Title: Patient-Centered, Interprofessional Approach to Improve Functional Outcomes in a Skilled Nursing Facility

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COMIRB Protocol

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Protocol #: 19-2490
Project Title: Patient-Centered, Interprofessional Approach to Improve Functional Outcomes in a Skilled Nursing Facility

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I. Hypotheses and Specific Aims:

For many older adults, a skilled nursing facility (SNF) stay is required to address functional deficits stemming from hospitalization. However, during a typical SNF stay, patients receive rehabilitation for 1-2 hours of their day and remain sedentary for up to 14 waking hours, which is not reflective of the mobility levels needed to thrive in the community.[1-3] While a previous high-intensity strengthening intervention implemented by our group (COMIRB Protocol #: 14-2388, Intensive Therapeutic Rehabilitation for Older Skilled Nursing Home Residents: i-STRONGER) demonstrated superior outcomes when compared to usual care, the benefits of rehabilitation are likely negated by sedentary behavior outside of structured rehabilitation time. We propose that an interprofessional movement program combined with i-STRONGER strengthening will be feasible, acceptable, and will lead to superior patient outcomes.

AIM 1: Determine the feasibility and acceptability of implementing a structured mobility program **H**igh-Int**e**nsity **R**ehabilitation plus M**o**bility (HeRo) for SNF residents and staff

H1: HeRo will be acceptable to SNF residents: SNF residents will score ≥70% in the patient satisfaction survey and will indicate acceptability in semi-structured interviews. HeRo will also be feasible, as evidenced by >90% treatment fidelity scores by providers.

AIM 2: Determine the effectiveness of HeRo for improving patients' gait speed, short physical performance battery (SPPB), and physical activity levels (i.e. upright time, steps per day) compared to a) the usual care group and b) the i-STRONGER only group.

H2: Patients who participate in HeRo will demonstrate greater gains in gait speed, SPPB, and physical activity over the course of a SNF stay when compared to the usual care group and the i-STRONGER only group.

II. Background and Significance:

For many older adults, skilled nursing facility (SNF) care may not adequately address deficits in function because patient mobility levels are far below what is needed for successful community living.[4,5] Current rehabilitation paradigms do not sufficiently challenge patients to acquire meaningful physiological gains.[6-14] **This inadequate recovery of function directly contributes to poor community discharge rates.**

Strikingly, only 28% of all patients in SNFs are discharged to a community setting, which drastically impacts quality of life and patients' objectives to stay in their home.[15]

Physical function after hospitalization is a powerful biomarker of health for older adults. Although the risk factors for the development of disability are likely to be complex and multifactorial, **there is evidence to suggest that physical function alone may be a powerful biomarker of overall health following acute hospitalization.**[16-19] In older adults, lower extremity weakness is associated with poor mobility and increased fall risk.[20-23]

Barriers to mobility outside of structured rehabilitation include perceived safety concerns (pain, falls), staff shortages, lack of formal training on safety and equipment use, time constraints, and interdisciplinary communication barriers.[24,25] **This gap provides an excellent opportunity for the interdisciplinary SNF team to collaborate and use supplemental mobility to extend the gains made during formal rehabilitation sessions to levels appropriate for discharge into the community and set the stage for larger scale dissemination efforts.**[15,26] One study demonstrated that a twice-daily mobility program performed in the acute care setting demonstrated superior outcomes in life-space mobility that persisted one month after discharge.[27] However, no studies to date have evaluated mobility programs implemented in the SNF with behavior-change frameworks.

A critical question from our previous study is whether the positive functional results achieved with a progressive rehabilitation program (i-STRONGER) are negated by sedentary behavior. This will be the first study 1**)** develop a collaborative, patient-centered model to increase mobility in the SNF setting, **2)** apply concepts of behavior change to promote functional recovery after hospitalization by reducing sedentary time and **3)** combine a mobility program with a progressive, intensive rehabilitation protocol (i-STRONGER). The results of this study will inform large multi-site trials and provide a clinical framework to promote optimal functional recovery and discharge to the community for older adults following hospitalization.

III. **Preliminary Studies/Progress Report:**

Our research group analyzed activity monitoring data from similar patients just days before SNF discharge indicated patients took an average of 1,844 steps per day and were sedentary for 83% of the day. To put this finding into context: patients in the SNF were lower than the ~2,500 steps per day considered basal activity (i.e., baseline activity needed for an individual to perform activities of daily living at rest) and ~70% more sedentary than community-dwelling older adults.[28] This study demonstrates that there exists a great opportunity for improvement in mobility in this setting.

Our previous efforts to address functional recovery in the SNF using high-intensity, functional resistance training rehabilitation (**i-STRONGER**), demonstrated superior outcomes including improvements in physical function and gait speed, and cost-effective reductions in length of stay compared to usual care (COMIRB Protocol #: 14-2388 manuscript in preparation). However, during a typical SNF stay, patients receive rehabilitation for 1-2 hours a day and remain sedentary for up to 14 waking hours, which is not reflective of mobility levels needed to thrive in the community.[1-3] **A critical question from the previous study is whether the positive functional results with i-STRONGER**

are negated by sedentary behavior. The purpose of this study is to determine if an interprofessional mobility program (HeRo) has a synergistic effect with i-STRONGER in improving patient outcomes.

IV. Research Methods

A. Outcome Measure(s):

Physical function testing will occur at the SNF by facility Physical Therapists (PTs), Physical Therapist Assistants (PTAs), Occupational Therapists (OTs), Certified Occupational Therapist Assistants (COTAs), or Speech-Language Pathologists (SLPs). The primary functional performance outcome is **gait speed (Aim 2).** Gait speed was chosen because it 1) has been shown to predict risk of disability, higher health care utilization, and increased mortality;[29,30] 2) is a valid and reliable measure;[31,32] and 3) is easily performed in the clinic and well tolerated by patients varying in condition and degree of health.[33-35] Gait speed will be measured by the time it takes to walk a 4 meter path using a stopwatch to the nearest hundredth of a second. The secondary outcomes include Short Physical Performance Battery (SPPB). The SPPB is a well-accepted global measure of lower extremity function consisting of walking speed, chair stands, and balance. It is a well-studied composite measure and a strong predictor of disability, institutionalization, and morbidity in older adults.[30] The SPPB is reliable with intra class correlation coefficients (ICC) >0.88 and demonstrates good sensitivity to change.[36] Both gait speed and the SPPB are collected as standard of care in the Community Living Center at Fitzsimons.

Numbers and reasons for **hospitalizations** and **emergency room** visits during the SNF stay will be documented by treating therapists. Falls will also be counted and documented by treating therapists or nursing staff. **Falls** will be defined as an unintentional change in position resulting in coming to rest on the ground or other lower level. Vital signs, use of assistive device, and pain will also be assessed during treatment sessions by therapists.

Patients will complete a 7 question survey at discharge, scoring each question on a 1-10 scale (1=not at all and 10=extremely) to determine satisfaction with care (per standard of care procedures at SNF).

Physical activity will be measured using the ActivPAL device (PALTechnologies: Glasgow, Scotland), which effectively measures sedentary time and steps per day. The ActivPAL is a small device which is attached to the participant's thigh for up to seven days at a time. This is a small (35x53x7mm) and lightweight (15 grams) device that uses accelerometer-derived information about thigh position to estimate time spent in different body positions (i.e., sitting/lying, standing, and stepping). The device is positioned on the midline of the thigh, ~1/3 between the hip and knee. The device is placed in a small nitrile sleeve and attached using a non-allergenic adhesive pad and thus can be worn during bathing and overnight, allowing for continuous measurement. Participants will be instructed to wear the monitor on their leg for up to ten consecutive days at all times except when submerged in water (e.g., bath and shower is acceptable). The time-stamped "event" data file from the ActivPAL software will be used to determine time spent sitting/lying, standing and stepping per day. Using a customized R program,[38] the event data file will be converted to a sec-by-sec file and additional metrics of sedentary behavior

(e.g., total time participating in activity, average duration of sedentary bouts) will be estimated. The ActivPAL has been validated for use in older and middle aged adults with very high levels of accuracy (99-100%)[39-41]

Feasibility and acceptability (Aim 1) will be assessed by patient surveys,fidelity assessments, and semi-structured interviews. Treatment fidelity will be assessed throughout the duration of the study by objective check lists for the mobility coach including 1) mobilization of patients.2) application of principals of behavioral economics and 3) safe patient handling techniques. Fidelity assessments will also be performed for i-STRONGER on PTs, PTAS, COTAs, and OTs to ensure appropriate application of principals of i-STRONGER. Fidelity checks will be performed by Dr. Stutzbach or Dr. Stevens-Lapsley one time per week and monthly thereafter as long as fidelity remains above 90%. Patient acceptability will be assessed through semi-structured interviews and analyzed using rigorous qualitative methods Twenty-two participants will participate in interviews, and participation in interviews will be voluntary. Interview participants will be recruited using purposive sampling from the total sample of participants.

Falls, rehospitalizations, ER visits, and the life-space mobility assessment will be assessed by self-report through two follow-up phone calls: one 7 days following discharge and one 60 days following discharge. These will not be considered as an outcome measure as we do not have this information from our historical comparison group but this will help us to 1) identify responders and non-responders to the treatment and 2) generate preliminary data regarding the potential role of mobility in determining adverse events such as ER visits and rehospitalization.

Covariates, clinical and background characteristics**.** Information on other patient characteristics to describe the patient population and interpret results will be obtained from facility medical records. These characteristics include age; sex; race; history of comorbidities; medications; primary diagnosis for hospital admission; medical record number; prior level of function; length of skilled nursing facility stay; complications in hospital; and hospital length of stay. SNF staff will administer the Brief Inventory of Mental Status (BIMS) to assess baseline cognitive status within 24-48 hours of admission to SNF in accordance with current standard of practice.

NIH PROMIS measures will also be completed in order to characterize this population and potentially to identify responders and non-responders to HeRo. NIH PROMIS measures are well-validated, patient-reported outcome measures of physical, mental and social health. PROMIS uses computer adaptive testing (CAT) to improve precision and decrease tester and participant burden.[42] The following CAT PROMIS measures will be assessed upon admission to and discharge from the SNF:

- Physical Function for Samples with Mobility Aid Users
- Sleep Disturbance
- Self-efficacy (Activities of Daily Living)
- Fatigue
- Satisfaction with Participation in Social Roles
- Social isolation

The Life-Space Mobility Assessment is a self-report measure assessing a patient's movements, extending from within the home to movement beyond a patient's town or

geographic region.[43] The life-space mobility assessment is a continuous measure which can be scored from 0 (totally bedbound and dependent with all activity) to 120 (independent with community ambulation without assistance). The scores take into account both the performance of movement within and outside the home, the frequency of the movement, and the amount of assistance required. Specifically, this measure allows evaluation of actual mobility performed in the home and community, and can be evaluated for older adults across all levels of function. LSA has concurrent validity with physical function measures, as well as self-reported health and ADL disability.[44] The Life-Space Assessment has good test-rest-reliability (ICC=0.96), and is responsive to change in community-dwelling older adults.[43]

Specified outcome measures (gait speed, SPPB, life-space mobility assessment, NIH PROMIS) are used in a variety of rehabilitation settings under current reporting and standard of care practices.

B. Description of Population to be Enrolled:

Patients will be enrolled from one SNF in the Denver metro area: **Veterans Community Living Center at Fitzsimons.** The Veterans Community Living Center at Fitzsimons has been a strong community partner and has served as a research site for two previous research studies (COMIRB Protocol #: 14-2388, COMIRB Protocol #: 16-2690). Outcomes data will only be collected on patients who fit the inclusion criteria: adults 18 through 120 years of age who are admitted to a skilled nursing facility,receive at least physical therapy and were ambulatory prior to hospitalization Exclusion criteria: Patients with neurological disorders, such as a acute stroke or acute traumatic brain injury, will be excluded as the best practice for managing these patients is based on motor-control theory versus the progressive strengthening and aerobic approach. Patients on hospice care will be excluded as hospice care is focused on palliative needs and not rehabilitation. Other patients to be excluded will include those with conditions where strength training is contraindicated (as indicated by the American College of Sports Medicine Guidelines for Exercise Testing and Prescription): recent unstable fractures, advanced congestive heart failure (ejection fracture <30%), bone metastasis sites, tumors in strengthening target areas, acute illness, recent myocardial infarction (within 3-6 weeks), weight bearing restrictions on graft or fracture sites, exposed tendon or muscle, absence of pedal pulses, presence of a fistula, and platelet levels <50,000/μL.

C. Study Design and Research Methods

This study is a preliminary investigation using a three-stage, pre-post training designs in one SNF (Figure 1). Stage 1 (usual care) and Stage 2 (i-STRONGER) have already been completed (manuscript in preparation; COMIRB #14-2388). Given that the average length of stay in a SNF is 21 days, the pre/post design will consist of three independent samples of patients to include only those that were admitted and discharged within a discrete period. During the 2 year Stage 3 (HeRo) period we will implement the interprofessional mobility program.

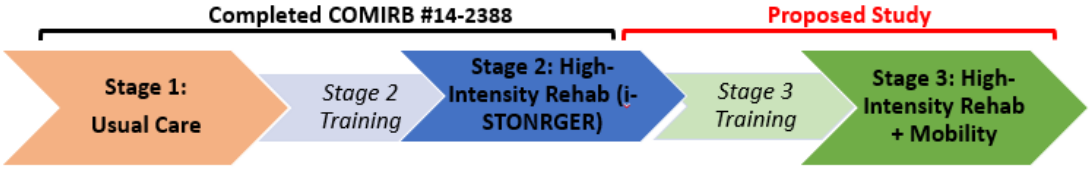

Figure 1. Study design

Consenting
Patients will provide written informed consent prior to participating in the study. Potentially eligible patients will be identified upon admission by PTs, OTs, SLPs, PTAs, and COTAs at the research site who have a treating relationship with the potential participant. The clinicians will describe the study to potential participants. If the patient is interested, they will sign a HIPAA A form. Following this, a professional research assistant (PRA) or Dr. Stutzbach will screen the patient for eligibility and will approach the patient for consenting within the first 4 days of admission to the SNF.

Intervention:
Mobility program
Participants in the study will participate in a regular, structured mobility program outside of rehabilitation time, guided by a mobility coach (a licensed certified nursing assistant [CNA] or physical therapist assistant [PTA]). In current SNF clinical practice, CNAs and PTAs regularly perform walking and other physical activities with patients, so this does not provide any additional risk to the participant. The CNA or PTA will be an employee of the University and a study team member included on the Personnel Form. A Professional Services Agreement between the University and the Veterans Community Living Center at Fitzsimmons will ensure adequate liability coverage, and will outline the services that the mobility coach will provide to the facility. In addition, the mobility coach will obtain Workers without Compensation (WOC) status through the Veteran's administration prior to providing the intervention.

During the first three days of the skilled nursing facility stay, the patient will wear an activity monitor (the Accusplit) to establish baseline level of mobility (i.e. steps per day) in the intervention in order to set and monitor goals, and provide patient feedback. The Accusplit is an inexpensive, non-invasive activity monitor that has been shown to have the best accuracy of commercially-availability activity monitors for older adults with slow gait speed.[45] Concurrently, patients will wear an ActivPAL device to monitor activity levels as an outcome for the study. Participants will not receive feedback directly from the ActivPAL, but it will be used for data collection as it is a more reliable and detailed measure of physical activity than the Accusplit.

Following the baseline period, the patient will select two goals: a daily step count goal/range for the remainder of the week, between 33-55% increase in step counts as well as a functional goal related to mobility and participation in life roles and activities (i.e. walking to the activity room or dining room twice per day, walking outdoors) or a goal related to time spent out of bed. Patients will keep a diary of activities performed outside of bed, which the mobility coach will review with the patient daily.[27] Patients will sign a pre-commitment contract in order to enhance accountability for reaching goals.

Following the baseline assessment period, participants will start out their week with 70 points. If the participant does not reach one of their two goals, then they will lose 10 points for that day. If they do reach their goal, they will remain at 70 points. If either of the two goals are unable to be assessed, then the patient will keep the 10 points. This method is used to leverage loss aversion, the idea that humans are more prone to change behavior if they fear losing as opposed to gaining a desired outcome.[46]

At the end of each week, the participant will choose a prize with levels depending on how many points he or she have remaining. Prizes may include mugs, medals, calendars, photo frames, jigsaw puzzles, tote bags, crafts, fanny packs, scarfs, and stress balls. These prizes will be provided by the University of Colorado and given by a professional research assistant. If the individual is admitted and discharges within one week, they will receive a prize if they reach goals for half of their days while admitted.

The intervention will also include training for staff on improving mobility. PTs, OT, COTAs, and/or PTAs will provide verbal presentations and demonstrations for nursing staff on safe patient handling techniques as well as a description of the mobility intervention and eligibility for the study.

Progressive rehabilitation
The Veterans Community Living Center at Fitzsimons is already implementing a progressive rehabilitation strengthening program (i-STRONGER) as a result of our previous work with the facility. In brief, i-STRONGER is a standardized, progressive, multi-component program consisting of strengthening, activities of daily living training, and motor control training. The therapists in this facility adopted i-STRONGER as a new standard of care and continue to implement the intervention. Therapists will continue to utilize i-STRONGER as their standard of care throughout the intervention period.

Treatment fidelity
Treatment fidelity visits will be scheduled using a fidelity checklist. Fidelity visits will be conducted by Dr. Stutzbach or Dr. Stevens-Lapsley with the mobility coach to ensure 1) adequate dosage of mobility (to patient tolerance, 2x day) 2) adherence to utilization of principals of behavior change and 3) safe patient handling techniques. Fidelity will be assessed 1 x per week with the mobility coach until scores reach 90%, after which fidelity assessments will occur monthly Fidelity will also be assessed by weekly documentation audits.

Comparison groups: Previous standard of care and i-STRONGER alone
Patients in the comparison arm of the study have received usual care as per the previous standard of care prior to the i-STRONGER implementation, or the i-STRONGER alone as mentioned above. We will compare the HeRo intervention to historical data we have collected on the previous standard of care and the i-STRONGER in Stage 1 and Stage 2 in COMIRB 14-2388.

Outcome measures
Outcome measures as listed above will be assessed at admission and discharge. ActivPAL monitoring will take place throughout the course of the SNF stay to determine the magnitude of change in activity levels from admission to discharge. A PRA will perform phone calls at 7 days and 60 days following discharge from the skilled nursing facility. Information collected at phone calls will include 1) Falls, ER visits,

rehospitalizations and 2) Life-space mobility assessment. This cannot be used as an outcome measure as it was not collected with our historical data. However, this will help us to determine responders and non-responders to treatment on a longitudinal scale.

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

Veteran data will be managed and stored on CCTSI RedCap and VA server.

The addition of the physical activity monitor does not pose increase falls risk to the patient. There is a possibility of skin irritation from the adhesive used to affix the ActivPAL, but we will use a hypo-allergenic adhesive pad, patient education, and frequent monitoring to reduce the risk of skin irritation at the site of the ActivPAL.

There is no expectation that the mobility program will cause serious cardiovascular responses or will increase risk of falls. Gardner et al[48] reviewed controlled clinical trials with exercise interventions for older adults at-risk for falling. No cardiac events or falls were reported in the 12 clinical trials reviewed. A similar mobility program implemented in the acute care setting demonstrated that the group that received the intervention had fewer falls than the control group.[27]

E. Potential Scientific Problems:

Missing Data. All patients with outcome measurements will be included in the intent-to-treat analysis. Although we will encourage patients to be fully compliant to their assigned treatment regimen. they will not be dropped from follow-up measurements for lack of compliance. Although statistical methods can be used to "adjust" for missing data, these methods rely on the untestable assumption that data are "missing at random" so that the effect of the missingness can be removed through statistical modeling. We will instead focus on preventing missed follow-up visits and evaluate missingness to determine whether the data are consistent with the hypothesis of missing at random or missing completely at random.

Patient population: The SNF population is highly heterogeneous and often demonstrates fluctuations in medical status and is at risk for rehospitalizations. This heterogeneity will lead to variability in data, which will try to address by controlling for variables such as gender, age, and comorbidities.

F. Data Analysis Plan:

Aim 1 analysis: The proportion of patients in the HeRo group with a score of ≥70% on the satisfaction survey will be compared to the null value of 75% using a one sample binomial proportions test. In addition, treatment fidelity checklist scores will be compared to the null value of 90% using a one sample binomial proportions test. For the qualitative component, verbatim transcripts will be independently coded by two study team members. Themes will be developed from those codes as an iterative process until consensus is reached among team members.

Aim 2 primary analysis*:* The primary analysis will be an intent-to-treat comparison of the differences among treatment groups in change in gait speed at time of SNF discharge. Statistical inference regarding the difference between treatment groups will be based on the estimated coefficient for a treatment group indicator variable in a linear regression

model with change in gait speed as the response variable, and explanatory variables that include an indicator of treatment group and the baseline value of gait speed. The baseline gait speed value is included to improve the precision/power of the inference about treatment differences. The conclusion about the statistical significance of differences between groups will be determined by this single statistical test to protect against an elevated risk of false-positive conclusions. Sensitivity analysis will be done to evaluate whether conclusions would differ when other important covariates are added to the model (age, gender, comorbidities). We will model gait speed change as a function of treatment group (categorical Stages 1, 2 and 3), controlling for the baseline value of function, study stage, sex, age, length of stay, total therapy minutes, and potential confounders.

Aim 2 Secondary Analysis*:* Differences between groups in SPPB, falls, successful discharge to the community at time of discharge from SNF will be analyzed as described above. Secondary analyses will be evaluated for their consistency with the conclusions of the primary endpoints. We anticipate that group differences in secondary measures will be correlated with the primary so that significant differences in the primary endpoint will be reinforced by similar effects on secondary endpoints. This approach will reduce the risk of false-positive conclusions resulting from multiple statistical tests.

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Sample Size Estimates

Statistical power was estimated based on measurements of gait speed change from admission to discharge on patients in both Stage 1 and Stage 2 (data collection complete, N=80). For the primary outcome (change in gait speed), we used the standard deviation of 0.28. A sample size of 155 patients (75 in Stage 3 [i.e HeRo]) will provide 80% power to detect a clinically meaningful difference in change of 0.16 m/sec between Stages 1 & 3 (primary analysis). In our previous research, 2/3rds of patients met the inclusion criteria at any given time. With an average length of stay of 21-25 days in SNFs, we should have no difficulty enrolling 75 patients for this study.

G. Summarize Knowledge to be Gained:

The proposed research is time-sensitive given increased pressures from the healthcare system to promote high-value, cost-effective care by optimizing short and long-term trajectories of functional recovery for successful community transition after hospitalization. This investigation will provide an essential foundation of evidence to support the interdisciplinary, multi-component, patient-centered methods for supplemental mobility to inform a large cluster-randomized trial. **Our 4 year history of collaborating with our clinical partners in a real-world laboratory will increase likelihood of success with the proposed research project.**

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