Project Title
Synergizing home health rehabilitation therapy to optimize patients' activities of daily living

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Conflict of interest
All the investigators declare no conflict of interest.

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Abstract
Regaining the ability to take care of oneself after an illness or medical episode is critical for older adults to maintain independent living at home in the community. Each year, 3 to 4.5 million older adults receive home health care services that provide skilled rehabilitation therapy in their home. These patients experience reduced capacity to perform activities of daily living (ADL) independently, which is a significant risk factor for long-term care placement. Recent data has shown that nearly 40% of home health patients do not improve in ADL at discharge. There is currently a lack of evidence-based rehabilitation programs in home health. Increasing activity-based intervention in home health care rehabilitation could be the key to improve patients' ADL independence. The objective of this study is to pilot test an ADL-enhanced program as an adjuvant therapy to usual home health rehabilitation to improve patients' ADL outcome. The ADL-enhanced program facilitates patients' participation in ADL first by lowering the task demand using a compensatory approach. As the patient increases physical capacity, the ADL-enhanced program shifts to a restorative approach, which increases the task demand to help the patient channel the improved physical capacity to better activity performance. Our specific aims were to: 1) estimate the preliminary effect of the ADL-enhanced program on improving ADL; 2) estimate the preliminary effect of the ADL-enhanced program on improving physical functioning of the upper extremity and the lower extremity; and 3) assess the program completion rate, satisfaction rate, and adverse event rate (e.g., falls and hospital admissions).

Study Objectives

Primary Objective.

The primary objective is to estimate the preliminary effect of the activities of daily living (ADL)-enhanced program on improving ADL at treatment completion, one month, and 3 months after the completion.

Hypothesis: Patients who receive the ADL-enhanced program plus usual rehabilitation therapy will show greater improvements in the Motor Skills scores of the Assessment of Motor and Process Skills (the primary outcome), Self-care items in the Outcome and Assessment Information Set (clinical outcome), and Activity Measure for Post-Acute Care Home Health Short Form (patient-reported outcome) at treatment completion and less decline at 1-month and 3-month follow-up than usual rehabilitation therapy.

Secondary Objectives.

Secondary objective 1: To estimate the preliminary effect of the ADL-enhanced program on improving physical functioning at treatment completion and one month after the completion.

Hypothesis 1: Patients who receive the ADL-enhanced program plus usual rehabilitation therapy will show greater improvements in the Box and Block Test (upper extremity physical function), Jebsen Hand Function Test (upper extremity physical function), Timed-Up-and-Go Test (lower extremity physical function), and Short Physical Performance Battery (lower extremity physical function) at treatment completion and less decline at one-month follow-up than usual rehabilitation therapy.

Secondary objective 2: To assess the completion, satisfaction, and adverse event rates of the ADL-enhanced program.

Hypothesis 2a: We hypothesize that the program completion and satisfaction rates will be greater than 75%.

Hypothesis 2b: Fewer patients who receive the ADL-enhanced program will have hospitalizations, emergency room visits, and falls than patients who receive usual rehabilitation therapy at 1-month and 3-month follow-up.

Background and Rationale

Preserving older adults' ability to perform activities of daily living (ADL) is critical to reducing risks of hospital admission and readmission, long-term care placement, and mortality, especially after an acute hospital stay or illness when they experience an ADL decline. Each year, 3 to 4.5 million U.S. patients receive home health care (HHC), which provides in-home skilled rehabilitation services to homebound patients. These patients are often of advanced age and with multiple chronic conditions, poor health, and worsened functional status. A recent study indicates that 6% of HHC patients show no improvement in ADL status, and 36% show a decline in ADL status from admission to discharge. Numerous community-based intervention trials have provided strong evidence of two intervention approaches to reduce ADL disability in frail older adults: (1) **the compensatory approach** reduces the demands of the patient's intrinsic capacity to perform activities through home or task modifications (e.g., adding a shower bench or taking a sponge bath by the sink); (2) **the restorative approach** increases a patient's intrinsic capacity to perform activities through exercise (e.g., resistance exercise to improve leg strength). However, neither approach has been tested in the HHC setting.

Our proposed ADL-enhanced intervention is innovative because it delivers the compensatory approach first in HHC rehabilitation services to help the patient engage in ADL tasks immediately, followed by the restorative approach to increase the patient's intrinsic capacity needed to perform activities. Additionally, the restorative approach incorporates principles of activity grading and motor learning to help older adults translate muscle strength from resistance exercise into greater ADL performance.

In this proposed pilot randomized controlled trial, we will test the preliminary effects of the innovative ADL-enhanced program, which combines the compensatory approach and restorative approach in six OT visits to boost usual rehabilitation services on the ADL outcome in enrolled HHC patients.

Study Design

Study design overview. This is a single-blinded, pilot randomized controlled trial of 48 Medicare patients referred to HHC for skilled rehabilitation services Twenty-four patients will be randomly assigned to the treatment-as-usual arm and receive usual rehabilitation services. The other 24 patients in the experimental arm will receive the ADL-enhanced program in six OT visits as well as usual rehabilitation services.

Selection and Enrollment of Participants

Participants will be recruited from partnered home health agencies

Inclusion criteria. Patients are eligible to the study if they are:

(1) ≥ 65 years of age,
(2) Medicare beneficiaries,
(3) referred for skilled rehabilitation services; and
(4) diagnosed with three or more comorbidities.

Exclusion criteria. Patients are ineligible if they have contraindications for moderate-intensity exercise, which include:

- acute fractures with surgical or weight-bearing restrictions,
- elective joint replacement surgery,
- lower extremity amputation,
- active treatment for cancer diagnosis,
- on-going dialysis treatment,
- acute cardiac surgery,
- acute stroke or a major neurologic disorder limiting motor movements,
- terminal stage of congestive heart failure,
- a referral to hospice care, or
- severe cognitive deficits limiting verbal communication.

Enrollment Procedures.

Screening procedure. The home health care team will obtain verbal permission from new patients to allow the research coordinator to contact and screen the new patients via phone. The coordinator will record the screening results (fail or pass) on a screening log. The coordinator will call the eligible patient, verify the eligibility, and introduce the study.

Consent procedure. The coordinator will then conduct a recruitment home visit to the eligible patient and obtain consent at the end of the visit. If the patient does not provide consent during the recurrent home visit but decides to participate in the study afterwards, a study outcome assessor will obtain consent at the beginning of the baseline assessment visit. Reasons of rejection will be recorded.

Patients who are eligible and agree to participate will be referred to the study outcome assessor, who will schedule the patient within 48 hours to obtain the consent, if not yet obtained by the research coordinator, and complete the baseline assessments (ADL and physical functioning assessments) at the participant's home. The assessor will be blinded to group assignments.

Randomization procedure. Dr. Qiu (Co-I) will generate a randomization list using a computer software and seal the list in opaque envelopes. The on-site research coordinator will open one envelope after a patient has completed the baseline assessments. If the patient is assigned to the ADL-enhanced group, the coordinator will notify the study OT to start intervention.

Study Intervention.

Description of ADL-enhanced intervention. The experimental arm will receive the enhanced-ADL program in 6 home visits from a study OT in addition to usual rehabilitation therapy. The 6 study visits will be delivered over

a 6-week period. The study OT visits will occur separately from usual therapy visits. If the patient cancels a study OT visit, the visit will be rescheduled. The patient will have a 21-day window to resume the intervention. The study OT will apply the compensatory approach in the first 2 visits and the restorative approach in the other 4 visits. Both approaches respect and incorporate the patient's activity preferences in the patient-centered treatment plan. The study OT and the patient collaborate to identify and address ADL tasks that are important and meaningful for the patient's independence.

Compensatory approach procedures. The study OT will conduct a semi-structured interview in the 1st visit to understand the patient's daily routine and to identify two or three ADL tasks that are meaningful but difficult for the patient because of reduced intrinsic capacity. The study OT and the patient collaboratively decide which energy conservation techniques to apply. The patient practices applying these techniques to the selected ADL tasks. The patient is instructed to carry out these ADL tasks with practiced energy conservation techniques until the next visit.

Restorative approach procedures. The study OT will deliver the restorative approach starting at the 3rd visit. The selected self-care tasks include any in-home activities that the patient does to take care of self and others, which are not limited to basic ADL. In the beginning of each visit, the study OT and the patient together identify 2 or 3 activities where the patient has experienced limitations or difficulties. The study OT will apply one or two activity grading principles to each selected activity. The intervention intensity will be kept at the moderate level (somewhat hard) using the Omni Scale, which is a rated perceived exertion scale. For example, if a patient experiences difficulty to returning pantry items to overhead shelves, the study OT can let the patient wear a weighted wrist cuff while sorting pantry items (increase the load), restore items to an overhead versus shoulder-high shelf (increase the movement distance), restore items into different locations on the shelves (change of movement direction), speed up while storing items (increase the movement speed), store 10 pantry items versus store five items at a time (increase the endurance), or carry groceries with a shopping bag and store pantry items from the groceries to the overhead shelves (increase the activity complexity by combining two tasks, carrying groceries and sorting the pantry items after shopping). Patients will practice each selected task for 15 to 20 minutes with a rest break if needed.

Allowed interventions. All participants will receive the care plan approved by their home health agency. The care plan should include regular home health rehabilitation therapy.

Adherence Assessment. The adherence for the ADL-enhance intervention will be evaluated by the number of sessions that the patient is able to complete within the study period (60 days).

Study Procedures.

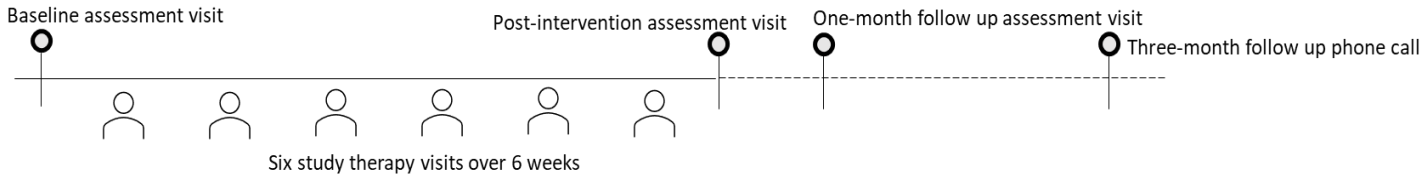
6.1. Schedule of Evaluations.

	Baseline	Post-intervention (Post intervention ± 7 Business days)+	One-month follow-up (Day 30 post intervention ± 7 Business days)	3-month follow-up (Day 90 post intervention ± 7 Business days)
Assessment of Motor and Process Skills	x	x	x	
Activity Measure for Post-Acute Care Home Health Short Form	x	x	x	x
OASIS self-care items from chart review	x	x		
Box and Block Test	x	x	x	
Jebsen Hand Function Test	x	x	x	
Timed-Up-and-Go Test	x	x	x	
Short Physical Performance Battery	x	x	x	
PEG three-item scale	x			
Patient Health Questionaire-9	x			
Saint Louis University Mental Status Exam	x			

Patient demographic background and medical info from self-report as well as chart review	x			
Patient satisfaction survey		x		
Adverse events (hospitalization, falls, emergency room visits)		x	x	X

+: The end of ADL-enhanced program, the last home visit of usual care, or 6 weeks from the baseline assessment, which occurs last.

Study visit schedule.



Description of Evaluations.

Screening evaluation.

The screening will occur over the phone within three business days after a home health care provider has mentioned the study opportunity to the patient and received verbal permission from the patient for the research coordinator to contact him/her. The research coordinator will follow a phone script approved by the UF IRB for this phone screening. The coordinator will obtain a verbal permission prior to proceeding with screening questions from the potential research participant after a brief introduction of the study. These screening questions are:

1. Are you aged 65 years or above?

2. How many medical conditions, including chronic conditions, that you currently have? Examples of the conditions include but not limit to diabetes, heart disease, high blood pressure, joint disease or arthritis, and lung disease.

3. Do you have any of the following conditions?

- an elective joint replacement surgery in the last month
- orthopedic or heart surgery in the last month
- lower extremity amputation
- currently receiving treatment for cancer
- an ongoing dialysis treatment
- a neurologic condition, such as stroke or Parkinson's disease, that significantly limits your movements
- congestive heart failure that is at the terminal stage

In addition to these questions, the interviewer will administer the "Six-item cognitive screener" to determine the potential participant's cognitive ability. If a participant scores a 4, 5, or 6 on the screener, they will be eligible for the study.

Enrollment, baseline, and randomization.

Enrollment. A patient is considered enrolled in this study when he or she meets the eligibility criteria and signs the informed consent form.

Consenting process. If the patient passed the screening, the research coordinator will then conduct a recruitment home visit to the eligible patient within five business days. During the visit, the coordinator will provide the patient with a detailed description of the research study and go over the informed consent process. If the patient does not provide consent during the recurrent home visit but decides to participate in the study afterwards, a study outcome assessor will obtain consent at the beginning of the baseline assessment visit. If the patient decided not to enroll, the reason(s) of rejection will be recorded.

Baseline assessment. The enrolled patient will be then referred to the study outcome assessor, who will schedule the patient to obtain the consent, if not yet obtained by the research coordinator, and complete the baseline assessments at the participant's home. The baseline assessment should occur within seven business days of the recruitment visit. The assessor will be blinded to patient group assignments. The blinded outcome assessor will conduct the following assessments during the baseline evaluation visit. These assessments are listed in suggested order. The outcome evaluator will alternate between self-reported assessments and performance-based assessments as well as upper extremity performance tests and lower extremity performance tests to reduce the testing burden for patients. Additionally, short breaks (one to five minutes) between assessments will be provided to patients as needed.

1. Demographic information of age, gender, race/ethnicity, chronic conditions, and number of medications
2. Assessment of Motor and Process Skills
3. Activity Measure of Post-Acute Care Home Health Short Form
4. Jebsen Hand Function Test
5. Box and Block Test
6. PEG three-item scale
7. Patient Health Questionnaire-9
8. Timed-Up-and Go
9. Short Physical Performance Battery
10. Saint Louis University Mental Status Exam.

The research coordinator will extract the patient's OASIS self-care item scores (scores at the start of care and discharge) from medical chart when the patient has been discharged from home health care or 60 days after admission.

Randomization. Randomization will occur after the baseline assessment. Dr. Qiu (Co-I) will generate a randomization list using a computer software and seal the list in opaque envelopes. The on-site research coordinator will open one envelope after a patient has completed the baseline assessments. If the patient is assigned to the ADL-enhanced group, the coordinator will notify the study OT to start intervention.

Post-intervention evaluation.

The satisfaction survey will be given to the patient in the experimental group after the last visit of ADL-enhanced intervention by the research coordinator over the phone.

For the group that will receive the ADL-enhanced program, the post-intervention evaluation conducted by the blinded outcome assessor will occur within seven business days after the completion of the last visit of usual home health rehabilitation therapy or ADL-enhanced intervention, whichever occurs last. For the control group, the post-intervention evaluation conducted by the blinded outcome assessor will occur either 6 weeks after the baseline assessment or after the last usual home health visit, whichever occurs last. Patients will be instructed not to discuss their therapy content with the blinded outcome assessor and vice versa. The following assessments will be administered during the post-intervention evaluation visit.

1. Assessment of Motor and Process Skills
2. Activity Measure of Post-Acute Care Home Health Short Form
3. Jebsen Hand Function Test
4. Box and Block Test
5. Timed-Up-and Go
6. Short Physical Performance Battery
7. Adverse events questionnaire

The research coordinator will extract the patient's OASIS self-care item scores (scores at the start of care and discharge) from medical chart when the patient has been discharged from home health care or 60 days after admission.

One-month follow-up evaluation.

The one-month follow-up evaluation conducted by the blinded outcome assessor will occur within seven business days one month after the completion of the last visit of usual home health rehabilitation therapy or ADL-enhanced intervention (Day 30 post intervention), whichever occurs the last. Patients will be instructed not to discuss their therapy content with the blinded outcome assessor and vice versa. The following assessments will be administered during the one-month follow-up evaluation visit.

1. Assessment of Motor and Process Skills
2. Activity Measure of Post-Acute Care Home Health Short Form
3. Jebsen Hand Function Test
4. Box and Block Test
5. Timed-Up-and Go
6. Short Physical Performance Battery
7. Adverse events questionnaire

Final evaluation or three-month follow-up evaluation.

The final evaluation will occur over the phone by the research assistant or coordinator within seven days three months after the completion of the last visit of usual home health rehabilitation therapy or ADL-enhanced intervention (Day 90 post intervention). The following assessments will be administered during the final evaluation.

1. Activity Measure of Post-Acute Care Home Health Short Form
2. Adverse events questionnaire

Data analysis plan.

Preliminary analysis. We will compare participant demographics and covariates (e.g., pain levels) between the two groups. Variables with statistically significant differences will be included in the subsequent statistical models as covariates. We will graph spaghetti plots for repeated measurements and examine for outliers.

Data analysis. Since ADL and physical functioning outcomes will be collected over three time points (baseline, post-treatment, one-month follow-up), the mixed-effects linear regression modeling will be conducted to fit the data, in which a random-effects term is included to accommodate within-subject data correlation and a quadratic growth curve is included to describe the temporal trend of the response.

For **Aim 1,** which will estimate the preliminary effect of the ADL-enhanced program on improving ADL, three separate mixed-effects regression analyses will be conducted for the Motor Skills scores of the Assessment of Motor and Process Skills (the primary outcome), the Activity Measure of Post-Acute Care Home Health Short Form, and the OASIS self-care items, in each of which sex, race, age, and other covariates will be included in the model.

For **Aim 2**, which will estimate the preliminary effect of the ADL-enhanced program on physical functioning of the upper extremity and lower extremity, four similar separate analyses will be conducted for the Box and Block Test, Jebsen Hand Function Test, Timed-Up-and Go, and Short Physical Performance Battery.

For **Aim 3**, the program completion rate and satisfaction rate will be compared to the benchmark, 75%. Fisher's Exact Test will be performed to compare the proportion of patients who experience adverse events of hospitalization, emergency room visits, or falls (adverse event rate) between the two groups.