Protocol: Adapted Lifestyle-integrated Functional Exercise Program for Medically Underserved Older Adults (LiFE)

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Version:
Last updated, September 18, 2018

Clinical Trial # NCT03704194

Funding for the Gephardt Institute for Civic and Community Engagement at Washington University in St. Louis

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A Introduction

Falls are an escalating public health issue that drastically interrupt the healthy aging of older adults functionally and economically.[1-3] Falls remain the leading cause of fatal death among older adults.[2] Falls also cause an estimation of 2.8 million injuries and 800,000 hospitalizations annually[4]. Exercise programs can effectively reduce falls by increasing balance and lower extremity muscle strength[5], but translation of these programs into clinical practice remains sparse[6]. Older adults, especially those who live in medically underserved areas[7] with few primary care providers and/or high rates of poverty are less likely to benefit from evidence-based exercise programs due to lack of exposure and access.[8, 9] Lack of translation and delivery of evidence-based interventions to medically underserved populations increase health inequities at the individual and community levels.[10-13]

To fill this gap, we propose to adapt the Lifestyle-integrated Functional Exercise (LiFE) program for medically underserved older adults. LiFE has demonstrated high rates of fall reduction (31%) and adherence (80%) for community-dwelling older adults in Australia.[14] This highly effective program uses habit formation strategies to enhance long-term behavior changes. Evidence, including our own preliminary data, suggest LiFE could be highly effective to reduce falls for medically underserved older adults, who commonly face economic hardship and other barriers to accessing health care.[15] To address the cultural and behavioral differences between medically underserved older adults in the US and more affluent older adults in Australia,[16-18] we will conduct a feasibility pilot study to test the feasibility of a randomized control trial (RCT) in preparation for larger trials for medically underserved older adults in the US.

A1 Study Abstract

The purpose of this study is to pilot test the feasibility of a study design for future larger trial of Adapted LiFE among medically underserved older adults. We will evaluate if : 1) Adapted LiFE is feasible for medically underserved older adults, and 2) the study design is feasible with working randomization module and appropriate measurements. Feasibility outcome measures include reach, acceptance, adherence, fidelity, safety, and appropriate efficacy outcome selection for balance, lower extremity muscle strength, and habit formation.

We will conduct a pilot RCT with an attentional control group. The treatment (Adapted LiFE) group (n=8) will receive 7-sessions of culturally Adapted LiFE over 12 weeks, while the attentional control group (n=8) will receive the same amount from an interventionist with a gentle flexibility program “Go4life”[19] developed by the Nation Institute on Aging during intervention period.

We will recruit older adults who: are age 70 or older; self-report falls in the past 12 months; and reside in a medically underserved area. We will exclude participants who: have attention and memory impairment (Short Blessed Test score ≥ 8), are unable to stand with assistive devices, are severely depressed (The Geriatric Depression Scale ≥10), and have serious health conditions for which exercise is contraindicated. Paired t-tests will be used to test time effects, and independent t-tests will be used to test group effects of Adapted LiFE.

A2 Purpose of the Study Protocol

The purpose of this study protocol is to establish a clear and detailed record of the objectives, design, methodology, statistical analysis plan to ensure the safety of the trial participants and integrity of the data collected.

B Background

B1 Prior Literature and Studies

Research has evaluated the efficacy of various fall prevention programs, and exercise has been shown to be one of the most effective interventions to reduce falls.[5, 20] However, evidence-based exercise programs encounter multiple barriers that lower the effectiveness of implementing interventions for medically underserved populations.

Medically underserved older adults are defined as older adults who live in a medically underserved area,[7, 15] designated by the US government with indicators of higher poverty level and fewer healthcare providers. Medically underserved older adults often belong to, but are not limited to, groups that have low income, are Medicaid-eligible, or are facing cultural or linguistic barriers to healthcare.[21] Medically underserved older adults, who already experience more health inequities,[22, 23] are underrepresented in clinical trials,[24] and evidence-based interventions are less likely to be designed to meet their needs.[25]

It is also unknown whether exercise programs will translate to be effective for medically underserved older adults.[8] To capture and describe the body of work on how medically underserved older adults are engaged in physical activity (PA) participation and whether exercise interventions have been specifically designed for this population, we have conducted a scoping review to explore and map the nature/extent of research conducted for medically underserved older adults [26]. A total of 423 articles was identified with the search terms, 392 went through title and abstract review, 87 articles went through full text review. A final yield of 60 articles were included for data extraction. Twenty-one identified studies were intervention studies, only 4 of which specifically targeted underserved older adults aged 60 years and above. Three of these 4 studies were feasibility studies[27-29] indicating that strategies to increase reach, retention, and adherence for medically underserved older adults are needed.

A gap exists in translating research into practice as few evidence-based programs have been implemented for low-income, minority populations.[30, 31] Challenges in translating evidence-based programs for these groups may result from uncontrolled moderating factors that hinder the implementation and effectiveness of evidence-based interventions.[32-34] If health researchers leave these challenges unattended, health disparities are predicted to increase within a growing and increasingly diverse US population.[35] To meet these challenges, we need to reduce implementation barriers early on in research design to ensure external validity for diverse populations.[30, 31]

B2 Rationale for this Study

The Lifestyle-integrated Functional Exercise (LiFE) program has the potential to eliminate implementation barriers for medically underserved older adults through its design. LiFE is an evidence-based fall prevention program that embeds balance and lower extremity strength training activities into daily routines at home.[14, 36-38] We have targeted LiFE because it has strong face validity for medically underserved older adults[39] and potentially controls for common moderating factors, such as time, resources, and

transportation constraints. Compared to structured exercise programs, LiFE provides a flexible and easy-to-adopt approach that can motivate medically underserved older adults who might otherwise perceive traditional exercise with highly structured routines as less appealing.[14, 36-38, 40-42] LiFE demonstrated high rates of both adherence and fall reduction in previous clinical trials among Australian older adults.

However, we anticipate differences between our target population and the original LiFE participants.[43, 44] Differences in socioeconomic status and race/ethnic backgrounds will affect acceptance and uptake of the program, thus requiring adaptation of the original LiFE program to ensure external validity when generalizing research to a different population.[9] It is critical to conduct a cultural adaptation process to achieve the goal of translating LiFE for medically underserved older adults.

Before investing large amount of resources and money into the main study, we aim to conduct a pilot study to assess the feasibility for a larger study design.[45-47] The results of the feasibility pilot studies will inform researchers if it is reasonable to proceed with the main study.

C Study Objectives

C1 Primary Aim

The primary aim of this study is to establish feasibility of Adapted LiFE and a RCT design.

WE hypothesis that the feasibility pilot study will have high reach (60% recruitment and 80% retention rate of targeted participants), acceptance (80% of participants rating high satisfaction with Adapted LiFE), adherence (80% of all exercise activities achieved during the intervention period for each participant), fidelity (90% consistency of elements delivered by occupational therapists throughout the study period), safety (no adverse events caused by Adapted LiFE), and appropriate efficacy measurement selection (70% of the participants do not show floor/ceiling effects among balance, muscle strength, and habit outcomes at pre- and/or post-tests).

C2 Rationale for the Selection of Outcome Measures

The feasibility outcomes will inform future studies if Adapted LiFE has the potential to reduce barriers for implementation. Outcomes have been selected based on literature review and the preclinical pilot study (see D1 for preliminary data). The feasibility outcomes were selected based on the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) framework including reach, acceptance, adherence, fidelity, safety, and appropriate efficacy measurement selection. [48, 49] Preliminary efficacy outcomes of balance, muscle strength, and habit formation measures are selected based on literature review on fall prevention and evidence-based exercise interventions for older adults. [50-52]

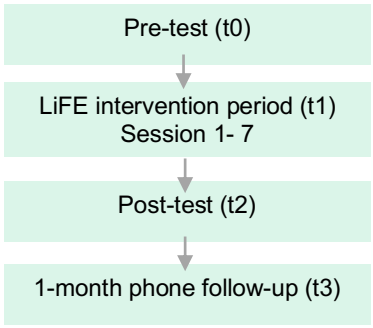
D Investigational Agent

D1 Preclinical Data

We conducted a mixed method study to adapt LiFE initially. The mixed-methods study consisted of two phases. At the first phase, a qualitative study was conducted to explore

stakeholders' opinion towards LiFE that included medically underserved older adults and occupational therapists (OT).[53, 54] Themes regarding intervention acceptance and concerns were used to adapt LiFE materials. Based on the themes emerging from the qualitative study, two changes to the LiFE user manual were made in the initial adaptation of LiFE. First, a graph explaining why fall prevention is important and how LiFE works was added to the beginning of user manual. We also reduced the number of words and pages by replacing text information with pictures in the manual. Second, pictures of African American older adults were used to reflect the demographic characteristics of medically underserved older adults in the city of St. Louis.[55]

Figure 1 Overview of single group pilot study



At the second phase, a single-group pilot study was conducted to test the feasibility of Adapted LiFE (Figure 1). Feasibility outcomes were selected based on the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) framework to evaluate initial Adapted LiFE (Table 1). Eight medically underserved older adults were recruited by convenience sampling from one senior apartment building in a health provider shortage area. Inclusion criteria were: (1) age 60 or older; (2) living independently; and (3) self-reported a slip, trip or fall in the past 12 months or were "concerned or worried about falling in the future." Exclusion criteria were: (1) Short Blessed Test score ≥10, indicating cognitive impairment consistent with dementia; (2) inability to stand independently with a walking device; and (3) a serious health condition for which exercise is contraindicated. Participants were recruited through flyers and information sessions held in the senior apartment building. After consent, an occupational therapist would conduct a pre-test of preliminary efficacy outcomes and then start the first session of Adapted LiFE. Once participants completed all 7 sessions, a post-test was conducted by the OT immediately after the last in-home intervention session. The result showed that Adapted LiFE demonstrated good feasibility among the target participants. Eight older adults completed the pilot study (mean age 66.4 ± 5.6, 4 males, 3 African Americans, 5 Caucasians). The recruitment rate was 44% (11 enrolled out of 25 screened). The retention rate was 89% (8 completed out of 9 enrolled). Participants had high acceptance of adapted LiFE with a mean satisfaction score of 6.89 ± 0.38. The average adherence rate was 81.3%. For fidelity, 98% of components were delivered during the intervention period.

Thus, we regard the Adapted LiFE has the potential to have high acceptance and adherence rate among medically underserved older adults. Future studies should aim to evaluated the efficacy of Adpated LiFE with larger trials.

D2 Dose Rationale and Risk/Benefits

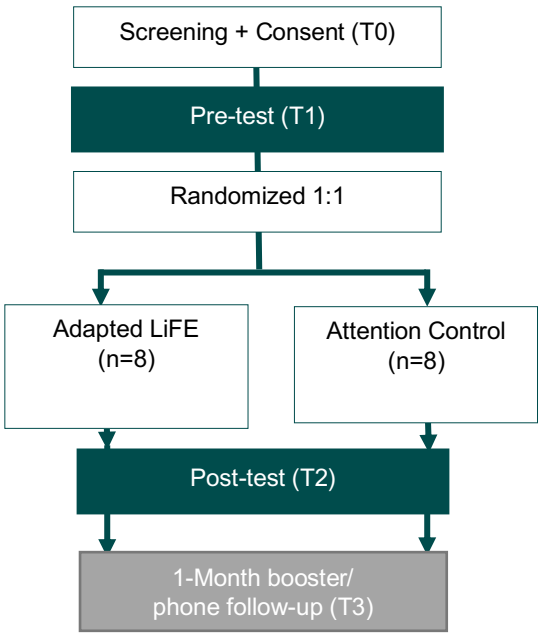
The Adapted LiFE has an updated user manual but it retains the essential components and dose of the original LiFE (Table 2). In addition to practicing a set of structured exercise, participants learn to embed functional exercise activities into their daily routines that include balance and muscle strengthening training. For example, a participant could practice one-leg stands while waiting for food to heat up in the microwave. Participants also learn to gradually increase the difficulty of balance and muscle strengthening activities included in LiFE (see E3, and table 3).

Clinical trials of LiFE,[14, 36, 56] where comparing LiFE to structured exercise program, indicated the risk of participating in LiFE is no more than minimal risk.[14] The benefit of LiFE has been proven in past study indicating LiFE could reduce falls, enhance balance and muscle strength among older adults.[14, 36, 56] We hypothesize Adapted LiFE will have the same effect as the original trial.

E Study Design

E1 Overview of Study Design

Figure 2. Overview of the feasibility pilot study



The pilot study will use RCT with an attentional control design (Figure 2). The purpose of the pilot study with the same design as the future main study is to test the study protocol, estimate recruitment/retention rate, and validate tools.[57, 58] This study design is appropriate for a future larger study because Adapted LiFE has strong face validity, good feasibility, and minimal risk when compared with structured exercise programs for medically underserved older adults.

We will recruit 16 participants and randomize them to receive 7 sessions of home visit and 1 booster phone call one month after the last session of Adapted LiFE or attention control (AC) intervention. Once an eligible participant is screened and consented in his/her home (T0 visit), the OT interventionist will either conduct or schedule the pre-test (T1). All pre- and post-tests will be conducted in participants' homes. After T1, the OT interventionist will randomize the participants to Adapted LiFE or the attention control group. The intervention period will start immediately after randomization and consist of seven sessions over 12 weeks. Post-tests (T2) will be conducted by a blinded OT rater after the last intervention session at the participant's home. Phone follow-ups (T3) will be conducted one month after post-test by a blinded OT rater. Any additional questions from the participants will also be addressed in the phone follow-up.

Feasibility outcomes such as reach, adherence, fidelity, and safety will be evaluated throughout the study session. Efficacy outcome such as balance and muscle strength will be evaluated at pre- test (T1), and post-test (T2). Habit formation will also be evaluated at T1, T2, and 1-month after post-test via phone.

E2 Subject Selection and Withdrawal

2.a Inclusion Criteria

Medically underserved older adults will be recruited by convenience sampling. Referrals from OT staff and members of a community advisory board of the Participation,

Environment & Performance Laboratory (PEPL) will be the main channels for recruiting medically underserved older adults. Inclusion criteria include:

(1) age 70 or older;
(2) live independently;
(3) live in a medically underserved/health professional shortage area;
(4) self-report two falls or one injurious fall in the past 12 months. The definition of a fall and injurious fall are described in Table 4.

2.a Exclusion Criteria

Exclusion criteria include:

(1) Short Blessed Test score ≥8, indicating cognitive impairment consistent with dementia;
(2) inability to stand independently with a walking device;
(3) having a serious health condition with a physician's order where exercise is contraindicated.

2.b Ethical Considerations

We will use convenient sampling to recruit medically underserved older adults, and we will not limit the number of participants due to their race/ethnic background.

2.c Subject Recruitment Plans and Consent Process

Purposeful sampling was used to recruit MU older adults in the greater St. Louis area. Potential participants will also be identified from the control group from a previous study. Participants will be recruited by word of mouth or at two Shepard senior apartment buildings (see letter of supports in attachments). Flyers will be distributed and study members will be available in the lobby and at events scheduled in the building to provide information on the study (study members will be contacted and invited by the building service coordinator).

Participants who are referred and contact study staff via phone or in person will be able to ask questions about the study procedures. If they are interested, study staff will start the screening process by phone or in person.

If the individual is eligible, a copy of the large-print informed consent document will be mailed or delivered, and an initial home visit will be scheduled. At the home visit, a trained staff member will obtain written informed consent.

To minimalize the possibility of coercion or undue influence during the consent process, all elements of consent will be reviewed with older adults prior to enrolling in the study. Elements such as the purpose of the study, risks, benefits, alternatives to the study, how confidentiality will be maintained, the PI's contact information, no consequences to withdrawal, and how study results will be shared are written in plain language. In addition, all staff members have participated in cultural competence training and are trained to interview older adults, which is particularly important for older adults with low vision, or low literacy levels. Written informed consent to participate in the study will be obtained before any test or measurements are performed. The consent form will be signed by a witness and will be stored in the office of the PI under double locks.

2.d Randomization Method and Blinding

After the consent process, the pre-test could be administered immediately or be scheduled at a different day**.** After pre-test, participants will be randomized immediately by a pre-programed REDCap (Research Electronic Data Capture) module. REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. A blinded rater will conduct the post-test and phone follow-up.

Participants will not be blinded to which group they are in. The REDCap module uses a blocked randomization design in which gender will be stratified to ensure balanced group sizes. A block size of 2 and an allocation ratio of 1:1 based on gender. Then, based on group allocation, the occupational therapy (OT) interventionist will start either Adapted LiFE or the attention control intervention.

2.e Risks and Benefits

Minimization of Risks and Confidentiality

We are a HIPPA covered entity and comply with all HIPPA regulations. To protect against and minimize potential risks, participants will be carefully screened and evaluated for eligibility by research coordinator. Participants may have the risks of feeling tired or disrupted by home visits, sore muscles after practicing exercise activities, feeling worn out, or confidential information of participants may be accidently disclosed. Participants may take a break at any time during participation and will be instructed to notify the rater or interventionist if they experience any discomfort.

An ID number will be assigned to each participant. All data collected from a participant will be labeled with the ID number. All participant electronic and hard-copy data will be kept under double-lock protection. All hard copy forms that contain personal identifiers (e.g., name, address, phone numbers) will be stored in a separate locked file drawer under double-lock protection. No publication or presentation of the study data will uniquely identify or provide sufficient information to uniquely identify participants.

To guard against unauthorized data access, all shared-use computer systems at the Washington University School of Medicine are protected with passwords, which are changed at 4-month intervals. Only individuals with a particular "need to know" status are given access, and system privileges are carefully restricted. All personal computers to be used in the Administrative Unit are located within a secure area, and the system is locked when not in use. SAS and SPSS software packages will be used for data management and analysis. Datasets generated from these programs will be password protected, which will make accessing study data difficult even in the event of unauthorized computer access occurs.

There is no proven benefit from being in this study. However, benefits to the participants enrolled in the proposed study are free in-home exercise sessions provide by OT interventionists. Participants in treatment group (Adapted LiFE) may be able to improve balance and muscle strength, and participants in the control group may be able to improve flexibility.

2.f When and How to Withdraw Subjects

Participants will be told that their involvement in this research study is voluntary and that they may choose not to participate or withdraw their consent at any time. There will be no penalty or loss of benefits to which participants are otherwise entitled. Participants

will be withdrawn if there is a serious adverse event (SAE) that may impact participant's safety (see F5).

2.g Data Collection and Follow-up for Withdrawn Subjects

Data is directly entered into a REDCap database. REDCap servers are securely housed in an onsite, limited-access data center managed by the Division of Biostatistics at Washington University. All Web-based information transmission is encrypted. All data are stored on a private, firewall protected network. All users are given individual user IDs and passwords, and their access is restricted on a role-specific basis. REDCap was developed specifically around Health Insurance Portability and Accountability Act security guidelines and is implemented and maintained according to Washington University guidelines. Study data will be collected via tablet in the field and managed using REDCap electronic data-capture tools hosted at Washington University. REDCap is a secure, Web-based application designed to support data capture for research studies. If a participant is withdrawn from the study, his/her information will be kept in REDCap securely until the study is completed.

E3 Study Intervention

The treatment group will receive Adpated LiFE, and the control group will receive equivalence attention and time with an flexibility intervention program from Go4life.[19]

3.a Treatment: Adapted LiFE

Adapted LiFE teaches older adults to embed balance and lower extremity exercise activities into daily routines. The objective of LiFE is to form a habit to complete balance and muscle strength activities daily to improve balance and lower extremely muscle strength. A short summery of Adapted LiFE is at Table 2.

Participants will learn 10 exercise principles and 19 activities to increase balance and muscle strength during a 12 week intervention period (Table 3). For balance training, the core principle is to continue to practice a challenging balance activity, manage it, and then progress to another more challenging activity. For muscle strength training, the core principles are to overload muscles by adding weight, increasing repetitions, and moving slower to make the muscles progressively work harder.

Adapted LiFE is an intervention that aims to enhance self-efficacy through goal setting and creating appropriate outcome expectations to enhance participants' ability to repeatedly perform a target health behavior, which, in this case, is to form and adhere to a habit of exercise. Therefore, OT interventionists will guide participants to review the user manual and use a self-monitoring calendar (Adapted LiFE calendar) to plan and implement planned training activities.

The dose (visits and time) of Adapted LiFE consists of five weekly sessions and two booster sessions, which will be delivered by the OT interventionist in 12 weeks. Each session will last 40-60 minutes. The two booster sessions will be scheduled based on the needs of participants. If a participant has not finished learning all the activities after the fifth session, one or both booster sessions will be used to teach and implement the remaining activities, which will be conducted in the same manner as previous sessions. If a participant has completed learning all the activities, the first booster session (the 6^{th} session) will be conducted with at least a two-week break after the 5^{th} session. The second booster session (the 7^{th} session) will be conducted at least a four-week break

after the 6th session. A phone follow-up call will be made after one month of the last intervention session as a booster session for participants to ask questions. feasibility outcome such as enrollment status, fidelity of intervention delivery will be documented by rater/interventionist log throughout the study period.

3.b Control: Go4life

Participants in the attention control group will receive a gentle exercise intervention that consists of flexibility activities. Materials are modified from the Go4Life program (an online material developed for general older adults by National Instituted of Aging).

Participants will learn 19 gentle stretching activities during a 12 week intervention period. The OT practitioner will teach participants to gently stretch neck, shoulder, upper arm, upper body, chest, back, foot, leg, and hip. The OT practitioner will not actively guide or request participants to set goals or record activities.

The dose (visits and time) of the attention control intervention is the same as Adapted LiFE, which consists of five weekly sessions and two booster sessions. Each session will last 40-60 minutes. Nineteen gentle flexibility activities from Go4Life will be taught to participants. The OT interventionist will deliver the Go4Life user manual to the participant during the first visit and serve as a consultant for participants to ask questions about the flexibility activities. The self-monitoring calendar will be removed because self-monitoring is an active ingredient of the treatment effect of Adapted LiFE. The OT interventionist will not actively guide or request participants to set goals or record activities. feasibility outcome such as enrollment status, fidelity of intervention delivery will be documented by rater/interventionist log throughout the study period.

3.c Subject Compliance Monitoring

Subject compliance is regarded as one of the feasibility outcome “adherence “ in this study (see F2).

3.d Blinding

Participants and OT interventionist will not be blinded to the purpose of testing Adapted LiFE, and will be informed at the consent visit.

Raters will be blinded from the study. At baseline, raters will be blinded by randomizing participants after pre-test. At post-test, a blinded rater will be assigned to conduct the assessments. At one-month phone follow-up: a blinded rater will conduct the follow-up questionnaires.

F Study Procedures

1.a Screening for Eligibility

The screening process is for confirming eligibility to enrollment. Potential participants will be screened by phone or in-person using a script by a trained interviewer (See appendix 1). All in person screenings will take place in the potential participant's apartment, or other private area (whichever the potential participant prefers for privacy and convenience). The trained interviewer will screen participants eligibility by asking participants’ age, how many time the participant had falling in the past year in a screening log (appendix 2), and evaluate if participants had attention/memory impairments with the Short Blessed Test (appendix 3).

1.b Consent visit and Pre-test

An OT interventionist will visit all participants who meet the inclusion criteria and invite them to participate in the study. The informed consent form will be administered to all patients interested in participating in the study. During the consent process, participants will: (1) have what the study is about and what is expected of them explained in detail; (2) discuss potential problems that could interfere with participation; and (3) have their questions answered; and (4) receive a summary of the study, and contact information for the PI and study coordinator. The consent form will be signed by a witness and will be stored in the office of the PI under double locks. Participants will be advised in the consent form that there is a possibility that their medical research record, including identifying information, may be inspected and photocopied by officials of federal or state government agencies and the Washington University Human Research Protection Office (HRPO).

Written informed consent to participate in the study will be obtained before any test or measurements are performed. After the participant signed the consent form, the OT interventionist will start the pre-test immediately or re-schedule another time for pre-test.

At pre-test, a demographic questionnaire will be used to collect general information about the participant. A set of questionnaires and performance-based assessment will be conducted to evaluate participants attitude and abilities. After pre-test, participants will be randomized in the field.

Table. Materials and assessments for consent and pre-test

Construct	Assessments	Time
Primary endpoints		
Static balance	• Four-Stage Balace Test*	T1, T2
	• Center of pressure (CoP) path measured by BTracks Balance Board	
Dynamic balance	• Timed tandem walk*	
	• Short Physical Performance Battery-Balance Test (SPPB)*	
	• Berg Balance Scale (BBS)	
Muscle strength	• Lower extremity muscle strength measured by dynamometers*	
Secondary endpoints		
Habit formation	• Self-Reported Habit Index (SRHI)	T1, T2 , T3
Balance efficacy	• The Activities-specific Balance Confidence	T1, T2, T3

Note. * indicated assessment was used in the original LiFE study (Clemson et al., 2012)

1.c Intervention Sessions

Participants in both treatment or control group will start treatment session after randomization. The first session could be conducted immediately after pre-test or scheduled at another time if the participant is tired.

A. Treatment: Adapted LiFE sessions

The following content are modified and copied from the trainer manual of original LiFE. A fidelity checklist of the activities of Adapted LiFE is listed in appendix 5.

I. *Adapted LiFE Session 1*

The aim of session 1 is to evaluate participant's daily routine, and introduce them to the principles of the Adapted LiFE program. This session will take 40 to 60 minutes. OT interventionist will conduct following activities:

(1) Assess the participant's ability and opportunity to embed training activities: The OT interventionist will assess participants ability by the LiFE assessment tool, and ask what is "a typical week" of the participant and record the opportunities to embed exercise activities with the Daily Routine Chart.

(2) Introduce participants to the program and user manual: The OT interventionist will use the user manual to explain how Adapted LiFE work with learning key concepts and exercise principles.

(3) Teach key concepts of Adapted LiFE: embedding activities into daily routine, changing habits, looking for opportunities to perform the activities, using event or environmental cues to remind the participants to do the activities, the concept of grading, and review the safety section in the user manual to inform participants safety first while participating in Adapted LiFE.

(4) Teach the exercise principles and selected activities: after teaching the principles (table 3), ask participants to pick 1-2 balance and 1-2 muscle strengthening activities. Demonstrate and practice with participants at the appropriate level.

(5) Plan and record how, when, where the activities will be performed: The OT interventionist will introduce participant to the Adapted LiFE activity planner and explain the importance of planning and recording these plans. The OT interventionist prompt the participant to find opportunities in his/her daily routine to embed the selected balance and muscle strengthening activities (see an example at Figure 3).

(6) Wrap-up: The OT interventionist will make sure the participants understand to do the activities, check the boxes daily for the planned activities, and beware of safety (do not encourage the participants to upgrade activities at this session). Participants will receive a 10-dollar gift card after session 1 is completed.

Figure 3. An example of recording an activity in the LiFE activity planner

Activity Planner-Strength Training

Strength Principle	Balance Activity	Example of Daily Tasks How, when and where	V check if done						
			Mon	Tue	Wed	Thur	Fri	Sat	Sun
Bend Knees	Bend knees								
Tighten Muscles	Move ankles								
	Bend/ Straighten Knees	I will bend and straighten my knees when I watch TV	x	x	V	V	V	V	x
On your heels	Stand on heels								

II. *Adapted LiFE Session 2-5 (week 2-6)*

The aim of session 2-5 is to finish teaching all the principles and activities. Session 2-4 should be conducted weekly, and session 5 should be conducted after a break of at least one week to allow participants to have some autonomy in setting and adjusting the program. Participants should also learn how to gradually increase their autonomy in managing the program.

The OT interventionist will also facilitate the participants to come up with their own ideas of where activities might be embedded. Each participant will be upgraded differently according to their setting levels and their progress. In the early stages, participants should check with the interventionists before upgrading their activities. However, participants should be able to safely upgrade their own activities. OT interventionist will conduct following activities during session 2-5:

(1) Review the balance and strength activities commenced previously with the LiFE activity planner.

(2) Check for problems and problem solve.

(3) Reinforce the integration/link to daily tasks and routine.

(4) Upgrade activities as appropriate.

(5) Introduction an additional one to two balance/strength activities.

(6) Develop plans for embedding the activities into the participants' daily routine.

(7) Complete the LiFE activity planner.

(8) Wrap-up

<u>At the end of session 2</u>, participants should:

- be able to do between 2-4 additional balance/strength activities,
- have begun to identify for themselves daily tasks where LiFE activities can be embedded.

<u>At the end of session 5</u>, participants should:

- be able to do 10 or all activities,
- complete the LiFE activity planners correctly,
- identified areas/ activities where they will be able to embed LiFE activities into their daily routine,
- manage to independently continue the program safely.

III. *Adapted LiFE Session 6-7 (booster sessions, week 8-12)*

If the participant has been able to learn all the activities and integrate them into their daily routines by session 5, then session 6 and 7 should be used to reinforce the program and to check on the progress and safety of the participant as required. Timing of session 6 (week 8) is suggested to be 2 weeks after session 5 (week 6), and session 7 (week 12) to be 4 weeks after session 6. However, these 2 sessions will be scheduled depend on the need of the participant. Participants will receive a 60-dollar gift card after session 7 is completed.

If the participants has not been able to learn all the activities, then the OT interventionist should used session 6 and/or session 7 to continue teach and implement the activities as previous sessions.

The aims, objectives and components of session 6 and 7 are in line with session 2-5. However, at the end of session 7, participants should be fully autonomous in embedding, performing and upgrading the activities in the LiFE program.

B. Attention control Intervention (Control) Sessions

The aims and objectives of the attention control intervention is to teach participants 19 gentle flexibility activities from Go4LiFE. A fidelity checklist of the activities of Go4LiFE is listed in appendix 5.

I. Go4LiFE *Session 1*

The aim of session 1 is to give an overview of the flexibility activities. The interventionist will introduce participants to Go4LiFE. This session will take 40 to 60 minutes. OT interventionist will conduct following activities:

(1) Introduce participants to the program and user manual: The OT interventionist will use the Go4LiFE user manual to explain what are the 19 flexibility activities are.

(2) Teach participants to conduct flexibility activities: after introducing the 19 flexibility activities, the interventionist will ask participants to pick 3 activities, and then demonstrate and practice with participants.

(3) Wrap-up: The interventionist will make sure the participants understand to do the activities safely, and suggest the participants to do each activities 3-5 times (but do not encourage the participants to upgrade activities at this session). Participants will receive a 10-dollar gift card after session 1 is completed.

The interventionist will not encourage participants to actively document how many times they performed the session and will not provide balance and muscle strengthening training.

II. Go4LiFE *Session 2-5 (week 2-6)*

The aim of session 2-5 is to finish teaching all the flexibility activities. Session 2-4 should be conducted weekly, and session 5 should be conducted after a break of at least one week to match the timing of the treatment group. OT interventionist will conduct following activities during session 2-5:

(1) Check for problems and problem solve.

(2) Introduce 3-4 flexibility activities.

(3) Demonstrate and practice the activities with participants.

(4) Wrap-up

III. *Go4LiFE Session 6-7 (week 8-12)*

If the participant has been able to learn all the activities and integrate them into their daily routines by session 5, then session 6 and 7 should be used to check on the progress and safety of the participant. Timing of session 6 (week 8) is 2 weeks after session 5 (week 6), and session 7 (week 12) is 4 weeks after

session 6. Participants will receive a 60-dollar gift card after session 7 is completed.

If the participants has not been able to learn all the activities, then the OT interventionist should used session 6 and/or session 7 to continue teach the flexibility activities as previous sessions.

1.d Post-test

After the last session, a blinded rater OT interventionist will start the post-test immediately or re-schedule another time if participant is unavailable. A set of questionnaires and assessments similar to pre-test will be administered except the demographic questionnaires. The feasibility questionnaire with open-ended questions will be conducted by the rater to explore participants' perspective of the programs.

1.e One-month phone follow-up

Both treatment and control group will receive a follow-up phone call one month after the last session. The objectives of this phone call is to check if participants have any questions or problems of the program.

1.f Safety and Adverse Events

To avoid or minimize adverse events, we will ask participants to notify the rater or interventionist if they experience any discomfort (see 2.e risks and benefits). Testing and interviews will be terminated if participants develop fatigue, agitation, or emotional distress. Participants will be trained in exercise principles and recognize environment barriers and situations that is not safe to conduct the activities at the first visit.

1.g Safety and Compliance Monitoring

Ms. Hu will be responsible for reviewing study progress and outcomes including recruitment, data quality, safety and efficacy with the supervision of Dr. Stark.

Because risk in the proposed study is considered minimal, the data monitoring plan will include continuous, close monitoring by the study investigator with prompt reporting of any adverse events. Given the small number of subjects undergoing treatment, problems will become more readily apparent through close monitoring of individual participants. In this study, Dr. Stark will monitor the study for adverse advents and adherence to the protocol and safety.

1.h Definitions of Adverse Events

Adverse events are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recorded regardless of their relationship to the study intervention.

Serious adverse event (SAE). An SAE is generally defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly or is another condition which investigators judge to represent significant hazards

1.i Data Collection Procedures for Adverse Events

Adverse events will be recorded in rater/interventionist log within the same day of the visit or phone call. Ms. Hu and Dr. Stark will discuss if the participants need to be withdraw when an adverse event occur within 2 days.

Should there be a serious adverse event that occurs that increases the risks to the participants, the study will be stopped, an investigation will be conducted, and a findings report will be generated before the study is resumed(see 5.d).

Data of the withdrawn subjects other than reasons of withdrawal and demographic information will be deleted and excluded from data analysis.

1.j Reporting Procedures

All serious adverse events will be reported to the HRPO in the following time frames: a) death – immediately; b) life-threatening within 7 calendar days; c) all other SAEs within 15 calendar days using the Electronic Serious Adverse Event Reporting System. Should there be a serious adverse event that occurs that increases the risks to the participants, the study will be stopped, an investigation will be conducted, and a findings report will be generated before the study is resumed.

1.k Adverse Event Reporting Period

The adverse event reporting period will starts from participant enrollment to one-month phone follow-up.

F2 Study Outcome Measurements

Feasibility outcomes include reach, acceptance, adherence, fidelity, safety, and appropriate efficacy outcome selection are described below. Feasibility outcomes will be assessed by the visit-by-visit grid, rater/interventionist log, the LiFE activity planner, and the feasibility questionnaire.

Reach is defined by recruitment and retention rate. Recruitment rate will be measured by the percentage of residents successfully enrolled in the study. Retention rate will be defined by the percentage of enrolled participants who complete the program. Reach will be documented by OT interventionists in interventionist logs and visit-by-visit grids in REDCap.

Acceptance will be surveyed by the feasibility questionnaire at the last session. The questionnaire contains a question, “Are you satisfied with the Adapted LiFE program?,” using a seven-point Likert scale from one (very unsatisfied) to seven (very satisfied). Follow-up questions will be asked to explore what makes the program satisfying or unsatisfying to the participant.

Adherence will be defined as the average percentage of exercise activities achieved during the intervention period that are recorded in the Adapted LiFE activity planner.

Fidelity will be assessed as the delivery of active and essential ingredients of the program as recorded by OT interventionists in visit-by-visit grids in REDCap. OT interventionists will meet weekly with the principle investigator to review the delivery of essential and active ingredients of Adapted LiFE for quality assurance.

Safety of the program will be evaluated by the number of adverse events documented throughout the study duration. This will be documented by OT interventionists in interventionist logs and visit-by-visit grids in REDCap.

The visit-by-visit grid is a checklist of all the elements that the interventionist should cover during each session. The interventionist will fill out the grid after every session is completed.

The rater/interventionist log is a survey that each rater/interventionist need to fill out after each visit to document any adverse event or special notes from a participant.

The LiFE activity planner is a weekly calendar for participants to fill out during the intervention sessions. Participants will record and check off the activities that they have completed.

The feasibility questionnaire consist of open-ended questions for participants and interventionists to review their experience in the study period.

Appropriate efficacy outcome selection are defined as few difficulties to administer questionnaires and assessments for balance, muscle strength and habit formation, which will be the primary and secondary endpoints of future larger trials. The second half of the feasibility questionnaire will also be filled out by the rater/interventionist to review if the questionnaires/assessments are easy to administer or not.

Balance will be evaluated to capture the nature of posture control and change of intervention. The literature suggests static balance and dynamic balance are both critical to prevent falls. Static balance will be measured by the Four-Stage Balance Test and the Center of pressure (CoP) path. Dynamic balance will be assessed using the timed tandem walk test, the Short Physical Performance Battery-Balance Test, and the Berg Balance Scale. Balance self-efficacy will be measured by the Activities-specific Balance Confidence Scale.

The Four-Stage Balance Test consists of four progressively more challenging stances (narrow base stand, half tandem stand, tandem stand, and one-leg stand). Each stance represents a different level of static balance ability.[59, 60] It is validated to screen for increased fall risk and functional decline.[60] The inability to hold the fourth stage or one-leg stand for five seconds further predicts injurious falls.[61] Participants will be categorized into low fall risk (passing the third stage tandem stand) or high fall risk (failure to pass the third stage tandem stand).[62] A balance board BTrackS[63] will be used to quantify the trajectory of center of pressure (CoP) while participants are being evaluated with The Four-Stage Balance test along with wide stance. The BTracKS balance board is portable and steady with customized software to evaluate the CoP trajectory of participants.

The Short Physical Performance Battery-Balance Test (SPPB) is an assessment of lower extremity function with three subtests: (1) standing balance, (2) four-meter gait speed, and (3) five repetitions of sit-to-stand motion. Subtest scores are added to obtain a summary score that represents mobility function.[64] The SPPB has been shown to be reliable (intraclass correlation coefficients [ICC]: 0.88-0.92), valid, and sensitive to change.[65]

The Berg Balance Scale (BBS) is a 14-item assessment of static and dynamic balance. Performance quality, time, and assistance required are rated on a scale of 0-4 based on pre-specified criteria [66, 67]. Total scores range from 0-56, with a score of 45 or below indicating high risk of falls.[68] The BBS has excellent test-retest reliability (ICC= 0.91) and intra-rater reliability (ICC = 0.98) [69] as well as good criterion validity.[70] It has 82.5% sensitivity and 93% specificity for predicting falls among older adults.[71]

CoP parameters were measured by the Balance Tracking System (BTrackS).[63] BtracKS is operated with a portable balance place, and the BTracKS software. The BTracKs software calculates CoP parameters such as total COP path length (cm) and mean CoP velocity (cm/s). The BTracKs system has good concurrent validity ($r > 0.9$) and test-retest reliability (ICC = 0.83) for community dwelling older adults[63, 72]. Participants were instructed to stand on the balance plate and perform 4 quiet standing conditions: (1) hip-width stand, eyes open; (2) hip-width stand, eyes closed; (3) narrow stand, eyes open; (4) narrow stand, eyes closed[72]. For each task, participants were instructed to stand still with hands naturally on the side of the hip. Each task was tested for three 30-second trials in order. Participants could chose to take a break after each trial.

Dynamic balance was assessed using the timed forward tandem walk test over a 3-meter course. The participant was instructed to place one foot in front of the other making sure that, with each step, the heel of one foot was directly in front of the toes of the other foot. The participant was told to walk forward as fast as possible without falling or making any mistakes. The average time recorded to the nearest 0.1 seconds from 2 trials was used in the analysis. In addition to time, the number of mistakes (misplacement of steps) was also recorded.[73]

The Activities-specific Balance Confidence (ABC) Scale is a 16-item assessment of balance confidence. Participant self-reports percentage points on the scale from 0% (no confidence) to 100% (very confident) of performing various ambulatory activities without falling or experience sense of unsteadiness. The final score is an average of the 16 items. The higher the percentage, the more confident a person is. The ABC is internally consistent and demonstrated good test–retest reliability, convergent and criterion validity.[74]

Muscle Strength. The literature suggests lower extremity muscle strength is critical in preventing falls. Muscle strength training is a core component of Adapted LiFE. Lower extremity muscle strength will be assessed using a Lafayette 01165 dynamometer. This measure has been selected based on the pilot study to avoid a ceiling effect. The dynamometer is an objective and accurate tool to assess lower extremity muscle strength. A standardized protocol will be used by all raters to guide strength measurements of hip flexion, knee extension, and ankle dorsiflexion using dynamometry. The groups of muscles responsible for these movements are critical for mobility and balance to prevent falls.[36]

Habit formation, will be measured using the Self-Reported Habit Index (SRHI). This 12-item assessment incorporates constructs such as habit strength, frequency, relevance to self-identity, and automaticity. Items are self-rated by participants using a seven-point Likert scale. Higher scores indicate that a behavior is more strongly habitual.[42, 75]

G Statistical Analysis Plan

G1 Sample Size Determination and Power

The goal of the pilot is to test the feasibility of the Adapted LiFE for medically underserved population, and is not hypothesis testing. Thus, sample size calculation are not necessary.[76, 77] We select to set our sample size at 16 to evaluate feasibility and effect size for future study.

G2 Analysis Plan

Data will be entered into REDCap. Descriptive statistics will be used to identify any trends in demographics, and feasibility outcomes.

G3 Statistical Methods

To detect effect of intervention. Wilcoxon signed rank tests will be used to identify trends in levels of balance, muscle strength, and habit formation.

To detect effect of intervention. Wilcoxon signed rank tests will be used to identify trends in levels of balance, muscle strength, and habit formation.

G4 Missing Outcome Data

For feasibility outcomes, all data will be used in the final data analysis. Participants who have missing data will still be included.

H Data Handling and Record Keeping

H1 Confidentiality and Security

We will protect participants' information with password protected data in REDCap, and HIPPA trained staffs. Data limited access to research team only. See 2e for details.

H2 Training

All research staff are covered entity and comply with all HIPPA regulations.

H3 Records Retention

Records will be kept only during study intervention. Data and records will be de-identified after and filed comply to HIPAA regulation after the study is completed.

H4 Performance Monitoring

Weekly staff meeting lead by Dr. Stark will monitor performance of all raters and interventionists. Data on REDCap and secured in the lab will be monitored and managed by Ms. Hu to ensure data safety and quality.

I Study Administration

I1 Organization and Participating Center

The clinical translational research of the Participation, Environment and Performance Laboratory (PEPL) focuses on the unique contribution that the environment can make toward improving the performance, participation and quality of life for persons living with functional limitations. Dr. Stark and her team study how the environment accounts for the differences between what individuals are capable of doing and their actual participation in society. The PEPL lab will provide study assessments, and research support including secured computer and storage spaces.

Two buildings of Shepherds senior apartments will collaborate with us to conduct this study. The Shepherds senior apartments resides in a medically underserved zipcode, and most of the residents aged 62 or over. The social service coordinator Ms. Billie Johnson will coordinate with us to provide space and time to recruit eligible participants.

I2 Funding Source and Conflicts of Interest

The funding for interventionist/rater hours and incentives for participant are provided by the Rehabilitation and Participation Science program (Occupational Therapy Program), Washington University School of Medicine.

None of the staff has conflicts of interest to disclose.

I3 Subject incentives

Participants will receive a $10 gift card after they finish the first intervention session, a $60 gift card after the last intervention session (7th session), and a $10 gift card after one month phone follow-up.

J Publication Plan

We plan to published the results of this pilot study in a peer-reviewed, rehabilitation focused journal to disseminated our findings.

K Attachments

K1 *Tables*

Table 1. Feasibility outcomes and measures of preliminary pilot study

Construct	*Instrument*	*Time*
Reach	Rater/interventionist log and visit-by-visit grid	t0, t1, t2, t3
Acceptance	Feasibility questionnaire	t2
Adherence	The LiFE activity planner	t1, t3
Fidelity	Rater/interventionist log and visit-by-visit grids	t1
Preliminary efficacy		
Balance	Tinetti gait and balance instrument (POMA)[78]	t0, t2
Muscle strength	Manual Muscle Testing (MMT)[79]	t0, t2
Habit formation	Self-Reported Habit Index (SRHI)[75, 80]	t0, t2, t3

Table 2. Adapted LiFE intervention for medically underserved older adults

Intervention composition	
Dosage and timing	Seven 40-60 minute sessions over 12 weeks (5 weekly session and 2 booster sessions). One follow-up phone call 1 month after tha last session
Essential ingredients	• Iterative practice of goal setting and achieving outcome expectations to increase self-efficacy
	• Behavior change elicited by habit formation strategies
Active ingredients	• Exercise principles to increase balance and muscle strength
	• Cognitive capacity to remember and carry out planned activities
Approach	• Goal setting of exercise activities begins at low frequency
	• OT as a collaborative partner
Standardized elements of tailored approach	• Seven sessions to add 1-2 exercise activities to participant's routine
	• In-home training, active practice

Note. OT = occupational therapist.

Table 3. Adapted LiFE balance and strength training principles and activities

Balance Principles	**Balance Activity**
Decreasing base of support	Tandem stand Tandem walk One-leg stand
Shifting weight and moving to the limits of stability	Leaning side to side Leaning forwards and back wards
Stepping over objects	Stepping forwards and backwards Stepping side to side
Strength Principles	**Strength Activity**
Bend your knees	Bend knees
Sit to stand	Normal chair Low chair
On your toes	Stand on toes Walk on toes
On your heels	Stand on heels Walk on heels
Up the stairs	Up the stairs
Move sideways	Step sideways
Tighten muscles	Move ankles Bend / Straighten knees Tighten / Relax buttocks

Table 4. Definitions of a fall and injurious fall as inclusion criteria

Construct	Definition
Fall	A fall is an unexpected event in which a person comes to rest on the ground, floor, or a lower level
Injurious fall	An injurious fall is a fall with a physical injury, which can be categorized as minor, moderate, or serious injury
minor	Had minor bruises or abrasions not requiring health professional assistance and that caused reduction in physical function (e.g. due to pain, fear of falling)
moderate	Had wounds, bruises, sprains, cuts requiring a medical/health professional examination, such as a physical examination, x-ray, or suture
serious	Had a medically recorded fracture, head or internal injury requiring emergency or inpatient treatment

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