

# Protocol of Implementing 3-Step Workout for Life to Improve ADL Outcome in Home Health

## Title:

Implementing 3-Step Workout for Life to Improve ADL Outcome in Home Health

## Investigators:

### Principal investigator:

Chiung-ju (CJ) Liu, PhD, OTR/L, FGSA, Associate Professor of Occupational Therapy

## Abstract:

Medicare beneficiaries referred to home health agencies are often in a frail status with decreased muscle strength and difficulty in performing activities of daily living. Although resistance exercise can improve muscle strength, its effect on the outcome of activities of daily living is limited. 3-Step Workout for Life is developed to augment the physical benefits from resistance exercise to greater functional gains for older adults. The purpose of the proposed research is to study how to adapt and implement the 3-Step Workout for Life program by the physical therapy staff and occupational therapy staff in a local home health agency. A series of learning cycles will be conducted to adjust the treatment dose and delivery mode, so that the program can be implemented at low cost but remains effective in improving self-care ability for Medicare beneficiaries.

**Participant eligibility criteria.** To be eligible, clients must: be recipients of rehabilitation service at the implementation site(s), be Medicare beneficiaries, be aged 65 years or over, consent to participate in the study, show functional decline on at least one of the OASIS self-care items, and experience a decline in muscle strength. The criterion of muscle strength decline is met when the client reports that he or she must use hands to help get up from a chair or couch, or take more than 13 seconds or is unable to perform the Timed Five-Chair Stand Test. Clients will be ineligible if they have 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 neurologic disorder limiting motor movements, terminal stage of congestive heart failure, a referral to hospice care, severe cognitive deficits limiting verbal communication, or significant medical complications that preclude safe participation in resistance exercise. The number of participants to receive the modified *3-Step Workout for Life* is expected to be 48.

**Implementation.** In home health care, care services are delivered at patients' home. The modified 3-Step Workout for Life will be delivered during regular home health therapy visits. The standard home health rehabilitation therapy often includes multiple treatment components that are tailored to each client's need. The modified *3-Step Workout for Life* program replaces similar treatment components in standard physical therapy (i.e., elastic band exercise) and occupational therapy (i.e., ADL training). The screening process will help identify clients who need the two therapy components, elastic band resistance exercise and ADL training. In other words, the modified 3-Step Workout for Life program will replace only the similar components in standard therapy. For example, a client may require balance training, strength training, ADL training, and recommendations of home modifications. The modified 3-Step Workout for Life will become the protocol to deliver the strength training and ADL training during the regular home therapy visits to this client. The study therapists or therapy assistants (therapy staff) will still deliver other components, balance training and recommendations of home modifications in this case, during home visits.

Study therapy staff will receive training of 3-Step Workout for Life from the PI. It is assumed that the physical therapists or physical therapy assistants will deliver the single-joint and the multiple-joint resistance exercise (i.e., elastic band exercise), and the occupational therapists or occupational therapy assistants will deliver the ADL exercise (i.e., ADL training). However, which therapy staff delivers which part of the 3-Step Workout for

Life may depend on the workflow at the implementation site(s). Note that the 3-Step Workout for Life is within the practice scope of therapeutic exercise and therapeutic activity in physical therapy and occupational therapy. The study therapy staff will follow the CDC guidelines and wear proper personal protective equipment (PPE) when in contact with the clients/patients during home visits during the COVID-19 pandemic period.

The study therapy staff will prescribe a portion of the single-joint resistance exercise as a home exercise program. The compliance of the home exercise program will be checked and reinforced during therapy visits. Multiple approaches will be taken to ensure exercise safety: taking vital signs before and after each therapy visit, providing “step down” movements or options if the client cannot perform the exercise or experiences discomfort, increasing exercise intensity in increments with proper warm-up and cool down, and tracking and monitoring adverse events.

**Clients or patients.** Forty-eight patients are expected to receive the modified *3-Step Workout for Life* program. Only the study therapy staff will conduct eligibility screening. The study therapy staff will use the standard screening form to identify eligible patients. The table below explains each screening item.

Table of Screening Items.

Item	How
Age between 65 and 85 years	Check age on the medical chart or patient self-reported information
Medicare is the primary payer for home health services	Check the medical chart or patient self-reported information
Have useful vision and hearing	Check whether the patient has functional vision and hearing?
Adequate cognitive status	Check whether the patient can understand and carry out a short conversation?
Show one ADL difficulty	Check the medical chart items, M1800 (grooming), M1810 (upper body dressing), M1820 (lower body dressing), M1830 (bathing), M1840 (toilet transferring), M1845 (toileting hygiene), M1850 (transferring), and M1860 (ambulation/locomotion). These items are located in Section G. The patient must show one non-zero item. Note that even if a patient appears to be independent, he or she is considered to have ADL difficulty because they accommodate to the difficulty. For example: don't do as often as before (cut back or give up doing it), take longer time/slower than before to complete it, or have to do it differently
Show muscle weakness	Ask the patient, <i>“Do you need to use hands to help you get up from a low chair or sofa?”</i> If the answer is “yes.” Stop here. If the answer is “no” or “unsure,” continue to the five-chair stand test.  The Five-chair stand test. Instruct the patient to sit on a standard chair (approximate 17-inch from the floor to the knee), fold hands crossed the chest, and stand up five times. Start the timer when you say “go” and stop the timer when the patient has stood up completely for the 5 <sup>th</sup> time. If the patient cannot do the test or takes more than 13 seconds to complete, then the patient may show muscle weakness.

The study therapy staff will provide eligible patient the study flyer, the study consent form (two copies), and a returned business envelope. The study flyer will instruct the patient to contact the UF research team (e.g., the PI or Co-I) to learn more about the study or to enroll the study. Additionally, the study therapy staff will obtain the patient's verbal consent for the study team to contact them. The consent process can occur over the phone, video conference platform (UF Zoom), or in-person. The recruitment rate will be kept at 2 to 4 patients per month on a first come, first serve basis.

The enrolled patients will receive the modified *3-Step Workout for Life* program during regular therapy home visits. The exercise movements, intensity, and frequency may change from a learning cycle to the next learning cycle because of the nature of the implementation study. During the therapy visit, the study therapy staff will take the vital sign and check adverse events before starting the exercise protocol. Proper warm-up and cool down will be performed. Study therapy staff will lower exercise intensity or provide a break or “step down options” for movements in which a patient experiences any discomfort. Several water breaks will be provided in a training session. The therapy staff will provide usual care to help the patient meet the rehabilitation need, for example, balance training or assistive device education. In other words, the modified *3-Step Workout for Life* program only replaces similar treatment components in usual care. These components are muscle-strengthening exercise, that is often used in physical therapy, and daily activity practice, that is often used on occupational therapy. The only distinction in the *3-Step Workout for Life* program is that the three-type of exercises (single-joint resistance exercise, multiple-joint resistance exercise, and ADL exercise) must follow the resistance exercise principles and activity grading principles.

Patients who complete the modified *3-Step Workout for Life* program will be invited to participate in the exit interview. The exit interview will occur within two weeks after the patient has completed the program. The interview will be conducted by a research assistant, the PI (Liu), or the CO-I (Kreider). The exit interview can occur in-person at the patient’s home or online. The exit interview questionnaire will be read to the patient during the interview. A series of questions will be read to the patient one at a time. The patient can respond to the questions by selecting a response from “Disagree,” “Neutral,” or “Agree.” The interviewer will then ask the patient to describe his or her experience with the modified *3-Step Workout for Life* program, and elaborate on earlier responses of “agree” and “disagree.” The interviewer will also take notes (handwritten or typing) during the interview. All data will be de-identified before being entered into the electronic database for data analysis. There is no direct way to link individual data with each patient in the electronic database.

**Specific Aim.** To estimate the clinical outcomes of the modified *3-Step Workout for Life* compared to usual care. The clinical outcomes consist of primary and secondary outcomes. The primary outcome is the improvement on the self-care items (Section GG) in the OASIS between the start of care and discharge. Section GG self-care items evaluate seven personal care activities: eating, oral hygiene, toilet hygiene, upper body dressing, lower body dressing, shower/bathe self, and putting on/removing footwear. Each activity is scored on a six-point Likert scale ranging from 1 (totally dependent) to 6 (totally independent). A ratio score (the sum of attempted activities scores divided by the maximal total score of attempted activities) will be computed to adjust for items that are not attempted because of refusal, not applicable, or environmental or safety concerns. For example, a client’s maximal total score is 30 if she/he only attempted five activities.

The secondary outcomes include the Section GG mobility items, Activity Measure for Post-Acute Care Home Health Short Form (AMPAC HH Short Form), and 5-Level version of the EuroQol five dimensions (EQ-5D-5L). Data collection of the AMPAC HH Short Form and EQ-5D-5L can occur at patient’s home or via Zoom or phone. The UF research team or the study therapy staff will complete the AMPAC HH Short Form, and EQ-5D-5L within a week after obtaining the consent and again within two weeks after the intervention completion.

**Descriptions of measurements.** The Section GG self-care items and mobility items will be collected via chart reviews by a research assistant or the PI (Liu). These are standardized assessments used in Medicare home health care. These items are included in the medical review form submitted to the IRB (item codes start with GG).

The AMPAC HH Short Form evaluates patient’s difficulty in performing basic mobility (7 questions), daily activity (8 questions), and applied cognitive (5 questions). Questions are read to the patient. For example, how much difficulty do you currently have getting up from the floor? The patient chooses one of the four responses: unable, a lot difficulty, a little difficulty, or none. The EQ-5D-5L is a self-reported, health related, quality of life questionnaire. The questionnaire measures quality of life on a 5-component scale including mobility, self-care,

usual activities, pain/discomfort, and anxiety/depression. Each component is rated on a 5-level scale (no problems, slight problems, moderate problems, severe problems, or unable). The tool also includes overall health scale where the patient selects a number between 1-100 to indicate the condition of their health, 100 being the best possible. The UF research team or the study therapy staff will complete the AMPAC HH Short Form, and EQ-5D-5L either in-person at the patient's home or over the phone.

**Data analysis plan.**

The preliminary analysis of the Section GG self-care items, mobility items, AMPACT, and EQ-5D-5L will be paired sample t-tests or one-sample Wilcoxon Singed-Rank tests for the the pre and post results. The statistical analyses may not reach the significant level at .05 because the study is not adequate powered. Additionally, the internal validity of the research may be compromised for the purpose of implementation. The exit interview results will be summarized by the percentage of "agree" question items.