Engaging Medically Complex Veterans in Tele-Rehabilitation Using a Biobehavioral Approach: A Pilot Study of Feasibility and Acceptability

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Project Title: Engaging Medically Complex Veterans in Tele-Rehabilitation Using a Biobehavioral Approach: A Pilot Study of Feasibility and Acceptability
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I. Hypotheses and Specific Aims:

This is a single-site, randomized pilot study using a two-group (GROUP1 and GROUP2) crossover design. Fifty Veterans with medical complexity and deficits in physical function will participate. Outcomes will be assessed at baseline (pre-intervention), 6 weeks (intervention mid-point), 12 weeks (end of intervention), and 24 weeks.

AIM 1: To determine the feasibility and acceptability of a multicomponent telerehabilitation program.

> **Hypothesis 1a:** 75% of Veterans will achieve ≥ 80% adherence as measured by attendance.
> **Hypothesis 1b:** At least 75% of Veterans will perceive the program as acceptable (≥ 4/5 on Acceptability of Intervention Measure[13]) and feasible (≥ 4/5 on Feasibility of Intervention Measure). In addition, we will monitor adverse events and categorize severity (mild, moderate, severe) and relatedness (definitely, probably, possibly).

AIM 2: To assess the preliminary response of a multicomponent telerehabilitation using a two-group randomized crossover design and determine variability estimates. Outcomes for this aim are accelerometer-based physical activity, physical function, quality of life, and loneliness.

> **Hypothesis 2:** At program end (GROUP1 12 weeks, GROUP2 24 weeks), participants will have a trend of improved outcomes (accelerometer 7-day average step count with ActiGraph physical activity monitors (ActiGraph Inc. Pensacola FL, primary) compared to program start (GROUP1 baseline, GROUP2 12 weeks). In addition, using the pooled intervention sample, variability estimates (standard deviation), will be determined for change in physical activity, physical function (,30 second sit to stand[14]) and self-report measures of physical function (Activity Measure for Post-Acute Care[15]), quality of life (PROMIS 29 Profile v2.0[16]), and loneliness (3-item loneliness scale[17] Berkman Social Disengagement Scale[1]). This will allow for sample size estimates for the subsequent larger effectiveness trial.

AIM 3 (exploratory): Explore patient perspectives of the multicomponent telerehabilitation program (physical therapy, biobehavioral interventions, technology, and social support interventions) and how they contribute to program engagement and participation as well as changes in physical activity.

Objective 3a: Qualitatively identify factors Veterans associate with program engagement and participation as well as short-term changes in physical activity (immediately post 24-week outcome assessment); these data will deepen our understanding of how and why Veterans engage with the program and its components and identify targets for future interventions.

Objective 3b: Qualitatively identify factors Veterans associate with maintenance of physical activity up to 6 months after program completion, with an emphasis on social support, strategies learned from biobehavioral interventions, and technology. These data will help identify key factors related to maintenance of physical activity, inform future iterations of this multicomponent program, and identify targets for future interventions.

II. Background and Significance:

A.1. Older Veterans with complex health conditions are often excluded from rehabilitation research

Veterans with multiple comorbidities are one of the most vulnerable patient populations as well as a large and growing proportion of Veterans Health Administration (VHA) beneficiaries.[18] Older Veterans with complex health conditions are at high risk for isolation,[19] disability,[20] adverse health events (e.g., hospitalization and death), mental illness,[21] and heavy healthcare utilization.[20] Historically, musculoskeletal research has often excluded medically complex older adults, which has hindered development and evaluation of practical and effective rehabilitation strategies for this population. The reason for this selection bias is multifaceted. The population is heterogeneous in age, cognitive status, medical status, psychological comorbidity, living environment, and social support.[22] In addition, this at-risk population often experiences simultaneous acute and chronic conditions that contribute to variability in rehabilitation outcomes and high rates of loss to clinical follow-up. Ethical considerations also create additional barriers to research participation, as many older Veterans have cognitive impairments that impact the informed consent process.[23] However, such selection bias limits the generalizability of study findings and the likelihood that existing or new interventions will adequately address the needs of this growing population.[22] Therefore, rehabilitation research targeting medically complex older Veterans is needed to optimize their physical function and enhance their life participation.

A.2. Physical function is a powerful biomarker of health and clinical outcomes for older adults

Although disability risk factors are complex and multifactorial, there is evidence that physical function alone is a powerful biomarker of overall health following hospitalization, and a strong independent predictor of hospital re-admission.[24-27] Poor physical function is also associated with reduced walking ability, lower extremity weakness, and increased risk of falls.[24,28-31] Older adults with lower levels of physical activity at home are approximately 6 times more likely to be readmitted within 30 days of acute hospitalization than those with higher levels of physical activity.[24] Furthermore, objective lower extremity weakness is associated with increased likelihood of requiring assistance at home.[32] This

evidence highlights the need for intensive and multimodal interventions directly addressing factors that contribute to low physical function and physical activity in this population. Most importantly, physical function is a modifiable risk factor, even in medically complex older adults, which previous studies suggest can be effectively addressed with more intensive rehabilitation strategies.

A.3. Social isolation of older Veterans is associated with poor physical function

Social isolation is also associated with poor physical function,[33] and is predictive of rehospitalization, premature death, and poor health outcomes[34] in older Veterans. Active older adults perceive social support and connectivity as important motivators for exercise.[11,12] In studies of healthier populations the social connection provided by group exercise also boosts adherence,[35] increasing long-term sustainability of exercise benefits.

However, older Veterans with poor health status have geographic (e.g., rural) and physical barriers to rehabilitation participation and often experience greater social isolation. The use of technology, such as telehealth platforms, provides an avenue to address the problem of Veteran social isolation. While online social activity is a detriment to perceived health for young adults, older adults report feeling more social support and less isolation when connected online.[36] Increasing Veteran social connectivity may augment conventional rehabilitation to improve older Veterans' physical activity, life participation, and sustained outcomes.

A.4. Conventional Rehabilitation Strategies are Insufficient to Produce Meaningful Gains

We have found rehabilitation exercise dosage in a variety of settings often does not provide a meaningful physical challenge for older adults.[6] Across the U.S., the content and intensity of conventional rehabilitation for medically complex older adults is substantially under-dosed.[37-39] In the rare cases where resistance training is used, the loads are often equivalent to 2 pounds or less. This is not sufficient to induce physiologic adaptations.[40] In contrast, high-intensity resistance training tailored to individual patient tolerance integrates principles of physiologic tissue overload and resistance training into functional rehabilitation interventions to achieve better outcomes. Despite this, clinicians apply conservative interventions to medically complex populations because they fear patient injury or expect patients to resist working at higher intensities.[41,42] Yet, when employed correctly, there is no greater risk of injury or patient refusals.[43,44] In older adults, high-resistance, low repetition strengthening fosters better functional outcomes than traditional strength training, including greater gains in strength[45,46] and physical function.[47] Furthermore, data from our group suggests practice change from low-intensity to high-intensity functional resistance interventions is influenced by patient and clinician self-efficacy,[48] which are modifiable through enhanced patient engagement and enriched training for rehabilitation clinicians. Furthermore, improvements in physical function are sustained well beyond a discrete episode of care,[43] helping to protect against the decline that might occur with the next expected insult.

III. Preliminary Studies/Progress Report:

B.1.1. Clinical Research Experience

Dr. Stevens-Lapsley, PT, PhD (PI) has more than 20 years of clinical research experience in working with medically complex patients and interdisciplinary teams in implementing rehabilitation programs. Dr. Stevens- Lapsley also has prior experience with implementing a telerehabilitation platform for patients after total knee arthroplasty (NIA R44 AG055341). Dr. Lauren Abbate, MD, PhD (Co-Investigator) is the Associate Director- Clinical at the Eastern Colorado Health Care System (ECHCS) Geriatric Research, Education and Clinical Center (GRECC) and the Medical Director for the ECHCS Gerofit Program. She has recent experience through Gerofit with telehealth delivery of exercise interventions. Dr. Cory Christiansen, PT, PhD (Co-Investigator) has worked closely with Dr. Stevens-Lapsley over the past decade and has participated in the design, implementation, and publication of multiple rehabilitation research studies involving a variety of older adult populations. Most relevant to the current proposal, the Co-I has extensive experience implementing biobehavioral strategies to improve physical activity in patients following Total Knee Arthroplasty[9] and dysvascular lower limb amputation.[8] Dr. Katherine Nearing, PhD (Co-Investigator) is the Associate Director of Education and Evaluation for the VA ECHCS GRECC. She will serve as the lead evaluator for this study. Dr. Jeri Forster, PhD (Co-Investigator) is a biostatistician who is the Director of the VA Data and Statistical Core for the VISN 19 Mental Illness Research, Education and Clinical Center (MIRECC). She will provide expertise on issues related to study design, database management, quality control, data analysis, and the preparation of manuscripts. Dr. Hillary Lum, MD, PhD (Co-Investigator) clinical expertise in geriatrics within the VHA system, in addition to her experience with telehealth care delivery using VA Video Connect will facilitate smooth program implementation.

B.1.2. Preliminary Studies

This new line of research builds on the collective experience of the investigative team. The PI and Co- Investigators have worked together over the past 7 years to 1) develop progressive rehabilitation strategies for medically complex patients (VA RR&D I21 RX002054, VA RR&D I01 RX001978), 2) develop and test biobehavioral strategies to improve physical activity for patients following dysvascular lower limb amputation[8] and total knee arthroplasty,[9] and 3) test and refine telerehabilitation delivery for patients following total knee arthroplasty (NIA R44 AG055341). This study will be the first to combine these lines of research into a coherent multicomponent program. Further, this is the first study to determine the safety and feasibility of telerehabilitation approaches for a high-risk, medically complex population. The investigative team's collective experience and ongoing work in these areas positions them uniquely to lead the proposed investigation.

IV. Research Methods

C.1 Outcome Measures:

Aim 1: Feasibility outcomes provide information to help determine if a larger study should be performed. Feasibility includes adherence, acceptability, and safety, and satisfaction. Additional factors may influence feasibility, and the following surveys for will be assessed

at program end for Veterans and therapists: Feasibility of Intervention Measure,[13] Acceptability of Intervention Measure,[13] Intervention Appropriateness Measure.[13] Satisfaction is measured by V-signals which is a survey specific to the VA; it measures satisfaction associated with telerehabilitation services. Additionally, we will monitor recruitment rate (proportion of Veterans enrolled out of those screened) and retention (proportion of Veterans who complete program out of all enrolled) to inform feasibility of a larger randomized controlled trial for effectiveness.

Aim 2: Preliminary responses to the interventions will be determined via performance-based and self-report measures. Physical activity behavior outcomes (hypothesis 2) will include average 7-day step count (accelerometry; primary), self-efficacy (Self-Efficacy for Exercise Scale[2]) and exercise readiness to change (Exercise Stages of Change).[70] Physical function outcomes will include 30 second sit to stand test,[3] arm curl test,[72] 2-minute step test,[72] and self-report Activity Measure for Post-Acute Care (AM-PAC).[15] Social isolation and loneliness outcomes will include 3-Item Loneliness Scale[17] and the Berkman Social Disengagement Scale.[1] The PROMIS-29 v2.0[16] will measure quality of life (summative score), social support (subscale), and mental health (subscale). In addition, descriptive measures will be collected at baseline including demographics, medications, cognition (T-MoCA[69]), depression (Patient Health Questionnaire-9 for depression[73]), anxiety (General Anxiety Disorder-7[74]), Mobile Device Proficiency Questionnaire,[75] and comorbidities (Charlson Comorbidity Index[68]).

Aim 3: Qualitative data will be collected primarily through semi-structured one-on-one key informant interviews, which will be recorded with the participant's permission. All interviews will be conducted through the same virtual platform participants will have been using throughout program participation. To validate data and findings, additional qualitative data will be collected from documentation in CPRS (restricted to study-related documentation) and voluntary feedback provided though the veteran satisfaction survey (V signals—a validated survey instrument used routinely within the VA). *Objective 3a*: These interviews will be conducted within 3 weeks of program completion (12-weeks for participants in Group1 and 24 weeks for participants in Group2). The interviews will last approximately 45-60 minutes. We will purposively sample Veterans based on level of technology engagement [high engagers (respond to Annie ≥ 80%) versus low engagers (respond to Annie < 50%)] and group sessions attendance [high attendance (≥ 80%) versus low attendance (< 50%)]. We will continue to sample Veterans until thematic saturation is reached for each group. *Objective 3b*: We will conduct follow-up interviews with the Veterans who completed initial interviews (from objective 3a); these interviews will last approximately 30-45 minutes and will occur between 3 to 6 months following their initial interview.

Description of Population to be Enrolled:

In this study, the target population is older Veterans, including those identified as "high-need, high-risk" by the Geriatrics & Extended Care Data & Analysis Center (GECDAC); this designation includes Veterans who have experienced a significant health event in the last 12 months (e.g., hospitalization) and have a Frailty Index score ≥6. Veterans will be recruited through the VA Eastern Colorado Health Care System. Potential Veterans will be identified by the GECDAC and/or by providers in the Geriatric Specialty Clinic, Home

Based Primary Care, and inpatient and outpatient rehabilitation settings. Potential Veterans with whom we have a treatment relationship will be pre-screened through standardized chart review followed by standardized phone screen. If eligible and interested in participating, Veterans will provide informed consent and be enrolled in the study; once enrolled, they will be randomized to either a waitlist control (GROUP2) or experimental (GROUP1) group. Participants will complete surveys and direct observation (Aims 1 & 2). Veterans will also undergo performance-based assessments of physical activity and physical function and complete self-reported measures for physical function, quality of life, loneliness, social support, and mental health.

Formal Inclusion/Exclusion Criteria

Inclusion

- ≥ 60 years of age
- Multiple chronic conditions (Functional Comorbidity Index[68] ≥ 3)
- Impaired physical function (≤ 10 on 30 second sit to stand)

Exclusion

- Life expectancy < 12 months
- Acute or progressive neurological disorder (e.g., Amyotrophic Lateral Sclerosis, recent stroke)
- Moderate to severe dementia without caregiver assistance (< 18 on telephone Montreal CognitiveAssessment (T-MoCA)[69])
- Unstable medical condition precluding safe participation in progressive rehabilitation (e.g., unstable angina) as defined by ACSM guidelines

We plan to randomize 50 Veterans (25 randomized to each group), with the goal of having 40 Veterans complete the study (20% attrition rate). Due to our enrollment process, we plan to have 70 Veterans sign the informed consent; this will allow for up to 20 Veterans to complete evaluation but be found ineligible based on identified exclusion criteria. The goal of the study is to obtain a representative sample of older Veterans at risk for, or presenting with, impaired physical function contributing to fall risk, physical dependence, and risk for hospitalization. Both sexes and all races are included in the study, however the Veteran population is predominantly male and Caucasian, which will be reflected in the enrollment.

D. Study Design and Research Methods

We propose a pilot, two-arm randomized trial using a waitlist control to determine the feasibility, acceptability, and safety (AIM 1) of a 12-week multicomponent telerehabilitation program. We will also assess the preliminary response (AIM 2) to this 12-week intervention. Participants (n=50) will be randomized to GROUP1 or GROUP2 using computer-generated random blocks of 2 and 4, stratified by sex. A waitlist control (GROUP2) will be used to simultaneously achieve the aims and ensure that all participants receive the intervention. Data will be collected at baseline (pre-intervention),

6-weeks (intervention midpoint for GROUP1), 12 weeks (intervention end for GROUP1, primary endpoint), and 24 weeks.

Setting & Recruitment:

Following consent and prior to baseline assessment and randomization, each participant will complete a physical therapy evaluation performed by a licensed physical therapist. The purpose of this evaluation is to ensure the Veteran is appropriate for the planned intervention and is eligible for the study. The evaluation may include standard evaluation tasks including but not limited to chart review, subjective history, and functional assessment.

Initial evaluation, intervention, and testing will occur through telehealth via VA Video Connect using a site-to-home format. Dedicated telehealth rooms are available for the study team in the ECHCS GRECC. Veterans will have the option of using their personal device (e.g., tablet, computer) or a VHA-issued tablet.

Veterans will be recruited from the Geriatric Specialty Clinic, Emergency Department, Home Based Primary Care, and Inpatient and Outpatient rehabilitation services through the VA ECHCS. Veterans also will be recruited via flyers provided to/posted on: VA social media, VA GRECC (Geriatric Research Education and Clinical Center) Website; UCD Website, to facilities and clinicians in the VISN-19, VA CLC colleagues, in VAMC patient rehab discharge folders, to Colorado Visiting Nurses Association, and to non-VA clinicians throughout the VISN19 region. Additionally, we are approved via DART to review VISN19 medical records for study eligibility. We do not anticipate any difficulties with recruitment because of the large volume of candidates who are currently waiting for availability of rehabilitation services. However, if recruitment goals are not met after six months, additional recruitment of Veterans will occur through established relationships with regional Colorado hospitals. Potential participants will be pre-screened through standardized chart review followed by standardized phone screen.

Intervention

Waitlist Control: 25 Veterans will be randomly assigned to GROUP2 for the first 12 weeks prior to initiating the telerehabilitation program intervention. To encourage retention, Veterans will participate in an hour-long educational session every 2 weeks for a total of 6 sessions. These online educational sessions will also include a facilitated question/answer session. Topics will include general health management such as nutrition, stress reduction, and sleep hygiene. At the completion of 12 weeks, Veterans in GROUP 2 will crossover into the multicomponent telerehabilitation intervention.

Multicomponent Telerehabilitation Program: 25 Veterans will be randomly assigned to immediately receive the multicomponent telerehabilitation program intervention (GROUP1). The three components include 1) individual and group progressive, high intensity resistance training rehabilitation, 2) biobehavioral interventions, and 3) social support. A physical therapist (PT) will deliver telerehabilitation, and Veterans will participate in 12 individual sessions and 24 group sessions over the course of 12 weeks.

Biobehavioral interventions will occur 1time per week for a total of 6 sessions during the early part of the program and 2 booster sessions during the latter part of the program. Social support group discussions will occur following specified group telerehabilitation session for a total of 12 sessions.

Multicomponent Telerehabilitation Program Intervention and Rationale

Progressive Rehabilitation: Progressive rehabilitation involves physiologically-tailored high-intensity resistance training during functional movements (e.g., sit to stand transfer, stair navigation), balance training, and gait retraining to appropriately challenge individuals to facilitate desired change.

Physical therapists will deliver progressive telerehabilitation during both individual and group sessions. Individual sessions will allow for orientation, individualization, and familiarization of various progressive rehabilitative interventions. Virtual group sessions will occur with the group in a virtual environment; each Veteran will attend the group VA Video Connect visit from their preferred location (e.g., home). Group sessions will help facilitate social support.

Biobehavioral Interventions: Our research team has extensive experience implementing biobehavioral interventions[8,9] which are theory- and evidence-based.[7,10] There will be 8 individual sessions over the course of the 12-week program. During the early part of the program, the PT will deliver 6 sessions focused on behavior change techniques (Table 1). The PT will deliver these interventions at the end of individual progressive rehabilitation sessions. The first session will provide an overview of the biobehavioral program and the different techniques that will be discussed (e.g., self-monitoring, problem solving, action planning, education, barrier/facilitator identification, tailored feedback, and encouragement). Each session will include education on the primary topic for the day, and then focus on developing skills and independence applying that technique.

Veterans will receive two individual booster sessions during the latter portion of the intervention. A VA-approved App (Annie App) will be used to augment the biobehavioral treatments. For example, daily step count can be tracked by responding to SMS text message prompts delivered by Annie. The Veteran is then able to view their progress (through mobile App or web portal) providing feedback on their performance.

Table 1. Components of the Biobehavioral Intervention

Intervention Technique	Progression from Therapist Coaching (left) to Participant Self-Management (right)	
Education	Therapist delivers education topic* (e.g., Self-Monitoring, Problems Solving, Identifying Barrier/Facilitators, Action Plans).	Participant reports most importantinformation learned.
Self-Monitoring	Therapist guides participant in tracking daily activity minutes & session participation since last visit.	Participant tracks weekly activity minutesand session participation.
Tailored Feedback	Therapist leads collaborative review of activity and participation data for action plan goal setting.	Participant leads review of activity and participation data and other physical activity goals.

Barrier/Facilitator Identification	Therapist guides participant to identify barriers/facilitators ofgoal attainment.	Participant self-identifies barriers andfacilitators for goal attainment.
Promotion of Problem Solving	Collaborative generation of solutions to overcome barriers togoal attainment.	Participant generates solutions to identified barriers to goal attainment.
Action Planning	Collaborative activity goal generation. Therapist guides, using 5-10% increase from daily activity minutes from previous week target.	Participant-led weekly goal generation. Therapist ensures independence in action planning.
Encouragement	Therapist reviews plan for the next week, while encouraging participant on successes attained toward improved physicalhealth.	Participant leads the review of the plan for upcoming week.

* Each week will have a specific “take-home” message linking physical activity and movement behavior to health. Messages will bebrief and based on research evidence.

Social Support: Social support is a key component of our program to address social isolation and perceptions of loneliness. We will foster a sense of community and family among Veterans enrolled in the program through virtual group telerehabilitation sessions and group discussions. During group telerehabilitation,therapists will purposefully engage Veterans, providing encouragement on performance while also facilitating peer support and encouragement. The group discussions, which occur at the end of group telerehabilitation sessions, will have core components to reinforce biobehavioral strategies and allow Veterans to share their experiences, successes, and struggles implementing our program. Group discussions will be iterative by encouraging Veterans to suggest topics for discussion and ideas for improvement.

Outcomes: All outcomes will be evaluated by a blinded assessor. **Aim 1:** Feasibility outcomes provide information to help determine if a larger study should be performed. Feasibility includes adherence, acceptability, and safety, and satisfaction. Additional factors may influence feasibility, and the following surveys will be assessed at program end: Feasibility of Intervention Measure,[13] Acceptability of Intervention Measure,[13] Intervention Appropriateness Measure.[13] Satisfaction is measured by V-signals which is a survey specific to the VA; it measures satisfaction associated with telerehabilitation services. Additionally, we will monitor recruitment rate (proportion of Veterans enrolled out of those screened) and retention (proportion of Veterans who complete program out of all enrolled) to inform feasibility of a larger randomized controlled trial for effectiveness.

Aim 2: Preliminary responses to the interventions will be determined via performance-based and self-report measures. Physical activity behavior outcomes (hypothesis 2) will include average 7-day step count (accelerometry; primary), self-efficacy (Self-Efficacy for Exercise Scale[2]) and exercise readiness to change (Exercise Stages of Change).[70] Physical function outcomes will include 30 second sit to stand test,[3] arm curl test,[72] 2-minute step test,[72] and self-report Activity Measure for Post-Acute Care (AM-PAC).[15] Social isolation and loneliness outcomes will include 3-ItemLoneliness Scale[17] and the Berkman Social Disengagement Scale.[1] The PROMIS-29 v2.0[16] will measure quality of life (summative score), social support (subscale), and mental health (subscale). In addition, descriptive measures will be collected at baseline including demographics, medications, cognition (T-MoCA[69]),depression (Patient Health Questionnaire-9 for depression[73]), anxiety (General Anxiety Disorder-7[74]), Mobile Device Proficiency Questionnaire-16,[75] and comorbidities (Functional Comorbidity Index[68]).

ActiGraph physical activity monitors (ActiGraph Inc. Pensacola FL) will be used to obtain an objective measure of physical activity (PA). ActiGraph activity monitors assess PA using accelerometry, which allows objective evaluation of the relative volume (steps/day) and intensity (activity counts) of physical activity with high validity and reliability.[76-78] Each participant will wear the ActiGraph for 10 days at the beginning and end of their intervention window (baseline and week 12 for GROUP1, week 12 and week 24 for GROUP2). The ActiGraph monitor will be used only for outcome data (not intervention) and provides no feedback to participants.

E. Description, Risks and Justification of Procedures and Data Collection Tools:

Potential Risks (Aim 1 and Aim 2)

Study Intervention and Assessments

We anticipate no greater risk than the minimal risk associated with standard telerehabilitation for Veterans participating in this study. All interventions and assessments are considered a part of physical therapy clinical practice. Because a physical therapist is not physically present with the participant during sessions, there is an increased risk for falls compared to in-person rehabilitation. Exercise is associated with inherent risks including muscle soreness, muscle strain, shortness of breath, and cardiac events. Precautions will be taken to minimize risks as follows:

1. Veterans will receive education on expected side effects of exercise (muscle soreness, shortness of breath) and methods to reduce fall risk prior to initiation of interventions. Education will also include signs of distress that should be communicated to the study team (dizziness, light headedness, symptoms of myocardial infarction)
2. Veterans will verify their physical location (address) in the event that Emergency Medical Services need to be alerted during the session
3. Vital signs (blood pressure, heart rate) will be assessed pre- and post- intervention to monitor physiologic response to exercise (more details below); additional and repeated measures may be taken as indicated. Veterans will be provided with equipment (automated blood pressure cuff, pulse oximeter) to monitor their vital signs and will be instructed on proper use
4. A licensed physical therapist will provide supervision for all study-related intervention and assessment activities remotely through telephone and/or VA Video Connect, which will afford the ability to monitor for signs of distress (dizziness, shortness of breath greater than expected)
5. Interventions will be modified based on each Veteran's physical function, fall risk assessment, and safety concerns (exercises performed sitting versus standing; standing exercises performed inclose proximity to sturdy surface for hand support)
6. In addition to the physical therapist, support personnel will be present during group telerehabilitation to monitor for signs of distress and assist in the event of an emergency
7. Telerehabilitation sessions will be conducted when another adult is present as an additional safety measure
8. Veterans will be encouraged to take rest breaks as needed to manage exercise

associated fatigue, shortness of breath, and thirst.

Additional safety measures may be used based on each Veteran's individual need (self-reported perceived exertion, glucose monitoring).

Vital signs are an objective indicator of physiologic response to exercise. Physical therapists will be trained in appropriate vital sign ranges for rest and exercise to assess appropriateness and safety for exercise. Prior to any exercise, the Veteran will self-assess blood pressure and heart rate. If blood pressure is outside of normal ranges (systolic < 90mmHg or > 180mmHg; diastolic < 50mmHg or > 100mmHg), the Veteran will be instructed to rest for 10 minutes and reassess. The Veteran may assess up to 3 times total. If blood pressure continues to be out of normal ranges and/or the Veteran is experiencing symptoms (dizziness, shortness of breath, etc.),the PT will defer study related activities and consult with study physician. If signs or symptoms of distress occur during the telerehabilitation session, the Veteran will be instructed to sit and rest and self-assess vital signs. The same procedure as above will be followed. In the event of an emergency, the PT will alert Emergency Medical Services through VA Video Connect.

For the purposes of safety monitoring, all adverse events occurring during and between study related activities will be recorded. The physical therapist will assess for adverse events at the beginning of each telerehabilitation session. Falls will be defined as "inadvertently coming to rest on the ground, floor, or other lower level, excluding intentional change in position," (World Health Organization) and characterized as unrelated, possibly, probably, or definitely related to study procedures. Additional fall information including circumstances and associated injuries will be collected. Any reported falls occurring outside of individual/groupsessions will be discussed at the subsequent individual session or within 24 hours if medical care is required. Fall occurrences (injurious and non-injurious) and other adverse events will be reviewed on a monthly basis. Other exercise side-effects, such as muscle pain, fatigue, shortness of breath, and minor strains during therapy will be documented and monitored by Dr. Stevens-Lapsley. Based on the existing literature[80] and our own clinical experience with rehabilitation (VA RR&D I01RX002417), we anticipate the frequency of these side-effects to be extremely low.

Surveys

We will administer surveys to enrolled patients via telephone, VA Video Connect, or CCTSI REDCap, dependent on Veteran preference. All collected data will be stored in CCTSI REDCap. Surveys will be used to assess participants' cognition, perceptions of study-related activities, and perceptions of physical and mental health. Participants may experience discomfort when answering questions about their health; patients will be reminded that they can choose not to answer any question and that all study data will be coded with a participant ID to maintain confidentiality. Research team members will compile data into a secure database for analysis and all data will be de-identified. The main risks to this portion of the trial are risks of breaching confidentiality of data.

Interviews

The questions outlined in the interview guides (provided with this application) explore

perceptions of the program and how the different components of the program impacted participation and/or physical activity behavior change. Generally, participants will be asked to reflect on their experiences during the program. Questions do not delve into personal issues, but rather require individuals to be circumspect and to talk in terms of generalities. For this reason, we do not anticipate that the nature of the questions/ topics explored will cause participants any emotional or psychological distress. To the contrary, we will emphasize that aspects of their experience in relation to the telerehabilitation program that they choose to share can help the study team improve the program to optimize the benefit for Veterans. The opportunity to have their input potentially improve services and care for other Veteran tends to be viewed positively by Veteran peers. As is customary, members of the research team will communicate that participation in these interviews is voluntary, they can ask questions at any time, they can decline to respond to any question, they can stop or withdraw their participation at any time, and decisions to decline to participate or answer any question will not affect their healthcare.

The time required to participate in the interview and any associated inconvenience this may cause is also a potential risk. We will explain that interviews are estimated to require an hour of the individual's time, and we will schedule interviews on a day and at a time convenient for them. Participants who are being invited to take part in an interview will have completed a 12-week telehealth program, during which they consistently (2-3x/week) demonstrated the ability and willingness to take part in virtual activities for an hour in duration. This commitment is similar to the requirement of participating in the interview. We will use the same virtual, secure platform (VA Video Connect) to conduct the interviews so the technology will be familiar to each person. Therefore, we do not anticipate this aspect of participating in the interview to cause any undue stress.

General Risks

As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and we strive to maintain confidentiality. Only the researchers team members involved in the study will have access to the data that is collected. Paper data will be kept in locked filing cabinets in locked offices of the VA researchers. Electronic data will be storedand managed in a password protected computerized database that is behind a firewall (i.e., REDCap).

All assessments and interventions in this study are considered to be low risk. We believe we have minimized risks by applying usual safeguards for instructing participants in physical activity and for conducting telerehabilitation. Side effects, such as muscle pain, fatigue, minor sprains or strains, or falls during testing will be recorded by the physical therapist and monitored by Dr. Stevens-Lapsley. As indicated previously, we anticipate the frequency of these side effects to be extremely low based upon existing literature and our own clinical experience with the intervention.

We will maximize the safety of our participants with the following procedures:

1. Individuals with absolute contraindications to testing and training will be excluded based on the inclusion/exclusion criteria.

2. Prior to initiating any study-related activities during a telerehabilitation session, participants will be askedto identify their physical location (address) if Emergency Medical Services need to be alerted for anyreason during the session.
3. All study-related intervention and assessment activities will be supervised by a licensed physical therapist. Physical therapists will conduct a falls risk assessment at the first telehealth sessions to determine the participants' level of function and potential needs for support and safety during the session (e.g., use of hand-held support on a countertop during exercise); this approach will reduce the risk for falls and injury. Additionally, interventions and assessments will not be conducted for patients who are unable to perform the tasks (by patient report or clinicians' judgment).
4. Furthermore, when at all possible, sessions will be conducted when another adult is present as an additional safety measure.
5. When completing surveys with potentially sensitive questions, participants will be reminded that they can choose not to answer any question and that all data is only linked to a participant ID in order to maintain confidentiality and anonymity.

F. Potential Scientific Problems:

Mobile-Health technology: Durability and continued functionality of technology is a concern when using any technology. The mobile-health tablets used in this study have been implemented for standard-of-care use for a variety of purposes currently in the VA ECHCS. If a tablet becomes dysfunctional, replacement units are available so that an immediate back-up unit can replace the dysfunctional unit. The VHA will provide mobile-health technical support for the duration of the study. Finally, the intervention is not dependent on type of tablet used, so changes in mobile-health tablets in the future will not necessitate a change in intervention.

Lack of long-term follow-up: Creating a change in physical activity behavior for an older adult population is a major challenge. We will collect data out to 24 weeks (GROUP1) to determine maintenance of intervention effects. We expect that activity changes may be reduced at the 24-week time period for GROUP1 compared to the 12-week test point, but that the activity will continue to be higher than baseline, based on data from studies of patients with other chronic diseases.[79]

Heterogeneity of medically complex older adults: Medically complex older adults are heterogenous in age, cognitive status, medical status, psychological comorbidity, living environment, and social support.[22] Additionally, they experience acute exacerbations of chronic conditions impacting their response to treatment and contributing to high drop-out rates among this population. To accommodate for this from our experiences, we anticipated a higher attrition rate (20%) and adjusted enrollment accordingly.

G. Data Analysis Plan:

Analysis Plan. Analyses will be performed in SAS v 9.4 or above and hypothesis tests will be two-sided, assuming an alpha level of 0.05. Participant characteristics and outcome variables will be summarized using means, standard deviations (SD), medians, ranges, N and percent, as appropriate.

Aim 1. The percent of Veterans (1) achieving ≥ 80% adherence and (2) scoring ≥4/5 on the Acceptability of Intervention Measure will be calculated with associated 95% exact binomial confidence intervals. We will additionally calculate the proportion of adverse events that are found to be possibly, probably, or definitely related to the intervention.

Aim 2. Given the small samples, the median change from baseline to 12 weeks for those randomized to the intervention will be compared between the groups using a Wilcoxon rank-sum test for each outcome of interest (7-day average step count as primary). Estimates of variability (SD) in the change from pre to post-intervention for the pooled sample completing the intervention (N=40) will be calculated for each outcome and reported with 95% CIs. These estimates and the CIs will inform sample size calculations for a future effectiveness trial.

Aim 3: Semi-structured interviews will be recorded with permission and professionally transcribed. The accuracy and completeness of transcripts will be validated by a member of the study team. Thematic analysis will be conducted by two researchers as described by Fereday and Muir-Cochrane[52] using a hybrid deductive-inductive analysis approach. A codebook will guide systematic analysis. The initial codebook will be developed using key constructs from Social Cognitive Theory, Technology Acceptance Model,[53] and emerging social isolation theory specific to older adults.[54] Constructs will also be added to the codebook as new concepts emerge inductively throughout analysis. Multiple passes will be taken through the data to support iterative and reflexive processing of key insights salient to the research questions and hypotheses outlined for the study. Coding from both researchers will be compared and any disagreements/discrepancies will be resolved through weekly processing discussion meetings. Results will be transferred to a matrix to organize the data by salient themes and support further interpretation.

Data Management:

Interviews will be recorded with permission from the participant by a member of the study team. Sound files will be encrypted using the Olympus DS-9000 Digital Voice Recorder (a VA-approved device). The audio file will be transferred securely using box.com. The interviews will be transcribed by a contracted employee of Transcription Outsourcing LLC, a VA-approved vendor. Once transcripts are complete, these Word documents and the associated sound files will be downloaded and saved on a shared network drive accessible only by research personnel of the university; once files are downloaded and saved to the shared network drive, the associated sound file and transcript will be deleted from box.com. These data will be stored electronically on a secure network drive (maintained by the university) in subfolders with a complex directory path. Study staff will use password-protected computers maintained by and/or located at the university to process information collected for this study. Any hard copies of data collected during interviews (i.e., transcripts and hand-written notes) will be stored in a locked filing cabinet to which only designated members of the research study team will have access. The key to this filing cabinet will be kept in a separate, secure location. The participant's study ID will be used to label the electronic and hard copies of the data obtained for this study (e.g., sound files, associated transcripts, or interview notes).

If parts of an interview are featured in a report (e.g., a quote is used to represent a given theme and/or a composite story is featured to illustrate a common scenario/experience), we will confirm that there is no identifying information included. Names will be masked. For example, when sharing findings resulting from this study, specific names would be replaced in text with a descriptor such as [physical therapist] or [spouse].

H. Summarize Knowledge to be Gained:

The VA has established rehabilitation programs for inpatient, home, and outpatient settings, but these typically require in-person attendance, address one area of functional impairment, and under-dose the intensity of rehabilitation. Further, Veterans often face barriers to attending in-person appointments; for example, living in rural locations, lack of transportation, or limited social support. As a result, many Veterans continue to have residual physical function limitations that prevent them from participating in life roles, navigating their home and the community, and participating in continued rehabilitation exercises in the community setting. It is unclear how telehealth strategies could be effectively and safely utilized to provide rehabilitation services to Veterans who lack access to these important services. Indeed, telehealth platforms offer a solution to overcome access barriers (rurality, transportation), but no current research applies telerehabilitation to medically complex older Veterans.

The current study will assess the feasibility, acceptability, and safety of the multi-component rehabilitation program for high risk, high need Veterans with multiple comorbidities and functional deficits. Additionally, response to the multicomponent telerehabilitation program will also be measured to determine preliminary effectiveness. Study findings will guide refinement of telerehabilitation methods, so they are effective, easily implemented, and safe. This study will provide critical insight for providers regarding telerehabilitation for medically complex older Veterans and its utilization to improve physical function and concurrently reduce the impact of social isolation.

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