Living in Fitness Together (LIFT): Testing an Innovative Fall Prevention Program

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Protocol Synopsis from Manual of Operating Procedures

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Foundation for Physical Therapy

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Introduction

Falls are the leading cause of non-fatal and fatal injuries in older adults.[1] Overall, 30% of adults over 65 fall every year, and the risk for falls increases dramatically with age.[2] Direct medical costs related to falls was estimated as 19 billion in 2000.[3] In 2005 there were 15,802 fall-related older adult deaths,[1] and in 2006 5.8 million older adults (16%) reported a fall in the prior 3 month period and 1.8 million had been injured.[4] Falls have major impacts on older adults, with potential for catastrophic mobility decline, loss of independence and institutionalization. The current trend in aging of the population makes this a critical problem for our time.

Current evidence and guidelines recommend multi-factorial assessment and intervention for older adults at increased risk of falls.[5,6] Strength, balance and gait training are among the most potent intervention components. Yet we know that fall risk benefits accrued from exercise are completely lost within 12 weeks.[7] The APTA recently published a Clinical Guidance Statement (CGS) for the management of falls in community-dwelling older adults.[8] The CGS underlined the gap between exercise intervention available within current physical therapy delivery models and substantial levels of challenging exercise required to achieve optimal fall prevention outcomes. It called for future treatment models to address behavior change, self-efficacy, and adherence to ongoing physical activity and structured exercise."[8] There is a critical need for fall risk management that systematically integrates patient-centered self-management to optimize long-term risk reduction.

The proposed project, Living In Fitness Together (LIFT) tests the feasibility and preliminary efficacy of a group-based PT fall prevention program using a within-group peer coaching intervention to improve outcomes for older adults at risk for falls by promoting sustained patient engagement in exercise and physical activity. The program will consist of group-based physical therapy for balance, strength, flexibility, and mobility training combined with a behavioral theory-based goal-achievement and peer-coaching training intervention targeting self-efficacy for the patients/group participants. It consists of 8 group sessions over 6 weeks plus one group booster session delivered by a physical therapist (PT) and trained staff. The program is designed to: 1) deliver progressive, tailored, and challenging exercise intervention for older adults at risk for falls; 2) empower older adults to achieve the required milestones for exercise and physical activity through training in theory-based behavior change, self-management, peer support and peer-coaching applied among the group participants; 3) incorporate evidence-based home safety intervention with necessary support for implementation of modification recommendations. By focusing on peers empowering each other within PT intervention as the center of exercise-based fall prevention for long-term patient engagement, this project will provide an innovative model for successful fall prevention.

Our Specific Aims are to:

1. Assess the feasibility of implementing the peer-coaching program in the physical therapy practice context by measuring enrollment, attendance, and completion of the program.

2. Evaluate whether the LIFT Fall Prevention program creates long-term behavior change as measured by exercise adherence at 6 months.

3. Evaluate safety and preliminary efficacy of the LIFT Fall Prevention program among 48 patients within an outpatient physical therapy practice. Safety will be assessed using self-reported falls, injuries, and adverse events. To support trial design for a future comparative

trial, we will measure indicators of initial efficacy including lower extremity strength and function, balance, balance confidence, concern about falls, mobility, physical activity, self-efficacy for exercise, and exercise adherence.

Intervention Program

Exercise Component

The design of the group exercise intervention is based on the evolving evidence for exercise and fall prevention.[8] This component was modified based on the evidence- based Otago Exercise Program (OEP),[9] and leverages preliminary research in a group-based modification.[10] It was designed to meet PT best practice recommendations for fall prevention from the APTA Clinical Guidance Statement[8] results of Sherrington et al.'s updated exercise meta-analysis and best practice recommendations,[11] and Power and Clifford's review: *Characteristics of optimum falls prevention exercise programs for community-dwelling older adults.*[12] This includes progressive, challenging exercise for strength, balance training, mobility and gait training. The intervention will also meet physical activity recommendations from the American College of Sports Medicine (ACSM) and American Heart Association (AHA).[13]

The strengthening /resistive and balance/neuromotor exercise components are based on the Otago exercise program with the addition of UE strengthening as recommended by ACSM guidelines. Cardiorespiratory/endurance exercise will be encouraged through an individualized progressive walking home program with the use of accelerator meter for feedback once cleared by the physical therapist. Flexibility exercises will be incorporated into the exercise program or within the peer coaching session.

The program frequency is two sessions/week for two weeks, decreasing to one time/week for 4 weeks. An additional group booster session will be scheduled 3 months post initiation of the program. The hour sessions will be divided between PT and a trained provider, initially forty five minute sessions for the first two weeks, for the physical components and education for tracking home exercise program. The exercise component will decrease to thirty minutes and increased time will be allotted to the goal-achievement component of the program.

Intensity for all components will be measured by self-report using the modified Borg Rating of Perceived Exertion (RPE) scale from "somewhat hard" (5-6) to "vigorous" (7-8).[14, 15] Exercise duration will be adjusted according to intensity.

The **strength training** component will target at least seven major muscle groups, knee flexors, extensors, hip abductors and extensors, ankle dorsiflexors and plantar flexors. The addition of 3 upper extremity exercises is an addition to the Otago program based on ACSM recommendations for older adults and these elements will be based on Miriam Nelson's Osteoporosis programs. Participants will be advised to perform 2-3 training sessions/week or split the sessions into two shorter sessions of 3-4 muscle groups. Initial resistance for exercises will be individualized based on current recommendations and tolerance. Strength training will be monitored so the amount of resistance can only be done 8-15 repetitions before muscle fatigue. The therapist will monitor for muscle substitution, proper breathing, exercise technique and timing and provide guidance to ensure that exercise level is challenging.

The **balance training** will incorporate progressive activities that reduce the base of support, leaning beyond base of support, shifting center of mass, minimizing upper limb support,

coordination of single/dual tasks with cognitive challenges. Training and guidance will be provided to tailor exercise to meet the requirement for all exercises to be challenging. Dynamic walking activities including obstacle courses for functional activities and strategies for transfers to and from the floor will be included.

The **flexibility exercises** will include a static stretching program involving all major muscle groups and yoga based stretches in both sitting and standing after warm up or cool down.

The **endurance/walking** will be prescribed based on examination results throughout the group sessions. Patients who are deemed safe for a home walking program will receive guidance for tailored, progressive walking program with the goal of >=3x/week. The intensity of walking will be self-rated using the Borg scale, and duration goals will be adjusted accordingly.

The home program will be based on the evidence-based Otago program, modified and individually tailored based on the goals and exercise progression achieved in the group sessions. Patients will be provided with exercise program materials based on the Otago manual, including calendar and exercise diary to manage and document exercise performance and progression. The manual will include detailed instructions for the material presented in group sessions, with visual aids, including frequency, intensity, time by exercise type, instructions for progression and use of the Borg scale to guide intensity. Patients will record steps taken as reported by their accelerometers in their exercise diary.

At the 3 month and 6-month visits, all tests will be conducted and measures administered, and exercise logs will be copied, and patients will provide self-reported exercise frequency and duration over the past month. At the 3 month session the physical therapist will discuss present program; review tracking system for home exercise program; review exercise intensity levels based on the Perceived Exertion Rating for each exercise type (e.g. resistance and walking). Individual progression and/or modifications will be determined by the physical therapist. The Goal-Setting program lead will facilitate a discussion about how goal-setting and peer-coaching activities have been going. Figure 1 provides a study diagram and Figure 2 illustrates the overall flow of content across the duration of the program.

Figure 3. Study Flow Chart

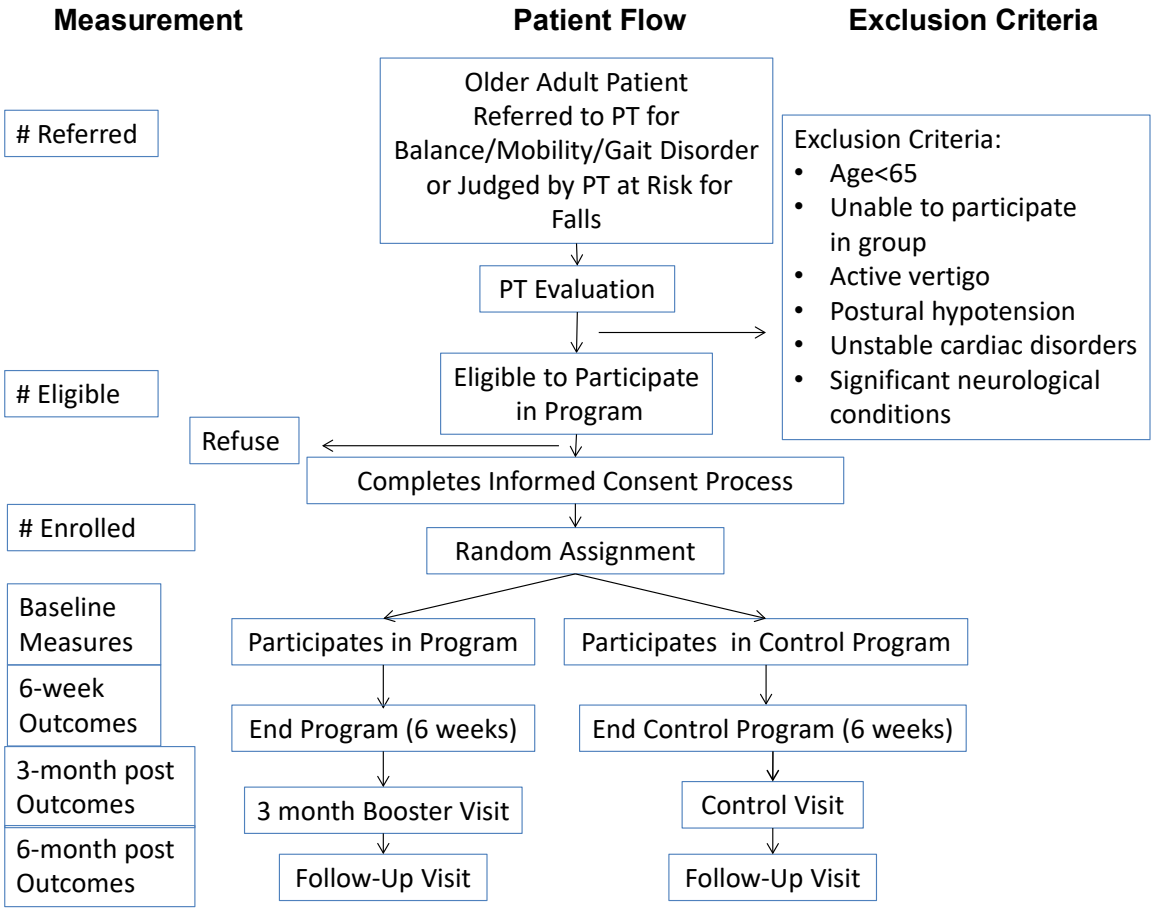
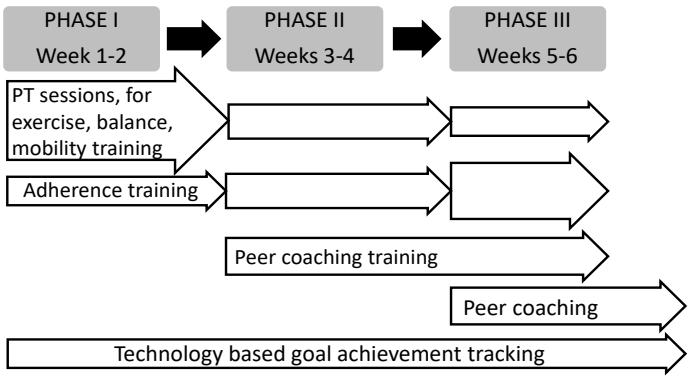


Figure 2. Flow of Program Contents up to 6 weeks

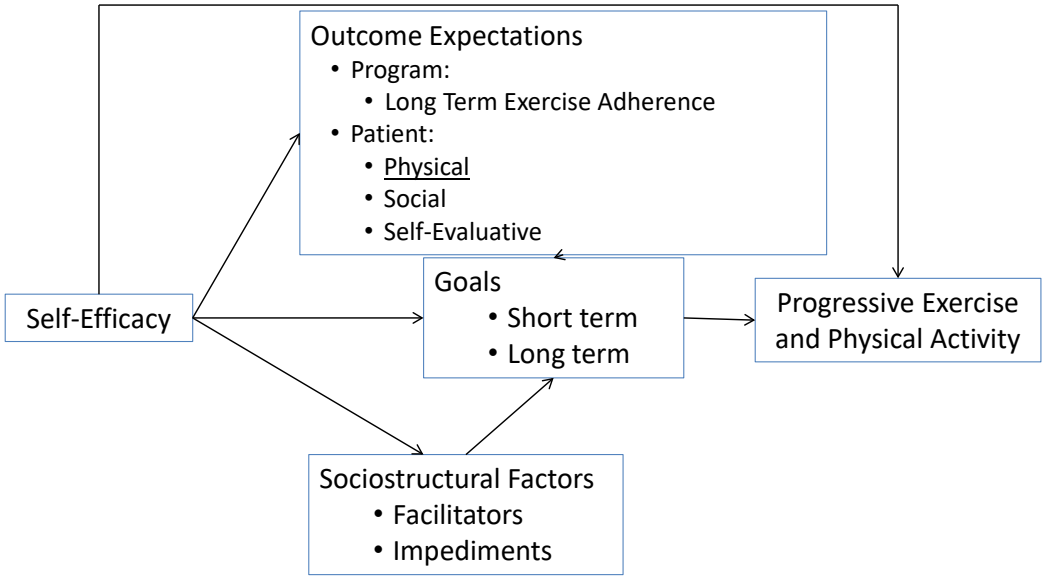


Safety of the program will be monitored by tracking self-report of falls, injuries, and adverse events. Participants will record falls or other adverse events in their tracking system, or Action Plan. They will be instructed to report all events to the clinical investigators. In addition, the research assistant will conduct calls bi-weekly telephone calls to collect these data.

Goal Achievement Component

The overall framework for the Goal Achievement component of the intervention is Social Cognitive Theory, as illustrated below in Figure 3.

Figure 3. Goal Achievement Component



Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavioral change. Psychological Review 84(2): 191-215.

The three main dimensions of the Goal Achievement component include:

1. Goal Setting
2. Self-Assessment
3. Self-Awareness

During the program, participants will be provided with education and participate in guided, individualized and group activities to promote independence in each of the three dimensions.

Goal Setting

Participants will receive education and training in goal-setting throughout the program. Goal Setting is a shared provider/participant activity that includes consideration of outcome expectations, potential short term (ST) and long-term (LT) goals, confidence in achieving the goals, potential facilitators and impediments, and problem-solving.

In order to facilitate Goal Setting the provider will work with participants to complete a Goals Worksheet (Appendix A). The provider will discuss and complete the overall program goals and individualized PT goals with the participant, and ask the participant to complete the activity goals.

Participants will be asked to refer back to these goals on a weekly basis and adjust the goals as appropriate. To support achieving their short term and long term goals, we will teach participants to create weekly Action Plans (Appendix B) in which they will include the specific action(s) they will take, and include details such as intensity, duration and frequency of exercise for the week. Within the Action Plan, participants will rate their confidence in carrying out the action plan as follows:

How much confidence do you have that you will complete the action plan?

None at all	A little	A lot	Full confidence
○	○	○	○

We will teach participants skills to use when they find that their confidence in achieving the goals is low. Identification of barriers and facilitators, brainstorming and experimentation will be used as described in Self-Assessment below.

Self-Assessment

Self-Assessment will be framed as dialogue with oneself, with peer coaches, or other sources of social support. The approach is aimed at fostering experiential learning and development of self-efficacy for exercise. A key feature of the training will be the focus on teaching participants to model the target behaviors in their group interactions. We will train participants to ask and answer key questions to assess their progress, build self-efficacy, problem-solve, and take positive action to achieve their goals (Appendix C).

Sample questions include:

- What went well? Did I do the exercises and activity I planned?
- What were my challenges? [Impediments/barriers]
- What are some solutions I could try/What could I do next time?
- Which one(s) will I try first?

Participants will use these questions to foster problem solving with an emphasis of experimentation, and solution focused success. Participants will be encouraged to write out their responses to the questions and to share with the group. If they report success then they

will be demonstrating good role modeling for the group. If they report barriers, then the group can help with group problem solving, by practicing brainstorming. They will identify the barrier(s), pick one, then brainstorm with the group and lastly chose one to try during the coming week. These steps will be repeated weekly by all participants to encourage experiential learning, self-efficacy and adherence to their exercise program and incorporated into their interaction in the peer-support sessions.

Self-Awareness

We will teach participants skills and activities to promote self-awareness and self-efficacy and independence in managing their impediments to goal achievement. Examples of activities will be self-rating of confidence in accomplishing goals (as shown in goal-setting above) level of calmness/peacefulness, stress, and energy and symptom levels. We will teach simple management strategies such as breathing and position and activity changes to improve self-efficacy and management. We will use self-rating to teach awareness. The following are examples of questions that can be asked. A worksheet of self-awareness self ratings will be provided in the binder (Appendix D)

Below are two examples:

How stressed do I feel right now?

Not at all	A little	Very
○	○	○

How much energy do I have right now?

None at all	A little	A lot	

Peer-Coaching Component

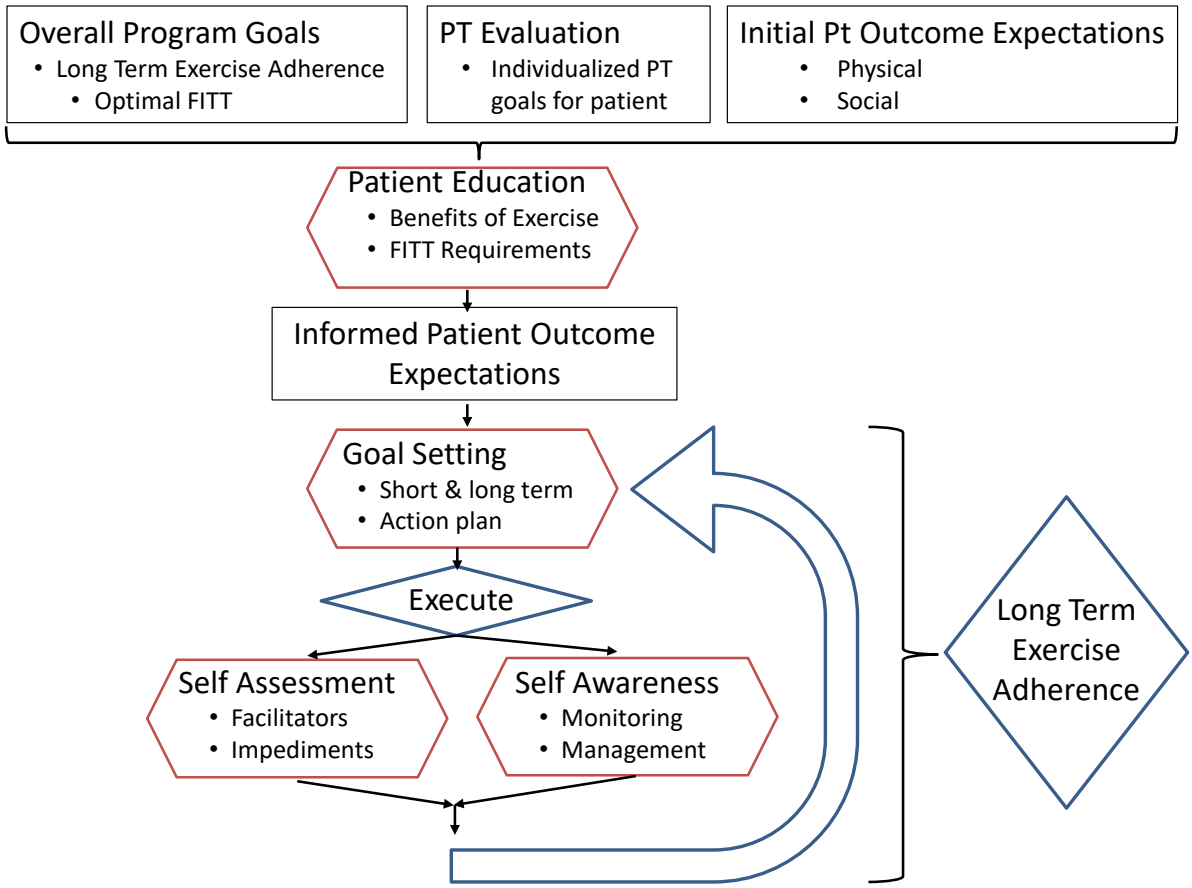
The goal of the Peer coaching component is for team members to provide social and emotional support to each other to support achievement of the exercise adherence goals. Peer coaching is a process in which 2 or more team members work together to implement their individual exercise Action Plans by modeling problem-solving and social and emotional support skills. This process includes sharing feelings, successful experiences, challenges, ideas, and results of personal experiments, and reinforcing skill achievement. In LIFT peer coaching is conducted by the participants themselves, rather than graduates or older adults who have succeeded in long-term adherence to exercise. The emphasis of the LIFT program is on learning adherence and peer support skills together.

Participants will receive instruction and training in roles and responsibilities and basic peer support skills including active listening, such as restating, summarizing, minimal encouragers, reflecting, giving feedback, using simple follow-up questions, validation, effective pause, and avoiding communication blockers. We will also teach the use of open and closed-ended questions. This material will be taught using lecture, discussion, video as well as role playing in which the participants will practice specific skills in multiple group sizes (pairs, and groups of 4) in the context of their own exercise goals. We will ask participants about their current technology use and incorporate technology as appropriate, including group calls and social media. We will

teach the participants how to conduct a group call/session, and how to fulfill the role of facilitator.

Support materials such as scripts and choices of probes are provided in the LIFT binder. Participants will have the opportunity to debrief after they practice the skills, and after they try peer-coaching on their own. They will be provided with contact information for the research team for questions or problems. Figure 4 below provides a detailed model of the elements of the Goal Achievement component.

Figure 4. LIFT Goal-Achievement Component to Improve Self-Efficacy and Exercise Adherence



The Overall Program Goals:

A. Long term adherence and self-efficacy for home exercise program

B. Improve strength, endurance and balance measurements to level of low or no risk for falls

Individualized PT Goals for Participant

Long Term Goals (12 weeks)

1. Participant demonstrates knowledge and understanding of components of home exercise program (flexibility, strengthening and endurance) including progression, proper technique and modifications. They will demonstrate proper and safe use of adjustable leg weights and pedometer.
2. Participant will meet the following goals :
    a. Walking 7,000-10,00 steps 3 or more days/week
    b. Perform strengthening exercises 3 days/week
    c. Perform balance exercises 3 or more days/week
    d. The total exercise goal per week will be at least 2 hours
3. Participant will meet personal functional goal as established at start of program.
4. Peer coaching goal: Participants will connect via phone or social media 1-2x weekly with a member of their peer coaching team.

Short term goals:

1. End of week 2
    a. Demonstrate use of pedometer tracking device and use flow chart to track steps taken per day
    b. Demonstrate use of ankle weights for strengthening exercises and flow chart to record flexibility, strengthening and balance exercises.
    c. Peer coaching goal. They will demonstrate active skills in small groups and 1:1.
2. Goals for week 3, 4, 5, 6 to be individualized on action plans
    a. Track weekly progress on flow chart
        i. steps walked/time walked per day
        ii. Repetitions and weights for strengthening
    b. Progression of balance exercises with diminished use of UE support

    c. Peer coaching goals: Participants will be able to demonstrate active peer coaching and support by utilizing the self-assessment questions

Home Safety Evaluation

Each participant in the LIFT study (intervention and control groups) will have the opportunity to have a home safety evaluation by an Occupational Therapist (OT) at no cost the participants or their insurers. The goal of the home evaluation will be to help the participant to identify any environmental changes or equipment that could decrease their risk of falling and make everyday tasks easier and safer at home.

At the time of baseline data collection, a series of questions will be administered to the participants to gather information about prior home safety evaluations and planning information, including whether or not the participant would like a home safety evaluation. Based on the results of these questions the OT investigator will follow-up with the participant to provide guidance or to schedule and conduct the home safety evaluation.

The OT will use the HOME-FAST tool to guide the home safety evaluation and to document results and recommendations (Appendix E)

Control Program

The control group will continue with "usual care" one-on-one physical therapy. In addition, they will attend a control group class that provides social interaction and interesting health information. They will be asked to track when and how much they do their PT home exercise program, walking, and any falls or adverse events or problems. Below is a description of the control group class.

"Healthy YOUniversity" is a program developed by Boston University and Mt Ascutney Hospital and Health Center (MAHHC) for the Living In Fitness Together Research Study to provide group education about activities and behaviors that promote healthy living. This 6-session program includes the following topics:

Home Safety: Content will be provided in the participant binder to address the range of ways to enhance safety inside and outside of the home. This content will be reviewed in the orientation session so that questions can be answered and participants can expect the OT's call. A Home Safety Assessment by an Occupational therapist will be offered, as described above in the Home Safety Assessment section.

Session 1. New Stress Paradigm. This session will discuss stress within the context of the Energy In - Energy Out paradigm. Participants will learn examples of healthy activities and choices across a range of topics including nutrition, sleep, positive thinking, social support, meaningful activities, and exercise. Activities and choices that may deplete energy and overall health will be discussed. Tools such as visual imagery, mindfulness, breathing exercises, and simple techniques to enhance healthy sleeping patterns will be presented. Handouts will be provided in the participant binder.

Session 2. Nutrition. This session will teach the heart healthy diet as outlined by The American Heart Association, National Institutes of Health and the American Medical Association. Handouts from government websites will be provided in the participant binder.

Session 3. Leisure Education for Quality of Life. This session will explore the PIESS approach to including a variety of healthy leisure activities.

- **P:** Physical
- **I:** Intellectual
- **E:** Emotional/Relaxing
- **S:** Social
- **S:** Spiritual/Meaningful.

Session 4. Social Capital This session will define social capital and how it aids a healthy lifestyle. Examples will be discussed including sharing information and resources, providing assistance, and building trust.

Session 5. Resilience What does the science say about bouncing back from a major life stressor? This session is based on the SAMHSA-HRSA Center for Integrated Health Solutions and will describe resilience and discuss the importance of this quality for our health.

Session 6. Community Resources: What resources are available in the area to help improve overall health and well-being? A comprehensive list of community resources will be provided in the participant binder and discussed.

Tracking Exercise. An activity log will be used to track exercise adherence, falls, and adverse events during and after the class. (Appendix F).

Documentation of PT and OT Services

PHYSICAL THERAPY

Participants who are eligible, have signed consent and are waiting for randomization (16 subjects) will begin one on one PT if time is >1 week for baseline testing. Documentation per protocol for outpatient PT.

After randomization:

All participants will undergo baseline data collection.

Control Group

Data will not be entered into eChart for Control Group. Data collection will be filed in a secure place and sent to BU for analysis. Patients will be registered under Recurring encounter for Therapies if they have not started outpatient PT or continue with primary outpatient PT. PT documentation will be performed by the PT as per the outpatient protocol in eChart.

Intervention Group

After baseline data collection the PT will conduct functional evaluation to determine appropriate starting level for the exercise program. The results will be documented under OUTPATIENT PT Progress note with Plan of Care by PT. There will be no charges and 0 (zero) will be inserted in charge and time under neuromuscular/Balance.

If a participant has been treated in outpatient PT and is randomized into the intervention group the patient will be discharged from PT, registered under the LIFT study and recurring encounter will be discharged.

Ongoing PT documentation: The PT will complete the Daily Documentation form using Group, Ther activity and Ther exercises and Education tabs as needed. Subjective, Assessment and modifications of Plan of Care will be documented. Time and Units will be entered as 0 zero under Neuromuscular and Balance.

At the end of the program, PT flow chart of attendance and progression of exercises will be scanned into the chart.

This encounter will stay open until end of data collection at 6 months.

Baseline, 6 week, 3 month and 6 month Data Collection.

Intervention group

Data from baseline testing plus additional strength test and POC will be entered in Progress Note.

6 week testing will be entered in the last session for the Intervention group (discharge information in last daily documentation note as would be in standard PT practice.)

3 month booster session will be reported in Note by PT/TR titled Intervention Booster Session. No data will be entered into E Chart.

6 month testing- Note will be entered by PT/TR documenting they participated in testing for LIFT study. No data entered into E Chart.

CONTROL group

Initial, 6 week, 3 and 6month testing data will not be entered into eChart. A note will be entered by PT/TR documenting that they participated in testing for LIFT study.

OCCUPTATIONAL THERAPY

Home Safety Evaluations

The provider conducting home safety evaluations will complete the HOME- FAST form (Appendix E) and assess mobility in the home, and identify environmental obstacles and hazards. Recommendations will be written and shared with participant. Both forms will be scanned into the medical chart. Time Spent with Patient ad hoc outpatient form will be used and 0 (zero) will be entered under Ther Act for time and units with patient.

Therapeutic Recreation Services (both groups)
INTERVENTION GROUP: The therapeutic recreation therapist will document using Recreation Therapy Progress Note. As per usual care, there will be no charges.
CONTROL GROUP – The therapeutic recreation therapist will track attendance and there will not be any additional documentation.

Training

MAHHC Outpatient Physical Therapists

LIFT investigators will provide information to the Mt Ascutney physical therapists who will be identifying eligible patients during a one-hour session. Information about the study and the eligibility criteria will be provided. The physical therapists will be trained in how to use the eligibility form, and where to submit it (Eligibility Form: Appendix G; Training Form for Outpatient Therapists: Appendix H). Printed copies of the Participant Study Summary will be provided.

MAHHC Secretaries

The MAHHC secretaries will fax the eligibility forms and refer calls about the study to Linda Hazard. A contact list for study investigators will be provided to the secretaries.

LIFT Research staff

Each member of the research staff will undergo Human Subjects protection training via CITI courses through Boston University. In addition, they will attend a 2 hour study-specific training in LIFT procedures conducted by the principal and co-investigator. A one hour retraining session will occur prior to the 2nd and/or 3rd class session if more than 6 weeks has elapsed between sessions. This content will include study specific human subjects protection, study procedures, data collection, adverse event reporting, including reporting if assessor is unblinded to study assignment. In addition to this training, members of the research team conducting the exercise class, the behavioral component (Goal-setting and Peer-coaching), the control sessions, and data collection (including adverse events) will undergo component-specific study training

Exercise Component: Providers conducting the group exercise component will complete certification in the Otago program, and undergo 1 hour training in study-specific content and progression of the group class, activity monitor use, and study documentation. See Appendix I: Training documentation form and Appendix L: Training for Exercise Component.

Data Collection: The data collectors will be trained in administration of the study questionnaires, and in the physical performance tests. See Appendix I: Training documentation form; Appendix J: Physical Performance Test Training Log; Appendix K: Physical Performance Tests: Strength, Balance, and Walking Assessments

LIFT Study subjects

Identification

Outpatient physical therapists will identify potentially eligible patients using the Eligibility form provided (Appendix G). If the patient is eligible, the physical therapist will inform the patient of the study and ask if they are interested in hearing more about it. They will provide the study summary to the patient, provide contact information on the Eligibility form, and let the patient know that study staff will contact them. They will submit the forms to the outpatient PT secretary, who will contact Linda Hazard to alert her that an eligible participant has been identified.

Enrollment

Study staff will call the patient to provide information on the study, answer questions and set up a time to enroll, likely before or after the next physical therapy session. At that session, study staff will provide specific information on the class meeting times and commitment, and clarify that the start date is to be determined when all 16 participants have been enrolled. She will obtain written, informed consent, and let the participant know that study staff will call them about when the program will begin. Linda will complete the Master Key document (Appendix M), assigning the participant a study identification number (study ID). The study ID will be used to identify the participant in the consent form and data collection forms.

Randomization

Linda will insert the study ID, age and sex into the Randomization Spreadsheet (Appendix N). When 16 IDs are listed on the sheet, she will email to the blinded study analyst, who will use a computer algorithm to randomly assign the participants to study condition, blocked by age and sex. The analyst will send the spreadsheet back to Linda with the assignments.

Notification

Unblinded study staff will contact the patients to notify them of their study group assignment, the day and time of the baseline data collection, and the schedule of the group sessions. Study staff

will inform the participants that at the baseline data collection, the data collector will not know their study group and should not be informed.

Data Collection

Feasibility Data

We will use the eligibility form (Appendix G) to collect data on:

Number eligible

Number refusing.

We will collect number consenting from the consent forms

We will track class attendance using an attendance sign-in sheet (Appendix O)

Cancellations (notification) and no-show status will be tracked by the class instructor (Linda for Intervention and Michael for control).

Adverse Event Monitoring and Reporting

We will follow the guidelines of Boston University Medical Campus (BUMC) IRB with respect to defining and reporting adverse events, serious adverse events and unanticipated problems. The following definitions will be used:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

SERIOUS Adverse Event (SAE) is any adverse event that

Grade (1) results in death**;**
Grade (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
Grade (3) results in inpatient hospitalization or prolongation of existing hospitalization**;**
Grade (4) results in a persistent or significant disability/incapacity;
Grade (5) results in a congenital anomaly/birth defect; or
Grade (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents (such as the IRB-approved research protocol and informed consent document); and (b) the characteristics of the subject population being studied; **AND**
- is related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); **AND**
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated problems must be reported to the BU IRB using the Reportable Events and New Information form. BU IRB requires that all Unanticipated Problems meeting the definition listed above and involving a fatal or life-threatening event be reported to them **within 2 days** of learning of the event. Unanticipated Problems not involving a fatal or life-threatening event must be reported to BU IRB **within 7 days** of learning of the event.

All Adverse Events and Serious Adverse Events that do NOT qualify as Unanticipated Problems must be reported to the BU IRB in section 5 of the Continuing Review submission and include the Principal Investigator's conclusion that the pattern of events does not suggest a greater risk of harm.

Adverse Event Recording from the Baseline Data Collection through Week 6 (in-person classes)

Because this study includes older adults at increased risk for falls, we expect adverse events in this study to include falls. In addition, we expect adverse events from exercise in both groups to include: fatigue, muscle soreness or other discomfort or a fall or injury during tests and exercise. As per Lamb 2005[16], falls will be described as "unexpected events in which the participants come to rest on the ground, floor, or lower level." Participants will be provided with the definition of falls used in this study in the Baseline Data Collection & Orientation session (prior to starting the program). They will be provided with their binders, and we will instruct them in the use of the Action plan to record daily any falls or adverse events, symptoms and questions, as they occur. At each session, the instructor will collect the forms, make copies for study documentation, and return them to the participants.

If participants report fall(s) and/or adverse effects/events through the Action Plan (intervention) or Activity Tracker (control), or verbally, in-person or by telephone, the instructor will provide appropriate clinical assessment and recommendations and modifications if safe to continue participating in the program and document in the clinical flow chart. In addition, the instructor will fill out the Adverse Event Form (Appendix P) and provide the form to the research assistant, who will document the event in a master log of all adverse events.

If a participant falls or experiences an adverse event while attending the class session, the instructor will provide appropriate clinical assessment and recommendations and modifications if safe to continue participating in the program and document in the clinical flow chart. If injury occurred and the participant was unable to participate in the class, the instructor will complete and submit an RL Solutions event as per Mt Ascutney procedures. The instructor will determine

whether the participant needs to seek medical attention at MAHHC and assist the participant to the clinic or emergency department. In addition, the instructor will fill out the Adverse Event Form (appendix P) and provide the form to the research assistant for documentation in the master log.

If any adverse event, either self-reported or experienced during class, meets the definition of Unanticipated Problem, the instructor will, in addition to providing the Adverse Event Form to the research assistant, notify the principal investigator immediately (same day). The principal investigator will notify the Boston University IRB within 2 business days if the adverse event meets the definition of Unanticipated Problem and involves a fatal or life-threatening event, and within 7 days otherwise. All adverse events that do not meet the definition of Unanticipated Problem will be reported by the principal investigator to the Boston University IRB at the time of continuing review.

Adverse Event Recording from Week 6 through Study Completion (6 months)

To identify adverse events after the regular class sessions have been completed, participants will record the events in their tracking forms, and a blinded assessor (separate from the outcomes assessor, study management and intervention teams) will contact the participants every 2 weeks by telephone to inquire about any events that have occurred. A standard script will be followed during these sessions to obtain consistent information and to maintain blinding (appendix P). The blinded assessor will fill out the Adverse Event Form for any event reported during a call and provide it to the research assistant for documentation and tracking. If the adverse event meets the definition of Unanticipated Problem, the blinded assessor will also notify the principal investigator immediately (same day). The principal investigator will report the Unanticipated Problem according to the BU IRB guidelines stated above. In addition, other study staff will report adverse events if they become aware of them during the post-group class time period (Week 6 – 6 Months) by filling out the Adverse Event Form, providing it to the research assistant, and notifying the principal investigator immediately if the event is an Unanticipated Problem.

Preliminary Efficacy Data

Baseline Data Collection (See Appendix R)

Both Groups	
Performance-based Measures	**Self-report**
4-stage Balance	demographics
TUG	LLFDI community mobility short form
30-second Chair Stand	FES-I
DGI	ABC-6
	Barriers Self-Efficacy
	Technology Use Questionnaire
	Get up from floor
	New/change in health status
	Recent fall(s) and mobility questions
	Home Assessment Questions

Baseline Data Collection and Orientation

LIFT Intervention group
Within 2 weeks of the start of the program, the participants will be invited to come to a baseline Data Collection and Program Orientation session. Blinded research staff will provide questionnaires, conduct the physical tests, and complete the Baseline Data Collection Form. The Intervention and Control groups will be invited to separate Data Collection times or rooms in groups of 4. For example, 4 of the Intervention participants will be scheduled for 10:00am on Thursday. They will be shown into one room. The blinded research staff (Andrea) will be informed of the room and time, but not the assignment of the group. She will inform the participants that she must not know their assignment. She will instruct the participants to complete the questionnaires, and offer to clarify as needed. While participants are completing the questionnaires, she will conduct the TUG, 30 second chair stand, 4-stage balance test and Dynamic Gait Index (10 minutes) individually. When participants have completed the questionnaires and physical tests, The Data Collector (Andrea) will release them to unblinded study staff (Meg), who will bring the participants to the appropriate location for their separate orientation sessions. She will also deliver the physical test results to the Intervention group instructor (Linda) to inform the Orientation session. The orientation will consist of an explanation of the overall structure of the class, provision of the Participant Binder and the activity monitors, and ascertaining the starting weight for strength training. Instruction will be provided on use of the monitors. Participants will be asked to wear the monitors daily and to record their steps in their Action Plan (Appendix B) until the first program session to establish their baseline walking activity. The Action Plan will also be used to track daily symptoms and falls on a daily basis.

Orientation to the Program (see Appendix Q)
Each participant leaves with his/her assessment form.
Intervention group meets with Linda who: Completes the Goals Form based on the assessment form and patient input. Linda will put copy in binder and make copy for records. Linda will document PT progress note with plan of care and goals in medical record (Initial evaluation was done by outpatient physical therapist).
Review program
Review program goals and baseline assessment results
Define falls
Discuss how to handle symptoms, falls.
Provide the activity monitor, teach use
Identify if safe for walking program
Orient to the Activity log; Ask participants to log steps/day, symptoms, falls.
Review calendar for future data collection, 3 month booster session, 6 month data collection.

Healthy YOUniversity
The Healthy YOUniversity instructor (Michael) will conduct an orientation that will consist of an explanation of the overall structure of the class, the calendar, and provision of the participant binder, providing our definition for falls, documentation of their exercise, falls and adverse events, and how to contact study staff.

Data Collection during the Program

The instructors will record attendance, and copy the Action plans/tracking sheets as record of exercise adherence, falls and adverse events. See above for procedures related to Adverse events.

6 Week Data Collection Assessment (See Appendix S)

Both Groups		Intervention Only	Control Group Only
Performance-based	**Self-Report**		
4-stage Balance	LLFDI community mobility short form or CAT		
TUG	FES-I		
30-second Chair Stand	ABC-6		
DGI	Barriers Self-Efficacy		
	Get up from floor		
	Exercise Adherence: walking, strength, balance (from Action Plan/Tracking doc)	6-wk Intervention program evaluation questions	6 week Healthy YOUniversity program evaluation questions
	Falls (from Action Plan/Tracking doc)		
	Adverse Events (from Action Plan/Tracking doc)		

3 Month Data Collection (See Appendix T)

Both Groups		Intervention Only
Performance-based Measures	Self-report Measures	
4-stage balance	LLFDI community mobility short form or CAT	
TUG	FES-I	
30-second Chair Stand	ABC-6	
DGI	Barriers Self-Efficacy	
	Get up from floor	
	Exercise Adherence: walking, strength, balance	
	Falls (from Action Plan)	
	Adverse Events (from Action Plan)	
	Falls Questions	Peer-Coaching Questions (Full)

6 Month Data Collection (See Appendix U)

Both Groups		Intervention Only
Performance-based Measures	Self-report Measures	
4-stage balance	LLFDI community mobility short form or CAT	
TUG	FES-I	
30-second Chair Stand	ABC-6	
DGI	Barriers Self-Efficacy	
	Get up from floor	
	Steps/Day	
	Exercise Adherence Walking, Strength, Balance	LIFT program overall questions
	Falls questions	Peer-Coaching Questions (full)

A summary of the program content is provided below.

	Exercise	**Goal-Achievement**
Week 1		
Class 1	*Time:* 45 min	15 min
	Content: Learn warm up, strength, balance and flexibility ex's, overall ex goals (2-3X/week: 2-3 sets 70% 1 RM; balance challenge, walking 3x/week), estimating 70% 1RM; safety, logging activity, symptoms, falls	Group building/Ice-breaker activities Homework: Look at the Action Plan
Class 2	45 min	15 min
	Learn warm up, strength, balance and flexibility ex's, overall ex goals (3X/week: 1 set of 10 70% 1 RM; balance challenge, walking 3x/week), estimating 70% 1RM; safety, logging activity, symptoms, falls	Work on Action Plan Introduction to Self-awareness
Week 2		
Class 3	45 min	
	How to progress activity (PT to determine by self-report of PEI and if able to perform 2 sets of resisted exercises progression of weight. Determine safety of decreasing support with balance and standing exercises.	15 minutes
		Problem-solving skills
		Self-awareness
Class 4	45 min Warm up, strengthening exercises, flexibility, balance exercises with progression of decreasing support	15 minutes
	Ramp/stairs	Self-Assessment
	Introduce methods of transferring safely to floor and up with modifications	
Week 3		
Class 5	30 min Warm up, strengthening exercises, flexibility, balance exercises with progression of decreasing support.	15 min Problem-solving
		15 minutes peer coaching
		Video; fall-specific coaching; roles and responsibilities
Week 4		
Class 6	30 min Encourage participants co-lead exercises. Warm up, strengthening exercises, flexibility, balance exercises with progression of decreasing support	30 min
	Set up obstacle course with foam, rocker board, static balance challenges, steps, reaching with and without UE support	Peer-coaching skills (active listening)
		Break-out in pairs
		Report back
Week 5		

	Exercise	**Goal-Achievement**
Class 7	30 min Warm up, strengthening exercises, flexibility, balance exercises with progression of decreasing support	30 min
	Incorporate dynamic balance training including head turns, change in gait speed, turning, stepping over objects.	Intro 2 groups of 4
	Practice standing to floor transfers as appropriate	Planning your conversation with peers
		Breakout in 4s; Try it; Debrief
		Method of contact; Schedule of calls and facilitator
Week 6		
Class 8	30 min Encourage participant co-lead Warm up, strengthening exercises, flexibility, balance exercises with progression of decreasing support. Determine progression of weights and support for balance exercises for final class and progression at home.	30 min
		Review how the meeting went
		Self-assessment
		Peer-coaching
		Set up goal for 1 month
Week 12	30 min Discuss present program; review recent flow chart for home exercise program; review exercise intensity levels based on the Perceived Exertion Rating for each exercise type (e.g. resistance and walking). Individual progression and/or modifications will be determined by the physical therapist.	The Goal-Setting program lead will facilitate a discussion about how goal-setting and peer-coaching activities have been going.

Statistical Analysis Plan

From grant submission 7-27-2015

Enrollment and safety data will be collected in the study database by the clinical co-investigators. Safety analyses will be conducted based on similarly basic data collection and tracking and will include summary falls, adverse events and protocol deviations, and summary statistics (n,%) calculated. This feasibility study will not be powered to detect differences in outcomes between the 2 groups. We will carefully examine baseline rates of falls and other variables to enable rigorous sample size calculations for a formal clinical trial. However, preliminary analyses of changes in the intervention and control groups will be assessed to inform study planning. We will calculate the means and standard deviations at pretest (baseline) and corresponding values at post-tests (6-week/program completion, 3-month post program, 6-month post program). The corresponding confidence intervals will be calculated to fully describe the plausible true population values.[63] We will explore differences between the intervention and control group in baseline characteristics, and relationships between these variables and outcome variables of interest. Differences between the groups will inform planning for randomization and baseline values may be used to adjust for differences in our preliminary analyses of differences between groups. At each post-test time point, we will apply analysis of covariance (ANCOVA) to examine the relationship between the post-test score and treatment controlling for the pretest score and demographic variables.

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