UNIVERSITY OF CENTRAL FLORIDA

PROTOCOL TITLE:

Optimizing a technology-based body and mind intervention to prevent falls and reduce health disparities in low-income populations.

PRINCIPAL INVESTIGATOR:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/6/2021	-Added the maximum sample size -Removed phone calls to record monthly fall incidence log (from two groups) and removed home visits from PEER group -Changed activities for group 2 from fall education to group-based exercise - Added the following information into the consent: a random assign, sharing the results, inclusion criteria, and withdrawal of subjects -Renamed the surveys	Yes
2	8/26/2021	-Revised the protocol section 5.0 study intervention, 6.0 Procedures involved, 14.0 Withdrawal of subjects, 17.0 data management and 19.0 Provisions to protect the privacy interests. - Removed study logs, phone calls, and home visits, Revised consent	Yes
3	9/2/2021	-Revised the protocol section 6.0 Procedures involved (added more details and increase incentive, Revised consent	Yes
4	10/6/2022	addendum request 10/2022 to add/change/remove: Add aim 3, change the study title to match the award title, update sample size, timeline, and funding source (NIH grant) in protocol and consent, remove the exercise activity for the attention control group and add the new activity (providing an information pamphlet about falls), add a tool to assess negative self-perceptions using the Brief Ageing Perceptions Questionnaire (B-APQ) and update Appendixes by adding B-APQ and, Appendix J Interview Questions (Aim 3), add co-investigators (Joon Park, Rui Xie, Nichole Lighthall, Victoria Loerzel), and two research assistants (Renoa Choudhury and Eunice Ojo).	Yes

5	03/13/2023	Revised Protocol Appendixes 0 (Screening questions and demographic survey), B (Psychological component surveys), C (Psychological surveys, G (Lower extremity function and balance test using SPPB), added FitBit Activity Tracker, Removed inclusion criteria number 2 and 3. Added PEER Leaders component and PEER leader ICF. Added the following research assistants to the study: Miguel Grisales-Coca, Ana Villegas,and Aleeyah Uddeen.	
6	06/02/2023	-Revised Protocol Appendix B by adding surveys to assess cognition, including Rowland Universal Dementia Assessment Scale (5 items), Subjective cognitive decline (SCD 1 item) and SCD-Instrumental Activities of Daily Living (SCD-IALDs, 3 items) -Revised Protocol Appendix J by expanding question #4 -Included the Spanish version of surveys, consents, tools and exercise booklet -Added a research assistant to the study: Renata Kamalasari.	Yes (Spanish version)
7	07/12/2023	- Added inclusion/exclusion criteria from Group 1: PEER Intervention and Group 2: Attention Control. Removed the first exclusion criteria for the Control group. -Added research assistant, Kworweinski Lafontant. -Removed two research assistants who no longer working on this project (Oscar Garcia and Jessica Sayers).	Yes
8	12/8/2023	The protocol was revised to add Fitbit data monitoring platform MetricWire and the use of the platforms smartphone-based Ecological Momentary Assessments (EMA). The Exercise log and study flyer was also revised. A postdoctoral research fellow was added to the study team (Dr. Dahee Kim) and study team member was removed (Aleatha Rossler). Revised Protocol Appendix B to remove survey variables for post assessment time points T2 and T3 and include the following surveys tools at Baseline T1 time point: Inquisit game-style Trail Making Test A and B English and Spanish versions, Groningen Activity Restriction Scale (GARS) Questionnaire in English and Spanish, Updated Morningness-Eveningness Questionnaire 2019 Version, Revised B-APQ Survey, Healthy Aging Instrument English and Spanish versions, Mindful Attention Awareness Scale English and Spanish versions. Provide an additional store gift card to participants if they want to complete the	Yes

		additional surveys in T1-T4 ($20 each for the total of $80).	
9	1/2/2024	Revised Ecological Momentary Assessment (EMA) Fear of Falling question so that it is clearer. Added two study team members: Dr. Sean Mondesire and Aleatha Rossler.	No
10	1/10/24	Added Dr. Nelson Roque as an external study team member. Added Pennsylvania State University as a research location. Clarified language in the protocol that the M2C2kit's EMA cognitive assessments will be collected via secure Amazon Web Services (AWS) and managed by Dr. Rogue at Pennsylvania State University. Added a question deployed by the Metricwire application to assess number of falls in the past month.	Yes
11	4/3/2024	Updated Appendix J: Interview Questions (Aim 3). Added a new clinical research coordinator (Herlinda Velez) and added two research assistants (Cecil Latta and Carla Leinbach).	No
12	6/12/2024	Updated Appendix J: Interview Questions by adding the Activity-Specific Balance (ABC) Confidence Scale (6 items) and the Cognitive Reframing (Pre-Post with 5 questions).	No
13	02/26/2025	Modified the delivery of the EMA cognitive assessments. Removed Fitbit data processing through MetricWire.	Yes

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1.0 Study Summary

Study Title	Optimizing a technology-based body and mind intervention to prevent falls and reduce health disparities in low-income populations.
Study Design	Intention-to-treat, single-blinded, parallel, two-arm clustered randomized controlled trial (RCT)
Primary Objective	Examine differences in balance, fall risk and physical activity after program completion, follow up 3-months and 6-months between older adults (OAs) in the PEER intervention and OAs in Attention Control (AC) condition
Secondary Objective(s)	-Explore differences in exercise adherence and the proportion of shifting in fall risk appraisal after program completion, follow up 3-months and 6-months between OAs in the PEER intervention and OAs in AC condition - Explore participants' experiences with the PEER intervention and potential barriers to access and adoption of the technology-based PEER intervention to inform future research.
Research Intervention(s)/ Investigational Agent(s)	Individualized, Physio-fEedback Exercise pRogram (PEER)
IND/IDE #	n/a
Study Population	Community dwelling adults ≥ 60 years of age
Sample Size	The maximum of participants to be enrolled = 340
Study Duration for individual participants	9 months
Study Specific Abbreviations/ Definitions	Older Adults (OAs) Physio-fEedback Exercise pRogram (PEER) Fall risk appraisal (FRA) Fear of falling (FOF) Attention Control (AC) BTrackS Balance System (BBS) BTrackS Balance Test (BBT) Research Assistants (RAs) Peer Coach (PC). Physical Activity (PA)

2.0 Objectives*

Aim 1*: Examine differences in balance, fall risk and physical activity after program completion, follow up 3-months and 6-months between older adults (OAs) in the Physio-fEedback Exercise pRogram (PEER) intervention and OAs in attention control (AC) condition*

Aim 2*: Explore differences in exercise adherence and the proportion of shifting in fall risk appraisal and negative self-perception on aging after program completion, follow up 3-months and 6-months between OAs in the PEER intervention and OAs in AC condition.*

Aim 3: *Explore participants' experiences with the PEER intervention and potential barriers to access and adoption of the technology-based PEER intervention to inform future research.*

3.0 Background*

Every 19 minutes, an older adult (OA; ≥65 years old) dies from a fall, and every 11 seconds, an OA is treated in an emergency department related to a fall.[1] One-third of OAs have maladaptive fall risk appraisal (FRA), a condition in which there is a discrepancy between perceived fall risk and physiological fall risk.[2] Maladaptive FRA consists of irrational FRA (high perceived but low physiological fall risks) and incongruent FRA (low perceived despite high physiological fall risks).[2] Adaptive FRA consists of congruent FRA (high perceived aligned with high physiological fall risks) and rational FRA (low perceived aligned with low physiological fall risks; the optimal FRA).[2] Among a sample of 500 OAs from Australia, ~31% underestimated or overestimated their fall risk.[3] However, no published study with OAs from the US has measured maladaptive FRA nor have reported on interventions to shift from maladaptive to adaptive FRA. In our pilot study with 102 community-dwelling OAs, 40% of them had maladaptive FRA.2 Of this group, 30% with irrational FRA and 19% with incongruent FRA reported falling in the past year.[2] A study in the UK found a strong alignment between postural control and perceived balance after a 4-week exergaming intervention.[4] However, no published study has evaluated interventions to help OAs shift from irrational/ incongruent/ congruent FRAs to rational FRA.

Our long-term goal is to provide preventive interventions that facilitate positive shifting for OAs with different fall risk profiles, with the potential of increasing exercise adherence and driving the development of a large-scale pragmatic clinical trial in the

community. We developed an individualized, Physio-fEedback Exercise pRogram (PEER)[5], which includes: a) physio-feedback using the BTrackS Balance System (BBS), a real-time portable innovative technology which allows for home testing, and provides instant playback showing OAs' static balance performance; b) cognitive reframing using a novel fall risk appraisal matrix, a graphical grid categorizing OA's perceived and physiological fall risks; and c) combined group and home-based exercises led by a trained peer coach (PC) focusing on balance, strength training, and exercise adherence. (see references #2 and #5 at the end).

4.0 Study Endpoints*

The intervention will be delivered per protocol until one of the following endpoints is met (whichever occurs first): 1) unable to perform balance and strength exercise, 2) past 6 months of the follow-up, and 3) other exclusion criteria are met. We expect to complete data collection within one year. The study will conclude after the study results are published (~10 years, October 30, 2032).

5.0 Study Intervention/Investigational Agent

1.1 Description: PEER is an exercise program, led by a trained peer coach that focuses on balance, strength training, and exercise adherence. It combines the concepts of physio-feedback, cognitive reframing, and exercise by motivating a shift in self-estimation of fall risk to align with physiological fall risk in order to improve balance and muscle strength and prevent falls. PEER uses a portable technology (BTrackS Balance System: BBS) to identify discrepancies of perceived and physiological fall risks and provide visual physio-feedback.

Group 1: PEER intervention: Subjects (n=170) in the PEER group will receive tailored activities that presented in Table 1 during Weeks 1-Week 8. The PI and trained Peer Coach (PC) will schedule a meeting (at a meeting room in Kinneret apartments or senior living apartments) to provide physio- feedback to the subjects in Week 1. In Weeks 1-8, subjects will participate in a group-based exercise training by the peer coach (PC) at an exercise room/a meeting room at Kinneret apartments and perform the individual exercise at home by themselves at least 30 minutes twice per week. Exercise training consists of four sets of exercise: a) warm-up (seated); b) strength upper and lower body (seated and standing); c) balance (standing and moving); and d) stretch lower and upper body (Please see the attached exercise booklet with photos). The dose of exercise is 120 min (60 mins per week for

group-based exercise and at least 30 mins twice per week for individual exercise) and for 8 weeks. Individual exercise at home comprises the same set of exercises as the group-based exercise. Subjects will receive an exercise booklet with illustrations that highlight steps for each set of exercises. The booklet will remind them of the exercise that they learn from the group-based exercise and provide them with a wide variety of exercises to integrate into their daily activities such as cooking.

Seventeen participants out of the PEER intervention group will be selected and trained as a PEER Coach (PC) to lead a group exercise class. PCs will be compensated a total of $400 in gift cards for their time.

Group 2: Attention control (AC): Subjects (n=170) in the AC group will receive an information pamphlet about falls, Simple Exercises for Improving Balance and Preventing Falls in Older Adults, (English or Spanish version) that was developed by the CDC Stopping Elderly Accidents, Deaths, and Injuries (STEADI)-Older Adult Fall Prevention. The topics contain information on fall risk, how to prevent falls, check for safety, postural hypotension and chair rise exercise included what you can do to prevent falls, check for safety, postural hypotension, and chair rise exercise. The control group will be encouraged to discuss fall prevention with their primary care provider and continue their normal activities (treatment-as-usual) for 6 months. They will be offered the PEER intervention when the study concluded.

Both PEER and AC groups will receive monthly phone calls from the research assistant to record a monthly fall incidence log.

Table 1: PEER intervention VS attention control (AC)

Week	Group 1: PEER intervention	Group 2: The Attention Control (AC)
Week 0	**Baseline assessment**	**Baseline assessment**
Week 1	- a meeting to provide the physio-feedback based on the test results (60 mins) - Group-based exercise 60 mins by peer coach (PC) and individual home-based exercise (30 min twice per week)	- receive an information pamphlet about falls, Simple Exercises for Improving Balance and Preventing Falls in Older Adults, (English or Spanish version) that was developed by the CDC Stopping Elderly Accidents, Deaths, and Injuries (STEADI)-Older Adult Fall Prevention.
Week 2- Week 7	- Group-based exercise (60 mins/week) - Individual home-based exercise (30 min twice per week)	- encourage to discuss fall prevention with their primary care provider and continue their normal activities (treatment-as-usual)
Week 8	- Group-based exercise 60 mins per week - Individual home-based exercise 30 min twice per week	

5.1 Drug/Device Handling: n/a

6.0 Procedures Involved*

6.1 Describe and explain the study design: We will employ an intention-to-treat, single-blinded, parallel, two-arm clustered randomized controlled trial (RCT), in which the test assessors will be blinded to the group allocation. We will collect data at four-time points (baseline assessment, post assessment, 3-month follow up and 6-month follow up).

6.2 Provide a description of all research procedures: We will recruit older adults who are living at senior living apartments (such as Kinneret apartments) in Central Florida. Subjects will be enrolled if they meet all of our inclusion criteria: 1) ≥60 years old of age; 2) live in their own homes or senior/retirement units. Approximately 340 older adults will be enrolled (170 per group). Subjects will be enrolled in this study for almost 9 months. After consent and completion of the baseline assessment, subjects will be assigned to the PEER intervention or the attention control (AC) group by a random sampling and no participant will know the assignment until after informed consent. The random assign will be disclosed in the consent. The intervention will be conducted at a meeting room in older adults' living apartment and/or in senior communities in Central Florida.

6.3 Describe:

Baseline assessment: Participants will be asked to complete the questionnaires and tests below:

1. Surveys related to demographic data (such as age, gender), fall risk, physical functioning, depression, anxiety, and fear of falling (Please see the attached questionnaires and instruments). *Assess* fall risk using the CDC's STEADI fall risk checklist and assess psychological functioning using the Patient Health Questionnaire-9 (PHQ-9).

   Assess cognition using the Rowland Universal Dementia Assessment Scale, SCD (subjective cognitive decline) and SCD-Instrumental Activities of Daily Living (SCD-IALDs).

   Assess negative self-perceptions using the Brief Ageing Perceptions Questionnaire (B-APQ).

   Assess social determinants of health using the following PhenX Toolkit questionnaires: Access to Healthcare Services, Health Literacy, Access to Health Technology, and Educational Attainment.

Assess individuals' orientation toward their goals using the Regulatory Focus Questionnaire (RFQ)

Assess individual differences in the sensitivity of two motivational systems: the behavioral inhibition system (BIS), which corresponds to motivation to avoid aversive outcomes, and the behavioral activation system (BAS), which corresponds to motivation to approach goal-oriented outcomes using a 24-item self-report questionnaire called the BIS/BAS Scale.

Assess anxiety using the Geriatric Anxiety Inventory-Short form (GAI-SF).

Assess fear of falling using the Short Fall Efficacy Scale International (short FES-I)

Assess and measure circadian chronotype using the Horne Östberg Morningness-Eveningness Questionnaire (MEQ 2019 Version). MEQ is a 19-item self-reported questionnaire based on individuals' activity preferences. The participants will be assigned to morning or evening type groups based on their MEQ scores (16 to 68). The lower scores (≤41) indicated an evening type, whereas the higher scores (≥59) indicated a morning type.

Assess sleep quality using The Pittsburgh Sleep Quality Index (PSQI). The questionnaire consists of 19 items of self-rated questions, which are broken into 7 categories (subjective sleep quality, sleep latency, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction).

Assess participant smoking status and sleeping pill and medication use using a self-reported single-item question.

Inquisit computerized game-style tasks will be used to assess the following: executive functions, working memory, processing speed, associations between concepts, and the strength of associations between concepts.

The Trail Making Test Parts A and B are computerized game-style tests used to assesses visual attention, mental flexibility and task switching. Part A specifically tests for rote memory and Part B is a test of executive function.

Groningen Activity Restriction Scale (GARS) measures disability in activities of daily living and instrumental activities of daily living.

Healthy Aging Instrument (HAI) is a multidimensional instrument that attempts to measure the process of healthy aging in a Thai context.

Assess individual differences in the frequency of mindful states over time using the 15-item Mindful Attention Awareness Scale (MAAS)

2. Assess hand-grip strength using a hand-grip dynamometer. This test will be administered with participants sitting in a chair with feet flat on the floor, and the elbow bent at 90°. You will be asked to squeeze the strength gauge as hard as possible for 3–5 s. Three trials on each hand will be performed with 30-s of rest given between trials.

3. Assess physical performance using the Short Physical Performance Battery (SPPB) test. The SPPB consists of a group of measures that combines the results of the gait speed, chair stand, and balance tests. It has been used as a predictive tool for possible disability and can aid in the monitoring of lower limb function in older adults. The scores range from 0 (worst performance) to 12 (best performance).
In the standing balance test, participants will be asked to remain standing with their feet positioned together side by side, then in a semi-tandem stance (i.e. the heel of one foot placed to the first toe of the other foot) and finally in a tandem stance (i.e., the heel of one foot directly in front of the toes of the other foot). Each stance is required to be held for 10 seconds and if a participant fails one aspect of this test, the subsequent aspects will not be attempted. In the gait speed test, the time required to walk a 4-meter marked course at a usual pace will be recorded. Two attempts will be allowed for this test, with only the fastest recorded time being used for the overall score. In the chair stand test, participants will be asked to stand and sit in a chair five times as quickly as they can with arms crossed over the chest and the time to complete five consecutive chair stands will be recorded. For the standing balance test, the score is given based on the ability to maintain balance in each of three stances. For the other two tests, scores are given depending on the ability to complete the tasks and on the time taken to complete each task. Each test is scored on a 0-4 scale. A total score for SPPB can be obtained by summing up all three test scores and it ranges between 0 and 12.

4. Assess static balance performance test using the BTrackS Balance System (BBS)

   They will be assessed balance performance using the BTrackS Balance System by taking off your shoes and stand as still as possible on the balance plate with hands on their hips and eyes closed for 2-3 minutes.



Fig. 1 BTrackS Balance

5. Assess dynamic balance performance test using the sit to stand test and the timed-up and go (TUG) tests. Subjects will stand up from a standard armchair, walk at a normal pace for 3 meters (distance will be marked out on the floor), turn, return, and sit down again. Then they will complete the sit to stand by full standing up from a chair as many as possible within 30 seconds.
6. Assess body composition using the Bioelectrical impedance analysis (BIA) (Figure 2). Subjects will be instructed and prepared for the body composition test. Subject will be asked to sit for 10-15 min before testing.



Fig. 2 InBody S10

We will wipe hands and feet using an InBody tissue (optional).



Fig. 3 Wipe hands and feet





Fig. 4-5 Place the touch-type electrodes

We will then place the touch-type electrodes to their left and right ankles, middle fingers, and thumbs. They will remain seated for one minute and then remove the touch-type electrodes from your left and right ankles, middle fingers, and thumbs.

7. Assess physical activity using the ActiGraph GT9X Link wireless activity monitors and using the Rapid Assessment of Physical Activity (RAPA)

   Participants will be asked to wear the activity monitoring device or ActiGraph GT9X Link wireless activity monitor on your non-dominant wrist for 7 consecutive days. They will be provided a phone number for the study team if you have questions about using the activity monitoring device.



Fig. 6 ActiGraph GT9X

   The assessments will take about 60-90 minutes per person and the assessment of physical activity will take 7 days.

   After 7 days, the researcher will meet with participants (at their place or based on their convenience) to collect the ActiGraph. The researcher will also ask the participant's availability for scheduling exercise class. Participants will receive a $50 Walmart gift card at the baseline-assessment.

8. Assess physical activity using the Fitbit fitness tracker (Charge 5). Participants will be asked to wear the Fitbit device on the non-dominant hand for six months throughout the study to self-monitor real time physical activity. The Fitbit fitness tracker will be gifted to participants after completion of the study.



Fig. 7 Fitbit Charge 5

9. Fitbit Charge 5 will be provided to all participants in the study. The Charge 5 is not intended to be used as a medical device. All participants will have the ability to monitor physical activity, sleep, and heart rate with the Fitbit Charge 5. Fitbit accounts will be created by the study team for the participant with a de-identified study email address and password. No identifiable information will be used. The study team will download the Fitbit App onto the participants smartphone and sign-in using the study created credentials. When the participant has completed the study, the study account will be removed, and participants will have the choice to continue use of the Fitbit with their personal email address and password. All data from the Fitbit will be continuously streamed to the Fitbit servers (see storage in 17.3). The following data metrics will be collected: Activity, Breathing Rate, ECG, EDA, Heart Rate, Heart Rate Variability, Sleep, SpO2.

Participants will also download the UCF EMA Study mobile application onto their phone to collect the M2C2kit's Ecological Momentary Assessments (EMA). EMA will be used to provide a more precise measure of participants' day-to-day levels/changes in cognition, and fear of falling. EMA will be used via smartphone multiple times a day, for 7 days, at each data collection point of the study. Participants will be paid $20 to complete the additional tasks. Examples of the puzzles include the following:

Symbol Search is a cognitive assessment used to assess attention and processing speed. In this task participants are asked to identify the matching sets of symbols.
The Grid Memory task is used to assess visual working memory. In this task participants are shown a grid with 3 dots, they are asked to remember the location of the dots and following a brief distractor task, indicate where the dots were.
The Color Dots task assesses associative memory and working memory in which participants are tasked with remembering the color and location of two of the three dots.

Participants will also be asked to rate their motivation for physical activity, fear of falling, and mood using a sliding scale.

Participants in the intervention group will be asked about their activity-specific balance (ABC) confidence using the ABC 6 items. Then, we will ask them using Cognitive Reframing (Pre-Questions) Please see Appendix J.

Post assessment:
Participants will be asked to complete the questionnaires and tests below:

1. Surveys related to fall risk, physical functioning, depression, anxiety, and fear of falling. Inquisit computerized game-style tasks will be used to assess the following: executive functions, working memory, processing speed, associations between concepts, and the strength of associations between concepts.
2. Assess hand-grip strength using a hand-grip dynamometer. This test will be administered with participants sitting in a chair with feet flat on the floor, and the elbow bent at 90°. Participants will be asked to squeeze the strength gauge as hard as possible for 3–5 s. Three trials on each hand will be performed with 30-s of rest given between trials.
3. Assess physical performance using the Short Physical Performance Battery (SPPB). The SPPB consists of a group of measures that combines the results of the gait speed, chair stand, and balance test.
4. Assess static balance performance test using the BTrackS Balance System (BBS)
5. Assess dynamic balance performance test using the sit to stand test and *the timed-up and go (TUG)* tests.
6. Assess body composition using the Bioelectrical impedance analysis (BIA).
7. Participants will be asked to complete a short interview (see 2 questions below) about their feedback from the exercises. Their feedback will be audio recorded. If they do not want to be recorded, they will be discuss this with the researcher or a research team member.

7.1 We will ask participants how they feel about the tests (BTrackS Balance System, Bioelectrical impedance analysis) to assess your balance and body composition.

7.2 We will ask participants how they feel about the group exercises.

8. Participants will receive a $50 Walmart gift card at the post-assessment. Also, they will receive their balance test and body composition results at the post-assessment.
9. EMA will be used to provide a more precise measure of participants' day-to-day levels/changes in cognition, number of falls, and fear of falling. EMA will be used via smartphone multiple times a day, for 7 days, at each data collection point of the study. Participants will be paid a $20 gift card to complete the additional surveys.

Participants in the intervention group will be asked about their activities-specific balance (ABC) confidence using the ABC 6 items. Then, we will ask them using Cognitive Reframing (Post-Questions).

3-month follow-up assessment

Participants will be asked to complete the questionnaires and tests below:

1. Surveys related to fall risk, physical functioning, depression, anxiety, and fear of falling. Inquisit computerized game-style tasks will be used to assess the following: executive functions, working memory, processing speed, associations between concepts, and the strength of associations between concepts.
2. Assess hand-grip strength using a hand-grip dynamometer. This test will be administered with participants sitting in a chair with feet flat on the floor, and the elbow bent at 90°. You will be asked to squeeze the strength gauge as hard as possible for 3–5 s. Three trials on each hand will be performed with 30-s of rest given between trials.
3. Assess physical performance using the Short Physical Performance Battery (SPPB). The SPPB consists of a group of measures that combines the results of the gait speed, chair stand, and balance test.
4. Assess static balance performance test using the BTrackS Balance System (BBS)
5. Assess dynamic balance performance test using the sit to stand test and *the timed-up and go (TUG)* tests
6. Assess body composition using the Bioelectrical impedance analysis (BIA).
7. Participants will receive a $50 Walmart gift card at the 3-month follow up assessment.
8. EMA will be used to provide a more precise measure of participants' day-to-day levels/changes in cognition, number of falls, and fear of falling. EMA will be used via smartphone multiple times a day, for 7 days, at each data collection point of the study. Participants will be paid a $20 gift card to complete the additional surveys.

6-month follow-up assessment

Participants will be asked to complete the questionnaires and tests below:

1. Surveys related to fall risk, physical functioning, depression, anxiety, and fear of falling. Inquisit computerized game-style tasks will be used to assess the following: executive functions,

working memory, processing speed, associations between concepts, and the strength of associations between concepts.

2. Assess hand-grip strength using a hand-grip dynamometer. This test will be administered with participants sitting in a chair with feet flat on the floor, and the elbow bent at 90°. You will be asked to squeeze the strength gauge as hard as possible for 3–5 s. Three trials on each hand will be performed with 30-s of rest given between trials.
3. Assess physical performance using the Short Physical Performance Battery (SPPB). The SPPB consists of a group of measures that combines the results of the gait speed, chair stand, and balance test

4. Assess static balance performance test using the BTrackS Balance System (BBS)

5. Assess dynamic balance performance test using the sit to stand test and *the timed-up and go (TUG)* test.

6. Assess body composition using the Bioelectrical impedance analysis (BIA).

7. Participants will receive a $50 Walmart gift card at the 6-month follow up assessment.

8. EMA will be used to provide a more precise measure of participants' day-to-day levels/changes in cognition, number of falls, and fear of falling. EMA will be used via smartphone multiple times a day, for 7 days, at each data collection point of the study. Participants will be paid a $20 gift card to complete the additional surveys.

Private identifiable information such as name and contact information will be collected. These data will be kept in a separate file linked to a unique subject ID so that subject will not be identifiable in the study database. Only those with a need to know (e.g., PI) will have access to the file that links to the unique code.

Most of the instruments were used in our previous studies and had satisfactory psychometric properties. No risks or discomforts were associated with the use of these instruments, and no one expressed concerns about the time to administer in other pilot studies.

Semi-structured interviews

We will use in-depth, one-on-one semi-structured interviews with up to 30 participants from the PEER and up to 30 from the AC group. The interviewees will be chosen by chance. We will randomly select 30 from 170 numbers using the listing ID from each group. The information on the interviews will be included in the main consent form. Semi-structured interviews will help ensure key concepts are addressed while allowing flexibility to adjust and rearrange questions to maximize interview flow and useful data collected. The interviews (30-40 minutes) will be conducted by a trained interviewer either in-person or by phone or web conferencing (in a private area) and will be audio recorded. Only the participant and the interviewer will be present during the interview. The Consolidated Criteria for Reporting Qualitative Research (COREQ) and the interview guide will focus on the (a) three domains of influence (biological, behavioral, sociocultural), and (b) two levels of influence (individual and peer group) which are most relevant to participant experiences and intervention evaluation. Interview questions will focus on their experience participating in this study and PEER intervention, acceptability of technology & intervention, the potential of and barriers to accessing and adopting PEER in the community, and recommendations for future work. Consistent with standard qualitative methodology, interview guides will be pilot tested and adjusted based on findings from early interviews. Participants will receive a $20 Walmart gift card after the interview.

6.3 *Demographic data* (such as age, gender), fall risk, physical functioning, depression, anxiety, and fear of falling will be collected by the UCF REDCap survey or by using paper and pencil and handing it to the research team.

6.4 *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period:* No plans for long-term follow-up

6.5 *For Humanitarian Use Device (HUD). n/a*

7.0 Data and Specimen Banking*

7.1 *n/a*

8.0 Sharing of Results with Subjects*

8.1 Those assigned to the PEER intervention arm will receive their printed balance performance result, body composition and know level of fall risk and fear of falling (low or moderate or severe) as a process of physio-feedback after the baseline assessment. Those assigned to the AC group will receive *the*

information pamphlet about falls, Simple Exercises for Improving Balance and Preventing Falls in Older Adults, (English or Spanish version) that was developed by the CDC Stopping Elderly Accidents, Deaths, and Injuries (STEADI)-Older Adult Fall Prevention.

9.0 Study Timelines*

9.1 Describe:

- *Potential subjects will be told that they will participate in this study approximately 9 months. They will participate in a baseline assessment, 8-week intervention, after program completion, 3-month, and 6-month follow-ups.*
- *The duration anticipated to enroll all study subjects: Approximately 24 months from first enrollment.*
- *The estimated date for the investigators to complete this study (complete primary analyses): Approximately 42 months from first enrollment.*

10.0 Inclusion and Exclusion Criteria*

10.1 After receiving IRB approval, we will contact the Kinneret apartments and other senior independent living apartments to post flyers and participate in open house events. We will schedule a meeting to introduce ourselves to older adults for performing the initial screening and determining study eligibility. The research team will maintain a log that tracks screening, eligibility, contact, and recruitment.

10.2 For Group 1: PEER intervention, participants will be enrolled if they meet all the following inclusion criteria: 1) ≥ 60 years of age; 2) live in their own homes or senior/retirement units. Exclusion criteria for Group 1: PEER Intervention: 1) a medical condition precluding exercise such as uncontrolled cardiac disease (shortness of breath or feel pressure, squeezing, burning, or tightness when doing a physical activity), or 2) currently receiving treatment from a rehabilitation facility.

For Group 2: Attention Control, participants will be enrolled if they meet all the following inclusion criteria: 1) ≥ 60 years of age; 2) live in their own homes or senior/retirement units

Exclusion criteria for Group 2: Attention Control: 1) Currently receiving treatment from a rehabilitation facility.

10.3 Indicate specifically whether you will include or exclude each of the following special populations

- *Adults unable to consent- Exclude*

- *Individuals who are not yet adults (infants, children, teenagers)- Exclude*
- *Pregnant women- Exclude*
- *Prisoners- Exclude*

11.0 Vulnerable Populations*

11.1 . n/a

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally: 340

12.2 *If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures or other attrition):* Approximately 570 participants are expected to be enrolled and screened and 340 participants needed to complete the research procedure.

13.0 Recruitment Methods

13.1 After receiving IRB approval, we will recruit older adults who are living at home/apartments and/or senior communities in Orlando, Central Florida.

13.2 Describe materials that will be used to recruit subjects. (See attached copies of these documents with the application). We will post flyers and participate in open house sessions and health fairs in the retirement and senior communities. Participants will also be recruited via word of mouth from their friends/family who took the flyers from open house sessions or health fairs. We will maintain a log that tracks screening, eligibility, contact, and recruitment. This protocol was successful in our previous studies.

13.3 Describe the amount and timing of any payments to subjects. The participants will receive four Walmart gift cards ($50 each) at the end of the baseline assessment, post assessment, 3-month follow-up assessment and 6-month follow-up assessment (total $200) as compensation for their time. Those who participate in the interviews will receive an additional $20 gift card, for a total of $220 for the study. Seventeen participants who consent to be trained as a PEER coach to lead group exercise classes for eight weeks will be paid $400 for their time. In addition, all participants will receive a Fitbit fitness tracker to keep after completion of the study.

14.0 Withdrawal of Subjects*

14.1 .

The participants who are unable to perform balance and strength exercise, signs and symptoms of exercise intolerance are noted (e.g., shortness of breath or feel pressure, squeezing, burning, or tightness in the chest when doing a physical activity), or other exclusion criteria are met (e.g., currently receiving a treatment program from a rehabilitation facility) will be removed from the study. Subjects in the PEER intervention group will be withdrawn if they did not participate or miss at least 2 sessions in the exercise group and individual exercise at home. Subjects in both groups will be withdrawn if they did not participate at 3-month and 6-month follow-up. The PI also reserves the right to withdraw participants at any time without their approval.

14.2 Describe any procedures for orderly termination.

Subjects can leave the research at any time, and it will not be held against them. If they decide to leave the research, they should contact the investigator so that the investigator can discontinue the follow up visits with them.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

Participation is entirely voluntary. The participants can withdraw from the study at any time without consequences of any kind. However, responses of participants that were submitted, and the data recorded will not be excluded from the analysis.

15.0 Risks to Subjects*

The potential risk to subjects is minimal. To ensure this, we will take the necessary steps to reduce risk for all participants. Procedures were tested during the preliminary work of the study team, and no adverse effects were noted. During the study, participant safety will be of the highest priority, and all standards of BTrackS Balance Test (BBT) and exercise training for older adults will be followed. All RAs will receive training before beginning the study, and periodic re-assessment of skills is scheduled through the study. The PI will be responsible for ensuring that all RAs are knowledgeable in their roles.

We will train RAs in all procedures and monitor subjects for any adverse responses. During the group based-exercise training, the trained peer coach will follow existing standards of exercise training to prevent falls. We have used the same procedures in our preliminary studies and the literature supported those exercises to improve balance are not associated with an

increased risk of adverse events. Also, from a literature review, the US Department of Health, American College of Sports Medicine, World Health Organization, and European Association of Cardiovascular Prevention and Rehabilitation guidelines state that regular exercise is generally safe for (healthy and frail) older adults, therefore, need not consult a medical practitioner before increasing physical activity levels.

16.0 Potential Benefits to Subjects*

16.1 Those assigned to the PEER intervention arm will know their balance performance from the BBT results, know level of fall risk (low or moderate or severe), learn how to perform exercise which focuses on balance and muscle strength, have a connection with their own peer coach, and may shift their fall risk perception from maladaptive fall risk appraisal to adaptive fall risk appraisal. Subjects in the future who have maladaptive fall risk appraisal may benefit from knowledge gained from this proposed study. Those assigned to the AC group will receive the information pamphlet about falls, Simple Exercises for Improving Balance and Preventing Falls in Older Adults, (English or Spanish version) that developed by the CDC Stopping Elderly Accidents, Deaths, and Injuries (STEADI)-Older Adult Fall Prevention.

17.0 Data Management* and Confidentiality

17.2

All questionnaires completed via paper and consent forms will be kept in a locked cabinet in the principal investigator's (PI) UCF office and scanned to a password-protected, end-to-end encrypted OneDrive folder that is only accessible by research team members. Participant folders will be marked with an ID number to protect confidentiality. Participant names and ID numbers will be stored separately in an encrypted and password protected file on OneDrive. All identifiable data will be destroyed five years after study closure via industrial shredder.

We aim to examine differences in balance, fall risk, physical activity, negative self-perception on aging, exercise adherence and the proportion of shifting in fall risk appraisal after program completion, follow up 3-months and 6-months between OAs in the PEER intervention and OAs in AC condition. The Chi-square test and the t-test will be used to analyze the categorical data and continuous data, respectively to compare outcomes between OAs participating in the PEER intervention and OAs participating in the AC condition. The longitudinal linear mixed models will be used to test for between-group differences with respect to the primary and secondary outcome measures from all follow-up assessment

visits. Whenever feasible, models may be adjusted for the covariates, including age, gender, perceived general health, and the number of falls in the past six months prior to the baseline, which is considered as relevant to the outcomes. Furthermore, we will form a 4x4 table. The standard 4x4 table analysis will be performed, either use a Chi-square test or exact test, depending on the actual counts observed in the 4x4 table. BBT and short FES-I scores will be collected in four planned visit time points. All data analyses will be performed with SAS version 9.4 for Windows (SAS Institute Inc.). An alpha level of 0.05 will be used in all analyses.

Participants completing the M2C2kit's Ecological Momentary Assessments (EMA) will complete the surveys on their smartphone via the UCF EMA Study mobile application managed by the study team. M2C2kit Web-based cognitive assessments are to be collected and sent to Qualtrics.

● *Participants receive a URL that refers them to the GooglePlay and Apple Store to download the UCF EMA app.*

● *Each time the app is opened, the participants are instructed to type in their initials. If initials are not sufficient, we will assign participants a number in addition to their initials.*

● *When data are collected through the UCF EMA app, the collected data will be sent to UCF through UCF Qualtrics.*

17.3 Several procedures will be implemented to protect subjects against loss of confidentiality. We will maintain a master list that will contain identifiable data and links the subject ID codes with the participant's information. The electronic version of this master list will be encrypted, password-protected, and stored on a computer that is not connected to the internet and is in a restricted access room at the College of Nursing. The master list is the only document with identifiable data. This data will be kept for 5 years after the study closes in accordance with Florida Law.

The de-identified data (i.e., results of the screening tasks, Fitbit data) will be password protected, encrypted, and stored on password-protected computers and external hard drives. This de-identified data will be kept indefinitely. The reason for keeping the de-identified data indefinitely is for scientific reproducibility and transparency. The audio recordings will be transcribed through a UCF-certified company, Deedose. With the subject's consent, the researchers will store the subject's contact information and contact the participant about future studies that may be of interest to the subject if they provide consent. This information would be

added to the encrypted password protected master list and physical master list that is stored in a locked cabinet in the PI's UCF office at the College of Nursing. By using such procedures in the past, we have successfully followed large cohorts of older adults with high rates of follow-up and no loss of confidentiality.

17.4 Data files will be built on a password-protected computer using REDCap, which will be housed on a secure University server. The PI, Ladda Thiamwong, Dr. Xie (Co-I and statistician) and the RA will be responsible for data cleaning in REDCap. Following an initial audit, the data will be double-entered, and files matched to verify the accuracy of the data for the first five participants, and then a random 5% of the total sample will be double-checked periodically throughout the study. The data will be systematically examined for out-of-range values and data inconsistencies. We anticipate no more than 5% missing values on any one item as data will be collected in-person on-site and via phone calls. Missing data will be identified and obtained during follow-up interviews or with follow-up contact with participants. We will create an audit trail to identify and correct issues, protect participants' privacy, ensure confidentiality, and maintain data integrity. If causes of error other than random variation are identified, we will modify or adjust our procedures and retrain team members as needed.

17.5 Describe how data or specimens will be handled study-wide :n/a

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

n/a

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 All study personnel, including RAs will complete the required CITI training on the protection of human subjects and will sign confidentiality agreements. The PI will be responsible for ensuring that all RAs are knowledgeable in their roles.

19.2 To ensure that subjects feel at ease, study personnel will receive training.

At the study's beginning, the PI will develop a Study Operations Manual, which will include procedures and checklists for participant enrollment, intervention delivery, data collection, and ongoing reporting related to the study such as IRB.

19.3 The recruitment and assessment RAs will be trained by the PI to learn how to ascertain participant interest in the study and whether participants meet eligibility criteria. Recruitment RAs will be taught

how to contact the PI about an OA's willingness to participate and how to complete questionnaires and tests at study sites. During the assessment, RAs will conduct screening, baseline assessment, and follow-up assessment per-protocol; they will be blinded to group assignment. The PEER coaches (PCs) will be eligible if they report having a regular PA routine or having an educational background in healthcare; aged $\geq$ 60 years of age, can read, write, and understand English and/or Spanish; and are committed to delivering the protocol for eight weeks. PCs will be trained by the PI and Dr. Stout (Co-I) in collaboration with a successful PC from our pilot study. The PI will provide ongoing support for the intervention. The PCs will be taught how to conduct the initial intervention session, balance and strength training and phone calls. To help ensure PCs' confidence, the PI will be available for direct phone calls or texts. All PCs will be individually supervised by the PI and receive monitoring of cases using PEER procedures. During weekly supervision meetings, each PC will review participants' progress and address challenges related to intervention concepts and use. In our pilot study, PCs also learned from each other through discussion of issues that commonly arose among participants, including the generation of potential solutions to problems that might arise in subsequent sessions. Each PC will be matched to 8-10 OAs in the PEER group based on place of residence. All trained PCs will supervise participants in groups while they are engaged in four sets of balance/strength training exercises.

20.0 Compensation for Research-Related Injury: n/a

21.0 Economic Burden to Subjects

21.1 n/a

22.0 Consent Process

The PI or RA will explain all aspects of the approved IRB consent form, including all required information (purpose, number of subjects, procedures, time requirements, potential risks, and benefits, measures to protect confidentiality) with subjects before obtaining written consent. The subjects will be informed that participation in this study is voluntary. They are free to decline to be in the study or to withdraw from this study at any point without any negative consequence. At the time potential subjects provide consent, they will be asked, for follow-up purposes, to provide their name, address, phone number, and email address along with the phone number and email addresses of their significant person or family member. Contact information will be kept separate from study records and will not be a permanent part of the study record.

Potential subjects will be told that they will participate in this study approximately 9 months. They will participate in a baseline assessment, post assessment, 3-month follow up, and 6-month follow-up.

Study subjects will be informed that study records will be kept as confidential as possible. No individual identifiers will be used on any reports or publications resulting from this study. Study information will be coded and kept in locked files at all times in a locked cabinet in the PI's UCF office or in a password-protected end-to-end encrypted OneDrive folder. Only study personnel will have access to the files.

The subject will read the informed consent form and will be able to hear a detailed description of the study and then will be given the informed consent document. This will occur in a private room. Subjects will be provided a copy of the consent form for their records.

Indicate what language(s) other than English are understood by prospective subjects or representatives: English and Spanish.

23.0 Process to Document Consent in Writing

23.1 We will be following "SOP: Written Documentation of Consent (HRP-091)."

24.0 Setting

24.1 This study will be conducted at a meeting room in older adults' living apartments (Kinneret Apartments) or other senior independent living apartments or in senior communities in Central Florida. Florida has one of the highest percentages of residents aged 65 and older in the U.S., as one in five Floridians is in this category.

25.0 Resources Available

25.1 Describe the resources available to conduct the research:

Dr. Thiamwong (PI) is an expert in fall risk assessment and fall interventions, especially with community-dwelling OAs. She has established connections with communities in Central Florida. These connections will serve in the efforts to recruit diverse OAs for this study.

Dr. Stout is an expert in exercise physiology and has extensive experience conducting studies examining various modes of exercise training. Dr. Stout has assisted the PI in

developing a balance and muscle training protocol and will tailor this protocol for participants.

25.2 Describe ancillary reviews and approvals associated with the research: n/a

26.0 Multi-Site Research*: n/a

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