accordance with VHA Records Control Schedule (RCS) 10-1.

Data sharing: Identifiable data will not be shared. Only de-identified data will be reported and/or shared with the public and other investigators in publications. The audio recording of the interview will be shared with the VA Centralized Transcription Services Program for transcribing. De-identified coded data will be reported and/or shared with the public and other investigators in publications or via network storage.

Because questions will be asked about mood in this study, the participant's study participation will be recorded in their Ralph H. Johnson VA Health Care System Medical Record İn the Computerized Patient Electronic Record (CPRS) system.

10.0 Withdrawal of Subjects

Subjects who do not show up to scheduled visits may be withdrawn by the investigator. For those who voluntarily withdraw from the research, their data collected up to that point may be used by the investigator.

11.0 Risks to Subjects

There is a slight risk for loss of confidentiality. Researchers will take appropriate steps to protect any information collected about the participants, such as coding the data at the time of data recording and keeping PHI in a locked cabinet in a locked room. The master code list will be stored separately from the study data. Coded data will be stored on secure VA network storage. During audio recording, interviewers will not refer to participants by name or ask questions that may disclose PHI.

There is a minor risk of physical and mental fatigue from engaging in the task practices, and rest breaks will be given to minimize these risks. In addition, participants may choose to end the first visit prior to completing all assessments and complete remaining assessments at a 2nd visit prior to beginning the home portion of the study. There is a minor risk of skin irritation from wearing the sensor. Participants will be instructed to remove the sensor at night. This time off from wearing the sensor should reduce risk of discomfort. There is a minor risk of discomfort in moving the arm/hand while wearing the sensor on the wrist. Participants will be educated to avoid pain with their movements and to gradually increase their UE movements to avoid discomfort.

There is a minor risk that participants could feel uncomfortable answering questions about their mood and how it affects their engagement in HEP. Participants will be told that it is ok for them to skip questions that they do not want to answer. The PI, who will administer questionnaires, will see participants' answers at the time of completion and will be able to identify at that time if the participant endorses emotional distress. The PI is trained to identify participants in experiencing suicidal ideation based on the individual's disclosure and/or any positive endorsement of question 9 on the PHQ-9. The PI is trained in screening for suicide risk utilizing the Columbia Protocol[56] and in administering appropriate safety interventions in the event that a participant endorses suicidal ideation. For participants at high risk, this will include arrangement of an emergency appointment with a VA psychiatrist to determine need for hospitalization, as well as notification of campus police in the event that a participant deemed to be imminently at-risk refuses to cooperate with a hospitalization plan. For participants at moderate risk, this will include connecting the participant with their VA health care providers for further resources, providing the participant with the VA Crisis Line number, and, if the participant is in agreement, completing the Stanley & Brown Safety Planning Intervention[57] together with the participant. For participants at low risk, the PI will provide VA counseling resources. All participant-reported emotional distress and suicidal ideation will be documented in the participant's VA medical record using CPRS as required by VA policy.

12.0 Potential Benefits to Subjects or Others

This research study is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge which contributes to the field. Using the results from this study, we will develop a new behavioral intervention to promote increased adherence to UE HEP post-stroke. Developing this new intervention will be an important step to improve rehabilitation for Veterans and may benefit stroke survivors in general. The risks are deemed reasonable in relation to the potential gain of knowledge regarding this technology's development and its future potential to enhance recovery of hand function after stroke.

13.0 Sharing of Results with Subjects

A participant's individual results will be disclosed to that participant upon request.

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