Shifting Rehabilitation Paradigms in Skilled Nursing Facilities

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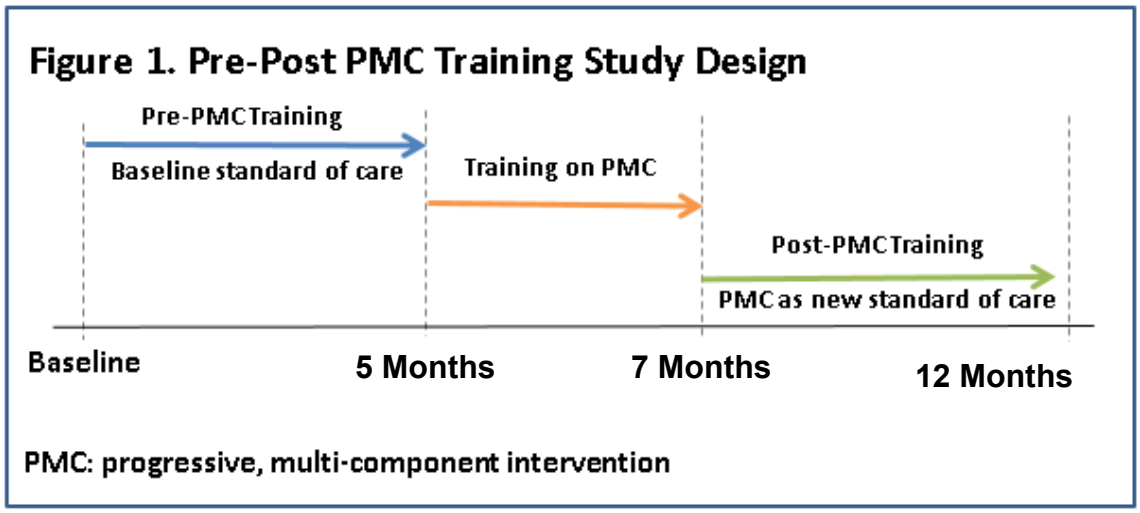
Each year Medicare spends approximately $31.3 billion on 2.4 million skilled nursing facility (SNF) episodes of care.[1] SNFs rely on interdisciplinary approaches to patient care to maximize rehabilitation potential for return to prior level of function and reduce the risk of adverse events in older adults. However despite a substantial increase in spending on SNF services and minimal change in complexity of the caseload, 68% of patients are below their pre-hospitalization level of function at discharge, 25% return to the community, and 18% are hospitalized.[2] This may be partially explained by current SNF approaches to patient care which foster inactivity[3, 4, 5] and participation in low intensity rehabilitation interventions (preliminary data). Both inactivity and low-intensity interventions may perpetuate further functional decline or impede maximal recovery. The serious implication of risk with functional decline is exemplified by studies which have shown declines in physical function can increase the risk of being re-hospitalized six-fold[6] and may infer other long term effects such as increased risk for mortality, morbidity, and institutionalization.[7] Muscle weakness, reduced cardiorespiratory reserve, and neuromuscular deficits have been attributed to this acute decline in function. However current rehabilitation strategies in SNFs do not promote adequate dose and mode of interventions to induce beneficial systemic adaptations, perhaps due to the lack of evidence on effective rehabilitation protocols for this medically-complex population. In addition, the lack of standardization across rehabilitation practices makes it difficult to discern which treatment approaches are the most effective. We propose to implement a standardized, progressive, multi-component program (PMC) to address this gap in research and clinical practice. The study will be completed concurrently in two SNFs and consist of three periods: 5 month pre-PMC training period, 2 month PMC training period, and 5 month post-PMC training period (Figure 1). We increased the data collection period from 3 to 5 months due to the variability in month to month census at the SNFs. The data from each facility will be pooled into the respective time period to dilute the effects of facility variability. Given the high turnover of patients in SNFs (average length of stay ~21 days), the analysis will consist of independent 2-sample t-tests. During pre and post PMC training periods, measures of physical function will be assessed on all patients weekly and at discharge from SNF. Any hospitalizations or emergency room visits and falls will be obtained from the medical record and documented. The discharge location of all patients will be documented. The length of stay will be recorded, but given the current reimbursement model, the average length of stay is not expected to change with implementation of PMC.



I. **Hypotheses and Specific Aims**:

Specific Aim 1: To determine if the group in the post-PMC training period demonstrates better physical function, as measured by *gait speed* (primary outcome), timed-up-and go test (TUG), and the Short Physical Performance Battery (SPPB) compared to pre-PMC training period.

Hypothesis 1: Patients in the post-PMC training period will demonstrate greater improvements in gait speed, TUG, and SPPB at time of discharge from SNF (primary endpoint) compared to the group in the pre-PMC training period.

Specific Aim 2: To determine if the group in the post-PMC training period demonstrates improved rates of discharge to the community from SNF facilities and lower hospital re-admission rates compared to pre-PMC training period.

Hypothesis 2: Following the post-training PMC period, patients will demonstrate higher rates of discharge to the community and have a lower frequency of hospital re-admissions during SNF stay compared to the pre-PMC training period.

II. **Background and Significance**:

Increased Costs and Resource Allocation in SNFs

Following hospitalization, older adults experience rapid declines in functional mobility.[8,9] Patients who are discharged to skilled nursing facilities (SNFs) participate in rehabilitation programs while being monitored by trained physicians and nurses to prepare for return to home or prior level of function. However, 24% of patients in a SNF will be readmitted to the hospital and 68% will be discharged at a lower level of function compared to pre-hospitalization levels, which calls for a change in current clinical practices across multiple health care providers in SNFs.[1] Physical mobility has been suggested to be a strong predictor for hospitalization readmission; [10-13] in fact those with lower levels of physical

activity are six times more likely to be re-hospitalized.[6] Rehabilitation services provided by physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) have the potential to impact physical function outcomes, discharge to community, and rates of rehospitalization. Though these effects have not been consistently observed in combination under usual care or specifically attributed to therapy services. [6,13,14,15,3,16] Observational data suggests patients are inactive more than 80% of the day and participate in conservative rehabilitation interventions over the course of their SNF stay, which may contribute to the persistently high rates of re-hospitalization, institutionalization, and poorer functional outcomes. The perpetuation of inactivity and use of conservative interventions presents an opportunity to develop and implement progressive, multi-component rehabilitation protocols that have the potential to impact practice patterns and outcomes in SNFs.

Lack of standardized care

Currently, there is little standardization of overall care across facilities and regions, which likely contributes to varying outcomes and increased costs. SNF care consists of a multi-faceted approach from a variety of health care disciplines. Thus, attention to the quality of care from individual disciplines and interaction between disciplines could contribute to improvements in the overall care quality and subsequent outcomes. Rehabilitative therapy constitutes a pivotal role in facilitating a patient's return to previous level of activity and participation. However therapy sessions only comprise ~2-3 hours or 6-13% of a patient's day and are generally dosed at a poorly defined intensity.[17-20] Therefore, greater concentration needs to be given to the quality and effectiveness of therapy interventions to induce greater gains within a shorter time. The reduced amount of time with a skilled therapist also diminishes the total activity or mobilization completed per day, which raises concern for further detrimental sequela stemming from immobility.

Limitations with Conservative Rehabilitation Approaches

In the literature, the definition of treatment intensity is variable and ranges from a monitoring of total therapy time per session, time per activity, total therapy time per LOS, magnitude of activity counts with accelerometers or effort (% maximum).[15,17-27] This evidence does give insight into the quality of the intervention and the amount of physiologic effort needed to complete activities. A preponderance of evidence exists which demonstrates the beneficial and safe effects of strength and aerobic training in older adults with and without chronic diseases. [28,29,30,31] These benefits also extend to adults over 80 years old and frail individuals.[32,33,34,29] In addition, the benefits of strength and aerobic training have been demonstrated in older adults with chronic conditions such as CHF, COPD, cancer, PVD, obesity, HTN, osteoporosis, CVA, dementia, osteoarthritis, hip fracture, joint arthroplasty, DM II, sarcopenia.[35,36,37] Patients with the aforementioned conditions are commonly seen in SNF, though our observational data revealed limited use of strength and aerobic training principles during the course of usual care, which may impede maximal recovery of function. Furthermore, whether the beneficial effects of strength on function can be observed within the average 21 day stay in a SNF has yet to be evaluated. The focus on progressive, multi-component rehabilitation programs extends previous work being done by our lab which indicates increasing the complexity or effort during rehabilitation interventions-- including strengthening, balance and functional mobility training-- is safe, feasible, and improves outcomes in home and outpatient physical therapy settings.[38,39] In our proposed study we will incorporate progressive strengthening, mobility, and aerobic interventions into a multi-faceted approach that provides carryover into performance of challenging functional tasks in multiple

environments. **This approach is novel in 1) the application of progressive exercise programs designed using the American College of Sports Medicine Guidelines to older adults in SNF settings and 2) the intervention occurs within current Medicare reimbursement guidelines for SNFs.**

Culture of Inactivity

In addition to progressive therapeutic interventions, education and training on graded mobility guidelines for allied health disciplines (nursing, aides) will promote a culture of mobility to prepare patients for return home or decrease burden of care. A major goal of rehabilitation in the SNF setting is to prepare individuals for return to the community and presumably tolerate community levels of activity and participation. Low levels of physical activity have been connected to mortality rates and further health complications in acute care settings. That being said, evidence suggests patients in SNFs are ~80% less active compared to community-dwelling, older adults and, when active, do not engage in activity at a moderate intensity adequate for systemic adaptations.[4,40,3] Barriers to mobilization by nursing staff may include perceived safety risk (falls, adverse acute events with exercise), staff shortages, lack of formal training on safety and equipment use, time constraints, etc. Nursing care directed at promoting independent self-cares and completion of exercise or walking programs may foster increased motor learning through high repetition practice, improved self-efficacy, and increased habitual activity.[17,41] Enhanced motor learning, increased self-efficacy and improved mobility which can contribute to functional gains and increased preparedness in completion of instrumental and basic daily activities after discharge.[17,41] **The implementation of a practical framework from which multiple disciplines can become involved in promoting activity outside of therapy sessions is a novel approach to reducing the detrimental sequelae stemming from the perpetuation of inactivity in SNFs**.

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

Preliminary Data in Home Health Settings

Our research group has conducted a preliminary investigation on the feasibility and safety of implementing a similar PMC program during home physical therapy sessions (manuscript in review). Patients who receive home physical therapy are often medically-complex and at high risk for re-hospitalization, which makes this population comparable to the proposed SNF population.

For the preliminary work, patients were recruited from the University of Colorado hospital (n=22) and randomized into the PMC intervention group or usual care (UC). Treatment of both groups occurred over the course of ~30 days with a total of 8-10 treatment sessions, which is consistent with current reimbursement guidelines and home health practice. Measurements of gait speed and short physical performance battery (SPPB) were assessed at baseline, 30 days (end of treatment), and 60-day follow-up (primary endpoint). Preliminary data from this investigation provides compelling evidence that implementation of the PMC intervention results in 1) substantially improved physical function over a short duration, 2) sustainability of improvements at 30 and 60-days post discharge, and 3) no increased risk for injury.

Results: PMC resulted in a 60% improvement in function at 60 days compared to only 9.7% improvement with UC. For walking speed, a 0.1m/s difference in walking speed represents substantial meaningful change, and we saw differences almost **twice this large** in our preliminary data. In fact, 30% of patients in the PMC group achieved >1.0m/s

walking speed (threshold for independent community ambulation) at 60 days; no UC group patients achieved this walking speed threshold. A one-point difference in the SPPB represents substantial meaningful change, and we saw differences **twice this large** in our preliminary data. In fact, PMC resulted in a 60% improvement in function at 60 days compared to only 9.7% improvement with UC. Importantly, both groups received a comparable number of visits. In the usual care group there were 4 total episodes in (3 re-hospitalizations, 1 emergency room visit), while the PMC group had only 1 emergency room visit. Furthermore, these results provide evidence for the investigative team's experience managing medically complex patients using the proposed intervention strategy to promote favorable outcomes.

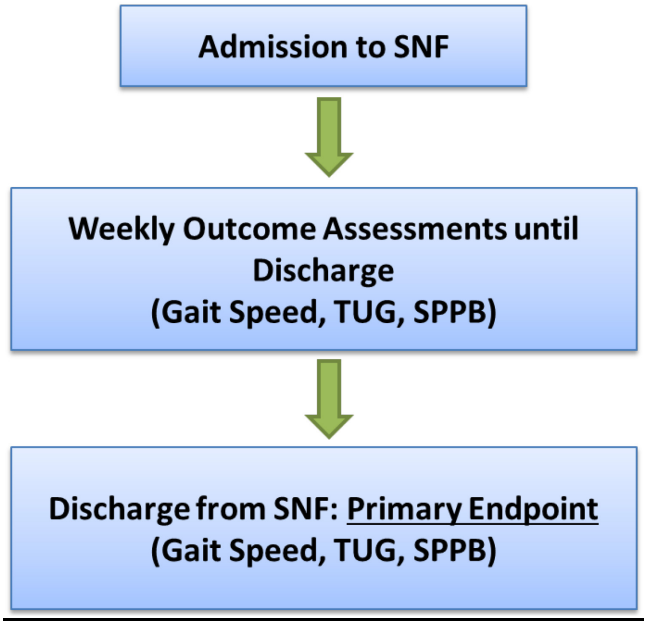
IV. Research Methods

A. Outcome Measure(s):

During both the pre-PMC and post-PMC training periods, a trained Certified Nursing Assistant (CNA) (blinded) will assess gait speed, TUG, and SPPB within 24-48 hours of admission to SNF. If the CNA is unable to assess within 24-48 hours of admission, then the physical therapist performs the assessments. The occupational therapist will administer the Mini Mental Status Scale to assess baseline cognitive status within 24-48 hours of admission to SNF. A trained CNA (blinded) will continue to perform functional assessments (gait speed, TUG, SPPB) weekly and at discharge from SNF (Figure 2). Physical therapists (PTs) and physical therapist assistants (PTAs) will perform weekly and discharge assessments as necessary.

Interventions: During the 5-month pre-PMC training period (baseline), all current patients at the SNF will receive usual care treatment as facility therapists will practice per current standard of care. We will collect pre-PMC training data for 3 months or until collection of data on 602 patients (half the number of patients approved to be consented) (Figure 1). Therapists will then be trained on the PMC intervention for 2 months. After training, the facilities and individual therapists will decide how to implement such care at their discretion. Following the training period, we will collect post-PMC training data for 5 months or until collection of data on 602 patients (half the number of patients approved to be consented) (Figure 1). The data collected in all facilities during the pre-PMC training period will be pooled into one group to dilute the effect of facility variability. The data collected during post-PMC training period will be pooled in the same way.

Figure 2. Outcome Measure Assessments Time points



Outcomes: All testing will occur at the SNF by facility PTs, PTAs, OTs or a trained CNA (blinded). Primary Outcome: **Gait speed** will be measured by the time it takes to walk a 4-meter path. Time will be measured with a stopwatch to the nearest hundredth of a second. This measure was selected as the primary outcome because: 1) it has been shown to predict risk of mobility and physical disability, higher health care utilization and increased mortality; [42,43] 2) it has been established as a meaningful outcome measure in older persons with a wide range of conditions; 3) it is a valid and reliable measure; [44,45] 4) it is easily understood by patients, their families, providers and health care policy makers (good face validity); and 5) it is easily performed in the home and well tolerated by patients varying in condition and degree of health. Secondary Outcomes: The **Timed Up And-Go (TUG)** test will be performed on each patient as a measure of basic mobility skill and evaluation of fall risk. [46] The TUG test well established cut-off scores to indicate falls in both frail and community dwelling older adults. The TUG has excellent inter-rater reliability, and is responsive to changes in mobility status.[47,48]The **Short Physical Performance Battery (SPPB)** is a well-accepted global measure of lower extremity function, which consists 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.[49] The test takes ~10-15 minutes to administer and was designed to be administered in a setting with limited space. The battery has an excellent safety record as it has been administered to well over 10,000 persons in various studies. The SPPB components and total score are derived from normative values obtained from a population-based study. The reliability of the individual components, as well as the summary score of the SPPB, are good with intra class correlation coefficients (ICC) >0.88 and good sensitivity to change.[50] The continuous scoring system minimizes ceiling effects and scores range from 0-12 with higher scores indicative of better performance.

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.
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; all data will be de-identified. These characteristics include age; gender; race; history of comorbidities, medications, primary diagnosis for hospital admission; length of skilled nursing facility stay; complications in hospital and length of stay.

Qualitative data will be collected through voluntary focus group discussions consisting of therapists in the SNFs with current IRB approval (Brookdale Mountain View, Veterans Community Living Center at Fitzsimons, PowerBack Rehabilitation, Gardens on Quail, Good Sam-Ambassador, Villa St. Louis Park). The data collected will inform future refinement of the PMC program for large-scale dissemination.

B. Description of Population to be Enrolled:
Patients will be enrolled from four SNFs in the Denver metro area: **Gardens on Quail, Brookdale Mountain View, Veterans Community Living Community at Fitzsimons, and Powerback Rehabilitation; and two in Minnesota: Good Sam-Ambassador and Villa St. Louis Park.** All patients temporarily residing in the designated SNFs will receive the current standard of care during the 5-month pre-PMC training period. Outcomes data will be collected for all patients who are admitted and discharged during the 5-month pre-PMC training period. Once SNF staff have been trained on the PMC protocol (2-month period), all patients will receive the PMC intervention (post-PMC training period) as the new standard of care per therapist discretion, unless contraindicated. Outcomes data will be collected for all patients who are admitted and discharged during the 5month post-PMC training period. All patients will receive the respective intervention (current standard of care or PMC) until discharge from the SNF. Outcomes data will only be collected on patients who fit the inclusion criteria: adults older than 18 years of age who are admitted to a skilled nursing facility and receive at least physical or occupational therapy. Exclusion criteria: Patients with neurological disorders, such as a stroke or traumatic brain injury, will be excluded as the best practice for managing these patients is based on motor-control theory versus the proposed 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.

Up to 30 therapists will be recruited from the Gardens on Quail, Brookdale Mountain View, Veterans Community Living Center at Fitzsimons, Powerback Rehabilitation, Good Sam-Ambassador, and Villa St. Louis Park staff who have been trained in the PMC intervention.
Inclusion criteria: Trained in PMC intervention, provided PMC intervention to patients at Gardens on Quail, Brookdale Mountain View, Veterans Community Living Center at Fitzsimons, Powerback Rehabilitation, Good Sam-Ambassador, and Villa St. Louis Park.
Exclusion criterion: Decline to participate.

C. Study Design and Research Methods

This study is a preliminary investigation using a pre-post training design in six SNFs (Figure 1). We will pool the data across the six SNFs into the pre and post-PMC training periods to dilute the effect of facility variability. Given that the average length of stay in a SNF is 21 days, the pre/post PMC training design will consist of two independent samples of patients to include only those that were admitted and discharged within a given period. As we get interest from additional facilities, we may submit an addendum to include them. Additional sites would help inform sample size estimates for a potential future, cluster-randomization study design. During the 5-month pre-PMC training period, the rehabilitation therapists will treat patients per the current standard of care and a trained CNA (blinded) or PT/PTA (as necessary) will collect outcomes data at admission, weekly, and at discharge. Then, training on the PMC intervention will occur over a 2-month period. Any patients admitted or discharged in the SNF during the PMC training period will not be used. During the 5-month post-PMC training period, therapists will implement the PMC protocol and collect outcomes data as indicated previously (Figure 1).

The medical records will provide information on prior level of function, age, other medical conditions, **re-hospitalization** and **emergency room visits**, medications, sex, admitting diagnosis, **falls**, SNF length of stay, **discharge location**, evaluation and treatment documentation.

Five focus group discussions of 4-6 therapists each will follow an interview guide and last a duration of approximately 1 hour. Therapist participation is voluntary, and all participants will be asked for informed consent. Discussions will be recorded and transcribed for content analysis.

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

Veteran data will be managed and stored on VINCI RedCap and VA server. Non-Veteran data will be collected and managed using REDCap (Research Electronic Data Capture). Study data will be collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium which includes University of Colorado–Denver and was initiated at Vanderbilt University. The database is hosted at the University of Colorado–Denver Development and Informatics Service Center (DISC), which will be used as a central location for data processing and management. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the *DISC*. This iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap also includes a powerful tool for building and managing online surveys. The research team can create and design surveys in a web browser and engage potential respondents using a variety of notification methods. REDCap is flexible enough to be used for a variety of types of research and provides an intuitive user interface for database and survey design and data entry.[51]

Patients in either training period may experience muscle soreness after the first few sessions. The soreness typically does not last more than 2-3 days and does not damage the muscle. The physical therapist will instruct the patient on the proper use of superficial heat or ice if muscle soreness occurs. A minimal risk for falls exists for patients receiving either intervention strategy (pre-PMC or post-PMC). This minimal risk is no different than the risk that is normally present during rehabilitation interventions or walking/moving around with assistance in the SNF.

The outcome measures specified are used in a variety of rehabilitation settings under current reporting and standard of care practices. Furthermore, some physical therapists already use the treatment principles included in the PMC intervention. Therefore, these treatment options are already implemented safely in some settings. Yet without concrete evidence to support the effectiveness of the PMC approach, it is not possible to change the standard of practice on a larger scale to improve the quality of care in this patient population.

E. Potential Scientific Problems:

There are some limitations that will need to be addressed in future studies. There are a large number of therapists treating patients, but we have methods in place for training to ensure ongoing procedural reliability across sites as a larger number of therapists/sites increases the generalizability of the results. We also acknowledge the heterogeneity in the patient population. While this could dilute the effect of the intervention, we will be then able to determine if the intervention is effective in a wide variety of patients or perhaps more effective in an identified sub-group. This will help guide therapists in future treatment plans.

F. Data Analysis Plan:

Analysis

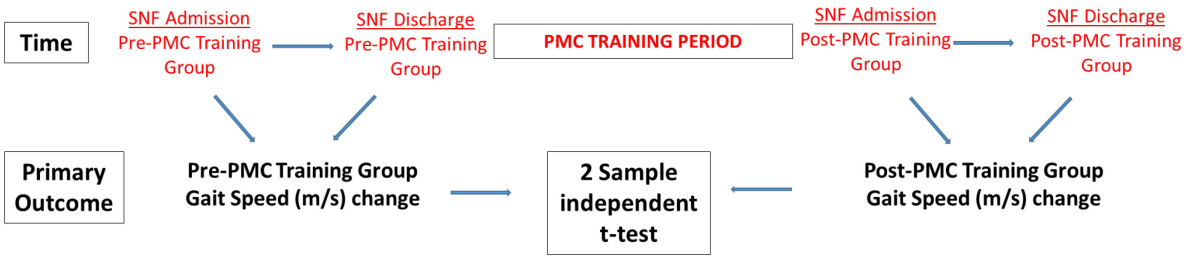
Primary and Secondary Outcomes*:* **The primary outcome (Aim 1) for this study is the change in gait speed between admission and discharge from a SNF. The change in gait speed will be pooled across the six facilities for the two respective time periods (pre and post PMC training).** The mean **change in gait speed** for the independent group of patients tested during the pre-PMC training period will be assessed and compared to the mean change in gait speed for the independent group of patients during the post-PMC training period.

Secondary outcomes include physical function measures (SPPB, TUG) and health care utilization outcomes (emergency room visits, falls, skilled nursing home length of stay, and re-hospitalizations), which will be recorded weekly and at discharge from SNF. Preliminary descriptive and graphical analyses (including boxplots, scatterplots, profile plots to examine change over time) will be used for data cleaning and visualization of primary and secondary outcomes.

Primary Analysis: The primary analysis will be an intent-to-treat comparison of change in gait speed from SNF admission to discharge between 2 independent groups of patients (pre and post-PMC training groups). Statistical inference regarding the difference between pre and post-PMC training groups will be based on independent sample t-tests. Comparisons will be made on changes in outcome measures (admission to discharge)

within pre/post PMC training groups. Groups of patients will be pooled from all facilities to form 2 independent samples for comparison of time periods (pre and post PMC training) (See Figure 3). The conclusion about the statistical significance of differences between pre/post groups will be determined by this single statistical test to protect against an elevated risk of false positive conclusions.

Figure 3. Data analysis plan



*Secondary Analyses (**Aim 2**):* We will estimate health care utilization outcomes rates (falls, emergency department visits, skilled nursing home length of stay or re-hospitalizations) for each pre/post PMC training period and compare rates between arms using a likelihood ratio test.

The characteristics of the time trajectory (weekly and at discharge from SNF) for treatment effects will also be analyzed in secondary analyses to inform the development of methods to improve long-term outcomes. The analytic methods will include maximum likelihood estimates from a repeated measures model of the mean effect of gait speed at each of the measurement times. The trend in means will be evaluated using a linear contrast as the summary measure of greatest interest. This approach will evaluate whether there are differences in the first-order trends (slope) between the pre/post PMC training groups. The evaluation of the time trajectory will be conditioned on the stratification variables and the baseline value of gait speed.

The qualitative study will be conducted after quantitative data collection for the parent study has been completed to better understand the process of implementation for future refinement of the program. The audio from the focus group discussions will be transcribed either by two study team members or by Transcription Outsourcing. Two coders will review the transcription and develop a code book in an iterative process until both coders reach agreement. Coded transcripts will be analyzed to identify barriers and facilitators to implementation of PMC.

Sample Size Estimates

Statistical power was estimated based on the results of a home-health pilot study of 22 participants: 10 were randomized to PMC, 12 to the usual care interventions. The home health population is similar to the SNF population given both experienced a recent acute hospitalization and subsequent decline in function. However, we anticipate patients in SNF will have less gain in gait speed compared to home health participants because the significant decline in function demonstrated in the patients in SNFs has rendered them unable to manage in the home. Therefore, we used the following results for the power analysis: means ± standard deviations (SD) of 0.31 ± 0.29 feet for PMC and 0.13 ± 0.12 for usual care. For the power analysis we used a SD of 0.29 and mean difference of 0.14, which is the midpoint between 0.1 (clinically significant difference) and 0.18 (the difference

of the means of from the home health study). Thus, a sample size of 184 patients completing the study (92/group) will provide 90% power (**assuming the same SD in both groups to be conservative**) to detect differences at least that great. This estimate is conditional upon using a 1-sided, alpha = 0.05 level 2-group t-test.

. Of the sites currently listed under COMIRB 14-2388, we have not begun collecting data at Powerback Rehabilitation. Powerback is a growing facility that, on average, provides rehabilitation services to 120 patients a day. Approximately 2/3 of patients will likely be appropriate for the intervention; thus, across a 10-month data collection phase, we will require an increase in enrollment numbers to 800. Our current number approved is 434, so a total of 1,234 is being requested for approval to accommodate the large numbers of patients being seen for rehabilitation at Powerback. While this exceeds our initial sample size estimates, each facility has more variability than we anticipated (e.g., patient population, ratio of PTs to PTAs, rehab coverage on weekend, in house vs contracted rehab services). Therefore, additional facilities are necessary to better determine the variability of patient outcomes across different types of facilities for a future, multi-site pragmatic clinical trial. Furthermore, anticipated funding through the VA requires us to include facilities with Veterans (e.g., Veterans Community Living Center at Fitzsimons).

G. Summarize Knowledge to be Gained:

Rehabilitation therapy is known to help improve function in older adults after an acute functional decline. However, we do not know if there is an additional benefit to implementing a progressive program with an emphasis on activity throughout the day in the SNF setting. Effective rehabilitation interventions in SNFs can improve function in adults, which allows patients to return to prior level of care and location. This study has the potential to not only improve individual functional outcomes but also increase community discharge rates and reduce hospital readmissions. The alternative treatment is to choose a different skilled nursing facility (non-research site) which employs a different standard of care.

H. References:

1. Health Care Spending and the Medicare Program. In: Commission MPA, ed. Washington DC2013.
2. Skilled Nursing Facility Services. In: Commission MPA, ed2013.
3. Peiris CL, Taylor NF, Shields N. Patients receiving inpatient rehabilitation for lower limb orthopaedic conditions do much less physical activity than recommended in guidelines for healthy older adults: an observational study. *Journal of physiotherapy.* 2013;59(1):39-44.
4. Grant PM, Granat MH, Thow MK, Maclaren WM. Analyzing free-living physical activity of older adults in different environments using body-worn activity monitors. *Journal of aging and physical activity.* 2010;18(2):171-184.
5. Smith P, Galea M, Woodward M, Said C, Dorevitch M. Physical activity by elderly patients undergoing inpatient rehabilitation is low: an observational study. *The Australian journal of physiotherapy.* 2008;54(3):209-213.
6. Fisher SR, Kuo YF, Sharma G, et al. Mobility after hospital discharge as a marker for 30-day readmission. *The journals of gerontology. Series A, Biological sciences and medical sciences.* 2013;68(7):805-810.
7. Miller EA, Weissert WG. Predicting elderly people's risk for nursing home placement, hospitalization, functional impairment, and mortality: a synthesis. *Medical care research and review : MCRR.* 2000;57(3):259-297.

8. Creditor MC. Hazards of hospitalization of the elderly. *Annals of internal medicine.* 1993;118(3):219-223.
9. Sager MA, Franke T, Inouye SK, et al. Functional outcomes of acute medical illness and hospitalization in older persons. *Archives of internal medicine.* 1996;156(6):645-652.
10. Nguyen HQ, Chu L, Amy Liu IL, et al. Associations between physical activity and 30-day readmission risk in chronic obstructive pulmonary disease. *Annals of the American Thoracic Society.* 2014;11(5):695-705.
11. Portegijs E, Buurman BM, Essink-Bot ML, Zwinderman AH, de Rooij SE. Failure to regain function at 3 months after acute hospital admission predicts institutionalization within 12 months in older patients. *Journal of the American Medical Directors Association.* 2012;13(6):569.e561-567.
12. Hoyer EH, Needham DM, Atanelov L, Knox B, Friedman M, Brotman DJ. Association of impaired functional status at hospital discharge and subsequent rehospitalization. *Journal of hospital medicine : an official publication of the Society of Hospital Medicine.* 2014;9(5):277-282.
13. Hoyer EH, Needham DM, Miller J, Deutschendorf A, Friedman M, Brotman DJ. Functional status impairment is associated with unplanned readmissions. *Archives of physical medicine and rehabilitation.* 2013;94(10):1951-1958.
14. Vincent HK, Vincent KR. Functional and economic outcomes of cardiopulmonary patients: a preliminary comparison of the inpatient rehabilitation and skilled nursing facility environments. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* 2008;87(5):371-380.
15. Chen CC, Heinemann AW, Granger CV, Linn RT. Functional gains and therapy intensity during subacute rehabilitation: a study of 20 facilities. *Archives of physical medicine and rehabilitation.* 2002;83(11):1514-1523.
16. Sauter CN, Pezzin LE, Dillingham TR. Functional outcomes of persons who underwent dysvascular lower extremity amputations: effect of postacute rehabilitation setting. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* 2013;92(4):287-296.
17. Jette DU, Warren RL, Wirtalla C. Rehabilitation in skilled nursing facilities: effect of nursing staff level and therapy intensity on outcomes. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* 2004;83(9):704-712.
18. Jette DU, Warren RL, Wirtalla C. The relation between therapy intensity and outcomes of rehabilitation in skilled nursing facilities. *Archives of physical medicine and rehabilitation.* 2005;86(3):373-379.
19. Mallinson T, Deutsch A, Bateman J, et al. Comparison of discharge functional status after rehabilitation in skilled nursing, home health, and medical rehabilitation settings for patients after hip fracture repair. *Archives of physical medicine and rehabilitation.* 2014;95(2):209-217.
20. Munin MC, Putman K, Hsieh CH, et al. Analysis of rehabilitation activities within skilled nursing and inpatient rehabilitation facilities after hip replacement for acute hip fracture. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* 2010;89(7):530-540.
21. Heinemann AW, Hamilton B, Linacre JM, Wright BD, Granger C. Functional status and therapeutic intensity during inpatient rehabilitation. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists.* 1995;74(4):315-326.
22. Karges J, Smallfied S. A description of the outcomes, frequency, duration, and intensity of occupational, physical, and speech therapy in inpatient stroke rehabilitation. *Journal of allied health.* 2009;38(1):E1-10.
23. Lenze EJ, Host HH, Hildebrand MW, et al. Enhanced medical rehabilitation increases therapy intensity and engagement and improves functional outcomes in postacute rehabilitation of older adults: a randomized-controlled trial. *Journal of the American Medical Directors Association.* 2012;13(8):708-712.
24. Seynnes O, Fiatarone Singh MA, Hue O, Pras P, Legros P, Bernard PL. Physiological and functional responses to low-moderate versus high-intensity progressive resistance training

in frail elders. *The journals of gerontology. Series A, Biological sciences and medical sciences.* 2004;59(5):503-509.
25. Singh NA, Quine S, Clemson LM, et al. Effects of high-intensity progressive resistance training and targeted multidisciplinary treatment of frailty on mortality and nursing home admissions after hip fracture: a randomized controlled trial. *Journal of the American Medical Directors Association.* 2012;13(1):24-30.
26. Talkowski JB, Lenze EJ, Munin MC, Harrison C, Brach JS. Patient participation and physical activity during rehabilitation and future functional outcomes in patients after hip fracture. *Archives of physical medicine and rehabilitation.* 2009;90(4):618-622.
27. Yoo JW, Kim S, Choi JH, Ryu WS. Intensified rehabilitation therapy and transitions to skilled nursing facilities in community-living seniors with acute medical illnesses. *Geriatrics & gerontology international.* 2013;13(3):547-554.
28. Mangione KK, Miller AH, Naughton IV. Cochrane review: Improving physical function and performance with progressive resistance strength training in older adults. *Physical therapy.* 2010;90(12):1711-1715.
29. Evans WJ. Exercise training guidelines for the elderly. *Medicine and science in sports and exercise.* 1999;31(1):12-17.
30. Nied RJ, Franklin B. Promoting and prescribing exercise for the elderly. *American family physician.* 2002;65(3):419-426.
31. Avers D, Brown M. White paper: Strength training for the older adult. *Journal of geriatric physical therapy (2001).* 2009;32(4):148-152, 158.
32. Fiatarone MA, Marks EC, Ryan ND, Meredith CN, Lipsitz LA, Evans WJ. High-intensity strength training in nonagenarians. Effects on skeletal muscle. *JAMA : the journal of the American Medical Association.* 1990;263(22):3029-3034.
33. Idland G, Sylliaas H, Mengshoel AM, Pettersen R, Bergland A. Progressive resistance training for community-dwelling women aged 90 or older; a single-subject experimental design. *Disability and rehabilitation.* 2014;36(15):1240-1248.
34. Lihavainen K, Sipila S, Rantanen T, Kauppinen M, Sulkava R, Hartikainen S. Effects of comprehensive geriatric assessment and targeted intervention on mobility in persons aged 75 years and over: a randomized controlled trial. *Clinical rehabilitation.* 2012;26(4):314-326.
35. Chodzko-Zajko WJ, Proctor DN, Fiatarone Singh MA, et al. American College of Sports Medicine position stand. Exercise and physical activity for older adults. *Medicine and science in sports and exercise.* 2009;41(7):1510-1530.
36. Savage PA, Shaw AO, Miller MS, et al. Effect of resistance training on physical disability in chronic heart failure. *Medicine and science in sports and exercise.* 2011;43(8):1379-1386.
37. Nelson ME, Rejeski WJ, Blair SN, et al. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. *Circulation.* 2007;116(9):1094-1105.
38. Bade MJ, Stevens-Lapsley JE. Early high-intensity rehabilitation following total knee arthroplasty improves outcomes. *The Journal of orthopaedic and sports physical therapy.* 2011;41(12):932-941.
39. Petterson SC, Mizner RL, Stevens JE, et al. Improved function from progressive strengthening interventions after total knee arthroplasty: a randomized clinical trial with an imbedded prospective cohort. *Arthritis and rheumatism.* 2009;61(2):174-183.
40. Peiris CL, Taylor NF, Shields N. Additional Saturday allied health services increase habitual physical activity among patients receiving inpatient rehabilitation for lower limb orthopedic conditions: a randomized controlled trial. *Archives of physical medicine and rehabilitation.* 2012;93(8):1365-1370.
41. Heinemann AW, Kirk P, Hastie BA, et al. Relationships between disability measures and nursing effort during medical rehabilitation for patients with traumatic brain and spinal cord injury. *Archives of physical medicine and rehabilitation.* 1997;78(2):143-149.
42. Cesari M, Kritchevsky SB, Penninx BW, et al. Prognostic value of usual gait speed in well-functioning older people--results from the Health, Aging and Body Composition Study. *Journal of the American Geriatrics Society.* 2005;53(10):1675-1680.

43. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB. Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability. *The New England journal of medicine.* 1995;332(9):556-561.
44. Jette AM, Jette DU, Ng J, Plotkin DJ, Bach MA. Are performance-based measures sufficiently reliable for use in multicenter trials? Musculoskeletal Impairment (MSI) Study Group. *The journals of gerontology. Series A, Biological sciences and medical sciences.* 1999;54(1):M3-6.
45. Bohannon RW. Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. *Age and ageing.* 1997;26(1):15-19.
46. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Physical therapy.* 2000;80(9):896-903.
47. Lin MR, Hwang HF, Hu MH, Wu HD, Wang YW, Huang FC. Psychometric comparisons of the timed up and go, one-leg stand, functional reach, and Tinetti balance measures in community-dwelling older people. *Journal of the American Geriatrics Society.* 2004;52(8):1343-1348.
48. van Iersel MB, Munneke M, Esselink RA, Benraad CE, Olde Rikkert MG. Gait velocity and the Timed-Up-and-Go test were sensitive to changes in mobility in frail elderly patients. *Journal of clinical epidemiology.* 2008;61(2):186-191.
49. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *Journal of gerontology.* 1994;49(2):M85-94.
50. Pahor M, Blair SN, Espeland M, et al. Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study. *The journals of gerontology. Series A, Biological sciences and medical sciences.* 2006;61(11):1157-1165.
51. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics.* 2009;42(2):377-381.