UNIVERSITY OF CENTRAL FLORIDA

PROTOCOL TITLE:

Technology-based fall risk assessments for older adults in low-income settings

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Version 1 8/26/2020
Version 2 9/3/2020
Version 3 9/10/2020
Version 4 2/01/2021
Version 5 11/03/2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	9/3/2020	1. Revise aim 1 2. Add the literature review related to the impact of COVID-19 on falls, physical activity, and fear of falling (Please see Background 3.1) 3. Revise to include details on when and where the consent process will take place. 4. Revise to include details on the screening process. 5. Add inclusion of living in the Kinneret community and update the general summary of inclusion/exclusion criteria in the protocol, flyer, and consent. Include participants who speak English or Spanish. 6. Increase the amount of Walmart gift card from $10 to $20. Participants will receive $20 gift card at the end of the second day (or second visit) of the study. 7. Update the data retention, all research data, including identifiers and linking sheets, needs to be retained for at least 5 years after the study closure.	Yes
2	9/10/2020	Include the Spanish version of the consent, flyer and surveys with a translation verification letter	Yes

		by a 3rd party. Include an assessment of day-to-day experiences with anxiety in Appendix D.	
3	02/01/ 2021	-Add two research assistants (Oscar Garcia and Maxine Furtado) and remove Lorraine Vicente -Add the recruitment methods (using social media and word of mouth to recruit low-income older adults in Central Florida -Indicate where the screening, consent, and experimental procedures will take place for each group (Kinneret apartments and general population) -Update the body composition measure from Inbody 770 to Inbody S10 and include a handgrip strength test -Discuss how to return the activity monitoring device via mail (with pre-paid mailers) or pick up -Discuss the attachment of the electrodes in detail (such as who places them, where) -Include the additional time (2-3 mins) for the handgrip strength test in the protocol, consent, and flyer - Increase the amount of Walmart gift cards from $20 to $30 in the protocol, consent, and flyer -Update the flyer (research locations, the total amount of time). -Update the exclusion criteria (include having a metal implant)	Yes
5	11/3/2021	-As of modification request 10/18/2021, add timepoint 2 for 60 participants out of the 120 participants that participated in timepoint 1. -Include additional questions related to behavioral changes in the fear of falling domain including ageing perceptions, regulatory focus and behavioral avoidance/inhibition (Appendix E). -Include additional questions in the Acceptability of fall risk assessments using technology interview form (Appendix J). -Add research team	

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1.0 Study Summary

Study Title	Technology-based fall risk assessments for older adults in low-income settings
Study Design	We will use a cross-sectional design to address our aims and test hypotheses.
Primary Objective	Examine the associations among fall risk appraisal, body composition, and physical activity.
Secondary Objective(s)	-Examine the feasibility of recruitment (e.g., how many older adults (OAs) need to be screened to recruit the sample?), especially during the COVID-19 pandemic, and acceptability of technologies and procedures for use among OAs in low-income settings. -Determine the dynamic relationships between fall risk appraisal, body composition, physical activity, and behavioral changes related to fear of falling
Research Intervention(s)/ Investigational Agent(s)	NA
IND/IDE #	NA
Study Population	Adults aged 60 years and older
Sample Size	120 participants for timepoint 1 60 participants for timepoint 2
Study Duration for individual participants	*Total 9 days with two visits (105-158 mins, total)*
Study Specific Abbreviations/ Definitions	Older Adults (OAs) Physical Activity (PA) Fall Risk appraisal (FRA) Fear of Falling (FOF) Assistive Health Technology (AHT) BTrackS Balance Plate (BBP) BTrackS Balance System (BBS) Body Mass Index (BMI) Bioelectrical Impedance Analysis (BIA) Fall-Efficacy Scale International (FES-I) Patient Health Questionnaire-9 (PHQ-9)

2.0 Objectives*

Aim 1. *Examine the feasibility of recruitment* (e.g., how many OAs need to be screened to recruit the sample?), especially during the COVID-19 pandemic, *and*

acceptability of technologies and procedures for use among OAs in low-income settings.

Aim 2. *Examine the associations among fall risk appraisal, body composition, and physical activity*.

H2.1: Rational FRA is associated with higher levels of PA and skeletal muscle mass, and lower levels of percent of body fat and BMI.

H2.2: Incongruent FRA is associated with higher levels of PA and skeletal muscle mass, and lower levels of percent of body fat and BMI.

H2.3: Irrational and congruent FRAs are associated with lower levels of PA and skeletal muscle mass, and higher levels of percent of body fat and BMI.

Aim 3. Determine the dynamic relationships between fall risk appraisal, body composition, physical activity and behavioral changes related to fear of falling.

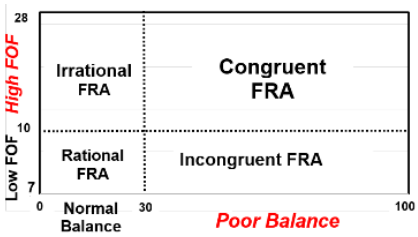
3.0 Background*

3.1

More than 15 million (30%) OAs in the US have incomes below the 200% of poverty line.[1, 2] Poverty rate increases with age, and is higher among women, Blacks and Hispanics, and individuals with poor health.[1] OAs who live in low-income communities are less likely to engage in PA,[3-5] defined as any bodily movement produced by skeletal muscle that results in energy expenditure.[6] Lack of PA is related to chronic conditions and reduced quality of life among low-income OAs.[7, 8] Limited data suggest that OAs who overestimate their fall risk and report fear of falling (**FOF**) are less likely to participate in PA, and the association between FOF and PA intensity differs by fear severity.[9] Changes in body composition also have a significant impact on functional capacity and quality of life.[10] However; these studies have not included OAs from low-income settings, who are more likely to report falls in the prior year.[11] Recent systematic reviews found that most studies have not used objective measures of fall risk and PA.[5, 12] We will use objective measures of body composition, balance performance, and PA among OAs from low-income settings.

Additionally, up to 50% of OAs who have FOF limit their daily physical activity **(PA)** because of the fear.[13] The COVID-19 pandemic is causing increased fear and related to perceived risks for loved ones and health anxiety.[14] Physical distancing and fear of the virus have led to reductions in OAs' use of routine healthcare and performing daily PA.[15] With the high levels fear; individuals may not think rationally when reacting to COVID-19 and taking care of themselves.[16]

3.2



<u>One-third of OAs have maladaptive **fall risk appraisal**</u> (FRA), a condition in which there is a discrepancy between perceived fall risk (levels of FOF) and physiological fall risk (balance performance).[17, 18] Measuring FRA in OAs can be challenging due to self-report bias and cognitive deficit.[19, 20] Using both subjective and objective measures provides better fall risk assessment among OAs.[20, 21] Thus, we developed a *fall risk appraisal matrix***,** a graphical grid categorizing levels of FOF and balance performance into four quadrants (Fig 1): **1)** *rational FRA* (low FOF and normal balance), **2)** *incongruent FRA* (low FOF despite poor balance), **3)** *irrational FRA* (high FOF despite normal balance), and **4)** *congruent FRA* (high FOF and poor balance).[17] In our pilot study (*N*=102), we measured FOF by a questionnaire and balance performance using a portable and novel force balance plate (BTrackS Balance System; **BBS**). We found that 40% of OAs had maladaptive FRA. Of this group, 19% with incongruent FRA and 30% with irrational FRA reported falling in the past year.[17] OAs with congruent FRA were 3.29 times more likely to fall than those with rational FRA.[22] However; our sample included only 11% of low-income OAs.

3.3

Maladaptive FRA may impede low-income OAs participation in PA and can result in social isolation.[20, 23] Irrational FRA serves as a barrier, creating an irrational fear that inhibits OAs from staying active. Conversely, incongruent FRA can act as an impediment to OAs' safety by fabricating a sense of wellbeing when more caution is warranted. Rational FRA is a crucial component of regular engagement in PA.[24] However, research has not examined the association between FRA and PA among low-income OAs. We will examine the association between FRA and PA among low-income OAs.

Body composition (e.g., obesity, low relative skeletal muscle mass) has been associated with FOF, functional impairment, and disability in American OAs.[25-27] Higher BMI and percent body fat were associated with poor physical function while percent appendicular lean mass was associated with better physical function (e.g., walking, balance test).[26] OAs who have higher daily PA have better physical function than those who engage in less PA.[28] Although Body Mass Index (**BMI**) is the most widely used measurement to classify overweight/obesity status. It is prone to measurement error and does not consider body fat distribution and skeletal muscle mass.[29] We will use the Bioelectrical Impedance Analysis (**BIA**) device, which measures body composition and has established normative data among OAs.[30]

Research has not examined the associations among body composition, FRA, and PA using Assistive Health Technology **(AHT),** which is the application of organization knowledge, skills, procedures, and systems in order to improve functioning.[31] Majority of studies have used self-reported measures of fall risk and PA among OAs.[32-36] OAs who overestimate their fall risk are less likely to participate in PA.[24, 37] AHT eliminates recall bias associated with subjective

measures.[38, 39] Systematic reviews also indicate the importance of technology-based assessments for PA and prevent falls.[40, 41] We will examine the associations among body composition, FRA, and PA using AHT, including the Bioelectrical Impedance Analysis[42], BTrackS Balance System,[43, 44], and accelerometer-based physical activity devices. These devices are portable, non-invasive, safe, valid, reliable, and allow for home testing.[26, 30, 45, 46]

4.0 Study Endpoints*

4.1

We expect to complete data collection within two years. The study will conclude after the study results are published (~10 years, October 30, 2031).

5.0 Study Intervention/Investigational Agent

NA

6.0 Procedures Involved*

6.1 *Describe and explain the study design.*

We will use a cross-sectional design to address our aims and test hypotheses. Using novel technologies to advance fall risk assessments is one of the essential recommendations for promoting PA.[47, 48 17, 37, 41, 49] To accomplish this goal, we employ the behavioral epidemiology framework[50] to understand the associations among body composition, FRA, and PA. This framework consists of 5 phases: (1) establish links between behaviors and health, (2) develop measures of the behaviors, (3) identify influences on the behaviors, (4) evaluate interventions to change the behavior, and (5) translate research into practice.[50] We focus on Phase 1 and in our model, body composition is an antecedent of FRA and the accelerometer-based PA is a consequence of FRA. We consider OAs' characteristics (e.g., sex) as covariates and control for them in the analysis (Fig 2).

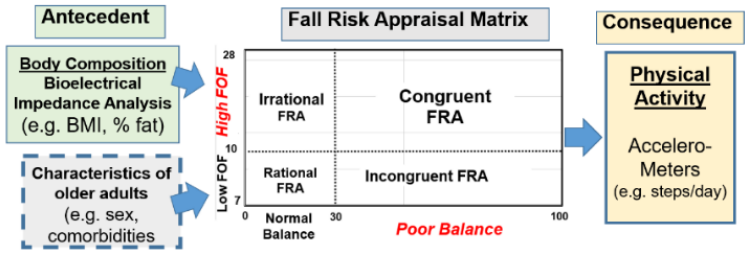


Fig. 2 Conceptual Framework

6.2 *Provide a description of all research procedures*

We will administer the study instruments which consist of objective and subjective measures (see Table 1) for total 120 participants. Participants will complete questionnaires about OA's characteristics, socio-demographic, medical history, cognition, depressive symptoms, anxiety,

and FOF. We will also assess static balance performance using the BTrackS Balance System[43, 44], assess dynamic balance using a sit to stand test, assess body composition using the Bioelectrical Impedance Analysis device[42], and assess handgrip strength test using a hand-grip dynamometer (JAMAR 5030J1). They will wear an accelerometer-based physical activity device for 7 consecutive days.

Table 1. Description of study variables and instruments

Variable	Instrument	Description
OA's Characteristics - Socio-demographics and medical history	Self-report questionnaire	e.g., age, gender, living status, education level, socioeconomic status, perceived general health, comorbidities, FOF, frailty, fall risk, and social network.
-Cognition	- Memory Impairment Screen (MIS)[51-53]	- The Memory Impairment Screen (MIS) is a widely used test of cognitive function and screening Alzheimer's disease among OAs. It is a 4-minute, four-item delayed free and cued recall memory test with controlled learning and high discriminative validity. The maximum score for the MIS is 8 and if score 5-8=no cognitive impairment and score ≤4 =possible cognitive impairment.
- Depressive symptoms	-Patient Health Questionnaire-9 (PHQ-9) [54, 55]	-10 items (e.g., feeling tired) on a 4-point scale; measures symptoms of depression within the prior 2 weeks; Total scores range 0-27, scores ≥10 moderate depression.[54] Cronbach's alpha=0.89 among OAs.[54, 55]
-Anxiety and day-to-day experiences	-Geriatric Anxiety Inventory-Short form (GAI-SF).[56-58]	- The GAI-SF is an abbreviated version of GAI comprising only five of the original items. The GAI-SF has good internal consistency, convergent and divergent validity, and was highly

	- Trait Mindful Attention Awareness Scale (MAAS).[59]	correlated with the original GAI.[57, 60] A score of three or greater was optimal for the detection of DSM-IV Generalized Anxiety Disorder (GAD) in community-dwelling OAs (sensitivity 75%, specificity 87%). Internal consistency was high (Cronbach's α = 0.81) and concurrent validity against the State-Trait Anxiety Inventory was good (rs = 0.48, p < 0.001).[57] Day-to-day experiences will be assessed by the trait Mindful Attention Awareness Scale (MAAS). The MASS is a 15-item scale with English and Spanish versions. The MMAS has been validated for use with community adults and has demonstrated high reliability and validity.[59]
Fear of falling (FOF), ageing perceptions, behavioral avoidance/inhibition, and regulatory focus. (Please see Appendix E)	Short Fall Efficacy Scale International (Short FES-I)[61] -Brief Ageing Perceptions Questionnaire	7-items (e.g., going in or out of a chair) on a 4-point scale; measures concerns about the possibility of falling when performing seven activities (e.g., getting dressed).[62] Total scores range 7-28.[61] Higher total scores=higher FOF.[63] Scores 7-10=low concern about falling; scores 11-28=high concern about falling.[62, 64] The short FES-I has been validated in community-dwelling OAs.[62] Cronbach's alpha =0.97 and ICC=0.979 among OAs.[65] - Brief Ageing Perceptions Questionnaire (B-APQ) is a multi-dimensional measure of aging perception which consists of 17 items (5 response choices).

	-Behavioral avoidance/inhibition scales -Regulatory focus Questionnaire (RFQ) -A single fear of falling scale	It has good construct validity and internal consistency. Cronbach's alpha =0.75-0.84.[66] -Behavioral avoidance/inhibition scales consist of 24 items with 4 domains and 4 response choices. Cronbach's alpha =0.66-0.76. [67] -Regulatory focus Questionnaire (RFQ) includes two domains including promotion on hopes and accomplishments and prevention on safety and responsibilities. The RFQ consists of 11 items with scores ranging from 1 to 5. [68] -Are you afraid of falling (Y/N) -If yes, did your fear of falling lead you to restrict some of your activities (Y/N).
Static balance performance	BTrackS Balance System (BBS)[43, 44]	See description in 6.3
Hand-grip strength test	A hand-grip dynamometer (JAMAR 5030J1)	Hand-grip strength will be measured in kilograms (kg) as maximal isometric force achieved on a hand-grip dynamometer (ICC3,1 = 0.959, SEM = 3.1 kg).
Dynamic balance	Sit to stand test [69, 70]	A sit to stand test has been widely used to assess balance and predict falls, and was reliable and validated in community-dwelling OAs.[69, 70]
Body composition	Bioelectrical impedance analysis (BIA**):** InBody S10.	See description in 6.3
Physical activity	ActiGraph GT9X Link wireless activity monitors (ActiGraph LLC.) [71]	See description in 6.3

Physical activity	Rapid Assessment of Physical Activity (RAPA)	9-items related to how physically active in aerobic activity level and anaerobic activity level in the last f weeks (Y/N).
Acceptability of technology	-Evaluation form -Short Version of Senior Technology Acceptance	-OAs evaluation of the devices and procedures. -14-items of 4 components, including attitudinal beliefs, control beliefs, gerotechnology anxiety and health conditions (rating from 1-10).

Balance performance will be assessed by the BTrackS Balance System (**BBS**).[43, 44] BBS includes the portable BTrackS Balance Plate (BBP), and BTrackS Assess Balance Software running on a computer device (Fig 3). The BBP dimensions are 15.5" x 23.5" x 2.5", weight 14.5 lbs., and operated on Windows 7 or higher via a USB port. The BBS is manufactured (by the Balance Tracking Systems, Inc.) in California in an FDA Qualified Facility that has achieved ISO 13485 Compliance. The FDA Registration is under Part 890 – Physical Medical Devices and is further categorized within 890.1575 as a Force-Measuring Platform. The FDA Registration number is 3010668481, and the CFDB License Number is 73881.

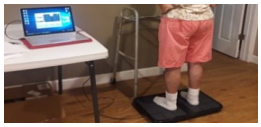


Fig. 3 BTrackS Balance

During the test, a piece of sturdy furniture or a standard walker will be placed within the participant's reach to reduce the risk that FOF will contaminate performance and enable even frail people to participate.[72] In comparison to the age group, the software utilizes the BBS Normative Database to compare the individual to others in their age group. BBS score is dependent on age and sex but not body size so that the percentile rankings can be determined across various age groups, and for men and women separately.[73] A scale from 0 to 100 represents the percentile ranking of the BBS. Score 0-30 indicates low fall risk (normal balance) and ≥ 31 moderate-high fall risk (poor balance).[73] BBS has excellent validity using Pearson correlations (r>.90) and high test-retest reliability [intraclass correlation coefficients (ICC)=0.83].[45]

This test consists of four, 20 seconds trials. For each trial, the participants will stand as still as possible on the BBP with hands on their hips, and eye closed. This test consists of four trials. This test will take about 5-10 minutes (Please see Appendix F for static balance performance test (BTracks Balance System).

Fig. 4 BIA InBody S10

Body composition will be assessed using a bioelectrical impedance analysis (**BIA):** InBody S10. The BIA is a widely used commercial device that is FDA approved. The BIA is manufactured by the Biospace Corporation Limited, Naple, FL. The BIA InBody S10 uses 30 impedance measurements, 6 frequencies at each of the 5 segments (Right Arm, Left Arm, Trunk, Right Leg, Left Leg). The BIA InBody S10 specification: Frequencies: 1, 5, 50, 250, 500, 1000 kHz, Weight Range 22-551 lbs, Age Range 3-99 years, Height Range 3 ft 1.4 in-7 ft 2.6 inch, Equipment Weight 4.4 lbs, and Dimensions 12.7 x 8 x 46.5 (L x W x H) inches with stand and Dimensions 8 x 2.1 x 12.7 (L x W x H) inches without stand. The BIA InBody S10 measures fat mass, muscle mass and body water levels. There are no risks, no dunking, no pinching, no discomfort associated with the use of bioelectrical impedance analysis. Test duration is 1-2 minutes. Reliability of the test-retest of the BIA was high with an ICC of 0.89.[74]

Fig. 5 ActiGraph GT9X

Physical Activity (PA) will be measured by activity monitoring devices. All OAs will wear the ActiGraph GT9X Link wireless activity monitor (ActiGraph LLC.), a tri-axial accelerometer, on the non-dominant wrist for 7 consecutive days. The GT9X Link has a sample rate of 30-100 Hz, a dynamic range of ±8G, 14 days battery life (rechargeable), 180 days/4 GB data storage, and is water-resistant. Data are collected in 1-minute intervals. A sensor determines whether the device is on or off the wrist. The GT9X Link provides objective 24-hour physical activity measures, including steps, energy expenditure, intensity, and participant's position. Accelerometry is a reliable method of assessing free-living physical activity (ICC=0.98)[75] and has been validated against direct observation, energy expenditure, and sedentary behavior.[76, 77] ActiGraph accelerometers have been used for data collection in the National Health and Nutrition Examination (NHANE) surveys and are the most commonly used device in research studies.[71] The device display screen can be disabled, so the device does not display the participant's activity (it will show date and time only).

6.3

We will follow the UCF COVID-19 Human Subject Research (HSR) Standard Safety Plan below:

6.4 Screening, consent, and experimental procedures

Screening, consent for participants in Kinneret Sr Apartments

Staff from this site will introduce the researchers to older adults in Kinneret Sr Apartments for performing recruitment. Our team will meet with participants at a meeting room in Kinneret Sr Apartments. We will screen participants by asking their age and language (English or Spanish). We will also ask if they have a medical condition precluding balance test and/or physical activity (e.g., shortness of breath, unable to stand on the balance plate) or currently receiving treatment from a rehabilitation facility or have a metal implant. Finally, we will assess their cognition using the Memory Impairment Screen (MIS) test. It will take about 3-5 mins (total) per person.

We will complete the informed consent in a private and quiet place in Kinneret Sr. apartments for participants who meet the inclusion criteria. If the participant needs time to discuss taking part in this research study with family members, friends, and other care providers, we will reschedule a visit for completing surveys and tests.

If he/she indicates that she/he is ready and wants to participate in this research study, she/he will be asked to complete the questionnaires such as socio-demographics and fear of falling.

Procedure for contacting participants for timepoint 2:

Screening, consent for the general population (outside Kinneret)

Our team will meet with each participant (by appointment) in a private and quiet place at the UCF College of Nursing. Participants will complete a simple COVID-19 self-checker questionnaire before coming to the UCF campus. We will screen participants by asking their age and language (English or Spanish). We will also ask if they have a medical condition precluding balance test and/or physical activity (e.g., shortness of breath, unable to stand on the balance plate) or currently receiving treatment from a rehabilitation facility, or having a metal implant. Finally, we will assess their cognition using the Memory Impairment Screen (MIS) test. It will take about 3-5 mins (total) per person.

We will complete the informed consent in the participants who meet the inclusion criteria. If the participant needs time to discuss taking part in this research study with family members, friends, and other care providers, we will reschedule a visit for completing surveys and tests.

If he/she indicates that she/he is ready and wants to participate in this research study, she/he will be asked to complete the questionnaires such as socio-demographics and fear of falling.

Procedure for contacting participants for timepoint 2:

Experimental procedures for both groups

We will assess the static balance performance using the BBS. Participants will take off their shoes and stand as still as possible on the balance plate with hands on their hips and eyes closed for 2-3 minutes. Participants will then complete the

dynamic balance performance test using the sit to stand by full standing up from a chair as many as possible within 30 seconds.

Participants will be stratified by the FRA matrix.[17] We will continually evaluate across four groups (rational/ incongruent/ irrational/ congruent) to maintain equal cell distribution (30 OAs/group)*.

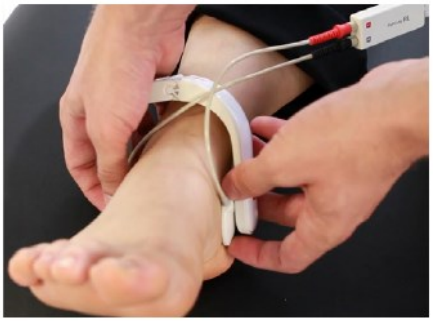
1) rational FRA: low FOF [Short Fall Efficacy Scale International (short FES-I) score ≤10] and aligned with normal balance (BBS score =0-30).
2) incongruent FRA: low FOF (short FES-1 score ≤10) despite poor balance (BBS score= 31-100).
3) irrational FRA: high FOF (short FES-I score >10) whereas normal balance (BBS score= 0-30).
4) congruent FRA: high FOF(short FES-I score >10) and poor balance (BBS score= 31-100).[17]

**Please note: This is not an intervention study and subjects will not be assigned to the study group.*

They will perform the hand-grip strength and sit to stand tests. Hand-grip strength will be measured in kilograms (kg) as maximal isometric force achieved on 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°. The dynamometer will be placed in the hand and adjusted so the palm side of the grip will be at the palm, and the front end will be lined up between the joints of the medial and distal phalanges. The grip size will be adjusted so that the second metacarpals were flat with a 90° bend at the knuckles. Participants will be asked to squeeze the strength gauge as hard as possible for 3–5 seconds. Three trials on each hand will be performed with 30-s of rest given between trials. Participants will complete the sit to stand by full standing up from a chair as many as possible within 30 seconds.[78]

Body composition will be tested, and all participants will be asked to empty their bladder, remove socks, shoes, and metal objects (e.g., watches, jewelry) before testing. The participants will be instructed to avoid exercise 6-12 hrs, eating 3-4 hrs, and drinking alcohol/coffee 24 hrs before the body composition test. We will obtain weight from a scale. Participants will be asked to stand for 10-15 mins before testing in a standing position or sit for 10-15 min for a seated position or lie down for 15 mins before testing in a supine position. The RA will present a photo of wipe hands and feet using an InBody tissue (optional).

The RA will also present photos of how to place the touch-type electrodes (labeled LT or RT) at the left and right ankles, middle fingers, and thumbs.



The participants will then place the touch-type electrodes to their left and right ankles, middle fingers, and thumbs. They will hold this position for one minute as the Bioelectrical Impedance Analysis (BIA) device; a minute electrical current will be conducted through the body to determine body composition. The participants will then remove the touch-type electrodes from their left and right ankles, middle fingers, and thumbs. The BIA machine is a widely used commercial device that is FDA approved. There are no risks or discomforts associated with the use of bioelectrical impedance analysis.

Participants will then be instructed to wear the ActiGraph GT9X Link wireless activity monitor on the non-dominant wrist for 7 consecutive days. Participants can remove the monitor only for imaging studies. Each participant will be asked to continue their normal activities while wearing the device. Written instructions will be provided to participants for the use of ActiGraph. The questionnaires and instructions will be provided in English or Spanish by bilingual research assistants (RAs) who will be trained and randomly monitored to ensure quality and consistency in administering questionnaires and tests. Participants will be

provided a phone number for the study team if they have questions about using the activity monitoring device.

Lastly, participants will be asked (using our evaluation form) about their reactions to the questions and technology (i.e., what they thought about the questionnaires and technology) and let them describe any concerns or problems in wearing the device (e.g., uncomfortable to wear during walking). We will provide feedback on the BBS and BIA test results, and participants will receive $30 Walmart gift card upon completion of the study.

After 7 days of wearing ActiGraph, the participants will return the monitoring device via mail (we will provide pre-paid mailers) or schedule a date/time for picking it up. Participants will leave the device in front of their place.

- Please see Appendix A for a demographic survey
- Please see Appendix B for the Memory Impairment Screen (MIS)
- Please see Appendix C for Patient Health Questionnaire-9 (PHQ-9
- Please see Appendix D for the Geriatric Anxiety Inventory-Short form (GAI-SF) and Day-to-Day Experiences with the trait Mindful Attention Awareness Scale (MAAS).
- Please see Appendix E for Short Fall Efficacy Scale International (short FES-I) and behavioral changes related to fear of falling
- Please see Appendix F for hand-grip strength test and static balance performance test
- Please see Appendix G for dynamic balance performance test (Sit to stand) and
- Please see Appendix H for Bioelectrical Impedance Analysis (BIA)
- Please see Appendix I for ActiGraph GT9X Link wireless activity monitors and the Rapid Assessment of Physical Activity (RAPA)
- Please see Appendix J for Evaluation form of acceptability of technology and procedures and the short version of Senior Technology Acceptance

6.5 *NA,* No plan for long-term follow-up in this study.

6.6 *NA*

7.0 Data and Specimen Banking*

NA

8.0 Sharing of Results with Subjects*

8.1

There are no plans to share the results for this study directly with the participants because the results have no direct benefits to the participants. The results of this study will be published in journals and provided to participants upon their request.

9.0 Study Timelines*

Participants will need about 105-158 minutes (total) to obtain consent and complete the questionnaires (e.g., socio-demographic, FOF, PHQ-9, fall risk, frailty, social network), the static and dynamic balance performance tests, body composition testing, learn how to wear the ActiGraph GT9X Link wireless activity monitor, and to complete the evaluation form of acceptability of technology and procedures.

Table 2. Timeline of activities and tasks to be accomplished during the proposed 2-year grant period

Activity	Year	1												2											
	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Convene team, develop a study operation manual, staffing training, and set up database																									
Screen, recruit, enrollment, inform consent, data collection, follow-up, and data management																									
Interim analyses																									
Final analyses																									
Dissemination and final grant report																									

10.0 Inclusion and Exclusion Criteria*

10.1

We will screen individuals who will be eligible to participate based on the inclusion and exclusion criteria listed

10.2

Participants will be enrolled if they meet all of the following inclusion criteria: 1) ≥ 60 years of age; 2) no marked cognitive impairment [Memory Impairment Screen (MIS) score ≥5], 3) speak English or Spanish, and 4) live in Kinneret Sr. Apartments.

Exclusion criteria:1) a medical condition precluding balance test (e.g., unable to stand on the balance plate) and/or PA (e.g., shortness of breath; feeling pressure when performing PA); or 2) currently receiving treatment from a rehabilitation facility, or 3) have a metal implant.

10.3

We will exclude all the special populations:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

11.0 Vulnerable Populations*

NA (This study will not include any vulnerable populations such as cognitively impaired adults, children, pregnant woman or prisoners)

12.0 Local Number of Subjects

12.1

About 120 participants for timepoint 1, 60 participants for timepoint 2.

13.0 Recruitment Methods

13.1 *Describe when, where, and how*

Approximately 150-200 older adults in Central Florida and Kinneret Sr Apartments will be screened to enroll 120 older adults in this study.

For the Kinneret Sr Apartments, staff from this site will introduce the researchers to older adults for performing recruitment. Our team will meet with participants in a common room or a meeting room in Kinneret Sr Apartments for screening participants.

In the general population, we will recruit them via social media, flyers, and word of mouth.

The research team will follow the UCF COVID-19 Human Subject Research Standard Safety Plan and maintain a log that tracks screening, eligibility, contact, and recruitment.

Approximately 60 adults of the 120 adults who participated at timepoint 1 will be contacted for enrollment for timepoint 2. We will contact participants who elected to be contacted for future studies in their original consent form.

13.2 *Source to subjects*

-Kinneret Sr Apartments, Orlando, FL (Please see Table in Section 24 for the source of subjects).

-General population who are living in Central Florida

13.3 *Methods that will be used to identify potential subjects*

In recruitment at the Kinneret Sr Apartments, authorized representatives will coordinate and support us as we participate and recruit within this site. They will introduce our team to their staff and older adults for performing the initial screening and determining study eligibility. Dr. Thiamwong (PI) has created continuing relationships with staff in this site in our previous study.

In the general population, we will recruit them via social media, flyers, and word of mouth. Potential subjects who want to participate in this study will contact us via email or phone.

13.4 *Describe materials that will be used to recruit subjects*

We will post an advertisement for participants screening in the form of a flyer on the public boards (in dining rooms, entrances, elevators) and social media. See the printed advertisement.

13.5

All 120 participants are estimated to complete the study, and they will be enrolled in this study for 9 days with two visits. The participants will receive $30 Walmart gift card after they are done with the second visit. If participants withdraw from the study, they will not receive them. All 60 participants are estimated to complete the second timepoint assessment, and they will be enrolled in this study for 9 days with two visits. The participants will receive $30 Walmart gift card after they are done with the second visit. If participants withdraw from the study, they will not receive them.

14.0 Withdrawal of Subjects*

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. The primary investigator also reserves the right to withdraw participants at any time without their approval.

15.0 Risks to Subjects*

15.1

The risks to participants are minimal and do not exceed the risks associated with activities found in daily life. Minimal risk of fatigue may occur related to the balance performance test, sit to stand test, bioelectrical impedance analysis test, and wearing an activity monitoring device. They will be encouraged to stop the test and rest in the area, which will be provided in the test area. In addition, the participant needs to answer the Patient Health Questionnaire-9 (PHQ-9), a 9-item survey, which includes questions about depressive symptoms. If they have a higher score (A score ≥ 10 points), which is suggestive of depression, the researcher will advise and recommend them to seek a comprehensive assessment with their doctor. The cost for any treatment will be billed to the participant or their medical or hospital insurance.

15.2 NA

15.3 NA

15.4 NA

16.0 Potential Benefits to Subjects*

16.1

There is no direct benefit to the participants in this study

16.2 NA

17.0 Data Management* and Confidentiality

17.1

Data Analysis. All analyses will be performed in SPSS version 25 or SAS version 9.4 with sufficient annotation for reproducibility. Descriptive and exploratory analyses will be performed first to investigate distributional assumptions. Although no differences are hypothesized, descriptive subgroup analyses by sex will be conducted.

Aim 1. Examine the feasibility of recruitment, especially during the COVID-19 pandemic and acceptability of technologies and procedures for use among OAs in low-income settings. We will assess the ability to recruit the sample by calculating the proportions of low-income OAs: (a) recruited out of the total screened, and (b) who completed all study procedures. We will track the number of days and time spent to recruit the sample. The results will inform planning for future larger studies. The acceptability of the technologies and procedures will be examined based on an evaluation form (e.g., what they thought about the questionnaires and technology) and their recommendations. We will identify code, categorize participants' responses, and determine the frequency for each category. Demographic data, including essential characteristics of OAs will be obtained for study participants. We anticipate no

more than 3% missing values on any one item, as data will be collected in person on-site.

Aim 2. Examine the associations among fall risk appraisal, body composition, and physical activity.

Aim 2 hypotheses are: **1)** Rational FRA is associated with higher levels of PA and skeletal muscle mass, and lower levels of percent of body fat and BMI, **2)** Incongruent FRA is associated with higher levels of PA and skeletal muscle mass, and lower levels of percent of body fat and BMI, **3)** Irrational and congruent FRAs are associated with lower levels of PA and skeletal muscle mass, and higher levels of percent of body fat and BMI. General summary statistics will be presented for continuous data, and percentages will be presented for categorical data. Participant demographic data will be summarized. Analyses will be performed without adjusting for any covariates, followed by the analyses adjusted for age, comorbidities, depressive symptoms, and fall history. Age, the number of comorbidities and the number of falls in the past year will be selected as covariates in the selected model because of their association with FRA, body composition, and PA. Data from InBodys770 (e.g., BMI) and ActiGraph (e.g., steps/day) could be modeled as continuous.

Regression models or one-way ANOVA will be used to examine differences in continuous variables (e.g., BMI, steps/day) across the four groups (rational, incongruent, irrational, and congruent FRAs), and categorical variables (e.g., comorbidities) will be tested using Chi-Squared tests. Rational FRA group will set as a base group, and the other three groups (incongruent, irrational, and congruent FRAs) will be compared with this base group. Whenever feasible, models will be adjusted for age, sex, day order, wear time (minutes/day), and the number of fall history. These following variables will add one by one to evaluate the role of each: mobility problems (Y/N), depression (score or category), fall risk (high/low), perceived general health (score of category), medication use (Y/N), and comorbidities (Y/N). A final model will include all significant potential variables to evaluate whether associations between FRA, body composition and PA, whenever feasible.

Specific Aim 2 Sample Size and Power Analysis. There is no historical precedent and limited information to inform the sample size for this study; therefore, the sample size estimate was based on the variable of the BBS score in our pilot study. The standard deviations of the mean BBS scores in our pilot study were 7.91 in the high PA group and 7.78 in the low PA group (PA by self-report), assuming a two-tail alpha 0.05 and a power 0.8, the estimated total sample size N=120 would allow to sufficiently detect a mean difference about 5 between the two groups. Furthermore, to be able to compare the effect sizes of the different body composition and PA measures, we will perform post-hoc analyses to compare the mean values between the two groups of PA, adjusted for the age group.

Aim 3. Determine the dynamic relationships between fall risk appraisal, body composition, physical activity and behavioral changes related to fear of falling

We hypothesize that higher percentage body fat, and lower frequency and duration of physical activity are associated with fall risk appraisal and the associations vary between four groups. We will collect data at the 2nd timepoint and then a dynamic prediction model will be used to investigate their temporal, dynamic associations.

17.2

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 and is located in a restricted access room at the College of Nursing. The master list is the only document with identifiable data.

All research data, including identifiers and linking sheets, will be retained for at least 5 years after the study closure.

The de-identified data (such as balance performance test data will be password protected, encrypted, and stored on computers and external hard drives in the restricted access laboratory). The de-identified data will be kept indefinitely. The reason for keeping the de-identified data indefinitely is for scientific reproducibility and transparency.

17.3 NA

17.4

Efforts will be made to limit the use and disclosure of participants' personal information, including research study to people who have a need to review this information. We cannot promise complete secrecy.

Organizations that may inspect and copy our information include the IRB and other representatives of this organization. Research records will be kept in a locked file in the PI's locked office; only the researchers will have access to the records. The researchers will maintain a computer encrypted, a password-protected master list that will contain identifiable data that links the subject ID codes with their information.

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

This research involves minimal risk to the participants.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1

Only the participant and researcher will be present during the interview and the tests.

19.2

To help participants feel comfortable, the researcher will provide small talk before beginning the surveys and tests.

19.3

The research team is only permitted to access the collected data on a needed basis.

20.0 Compensation for Research-Related Injury

20.1 NA. This research involves minimal risk to the participants. If needed, the researchers can help facilitate seeking medical care, such as calling for medical help or transporting them to the nearest medical facility. The cost for any treatments will be billed to the participant or his/her medical or hospital insurance.

20.2 NA

21.0 Economic Burden to Subjects

21.1 There is no cost to the participants.

22.0 Consent Process

22.1

We will obtain IRB approval at the University of Central Florida. The PI or trained research assistants (RAs) will obtain consent from the subjects within the designed enrollment period.

Potential subjects will be contacted via phone to schedule the first visit for obtaining consent and completing surveys and tests.

For the residents in Kinneret Sr. apartments, the consent process will take place at a private or quiet room in Kinneret Sr. apartments. For the general population, the consent process will take place at a private room at the UCF, College of Nursing. If participants have a primary language is Spanish and cannot speak English, our research assistant, who fluent in both Spanish and English, will perform the consent using the Spanish language. The bilingual research assistant will explain the details in such a way that the participant understands what it would be like to take part in the research study and answer all questions.

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 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 records.

Potential subjects will be told that they will participate in this study for approximately 9 days. They will participate in a screening, balance test, body composition test, and then wear activity-monitoring devices for 7 days.

Study subjects will be informed that study records will be kept as confidential as possible. No individual identifies 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. 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.

We will give subjects time to discuss taking part in this research study with family members, friends, and other care providers or take the written information home if they want, and we will reschedule a new visit for completing surveys and tests. If the subject indicates that he/she ready and wants to take part in this research study, we will perform the surveys and test as described above in the first visit. However, if the subject indicates that he/she does not want to take part in the research study, the consent process will stop.

23.0 Process to Document Consent in Writing

23.1

Because this is a minimal risk study using non-significant risk devices, we believe that this meets the requirements for a waiver of written consent documentation. Our devices (BTracks balance test, bioelectrical impedance analysis, and activity monitor devices) are not represented to be for use in supporting or sustaining human life and not present a potential for serious risk to the health, safety, or welfare of our participants.

24.0 Settings

24.1 *Describe the sites or locations where your research team will conduct the research.*

Name of site	**Contact name**	**Contact phone**	**Has the site granted permission for your to**	**Does the site have an IRB?**	**If the site has an IRB, select one**

			conduct the research?		
Kinneret Sr Apartments: 515 Delaney Ave. Orlando, FL 32801	My Dung Do	407-843-1695	Yes	No	The organization will rely on our IRB.

25.0 Resources Available

25.1 Dr. Ladda Thiamwong (PI) have successfully led interdisciplinary teams to develop research studies that demonstrate the effectiveness of strategies in different contexts related to falls, fear of falling, measurements and interventions, and established the feasibility of recruitment, retention, and adherence of community-dwelling older adults.

25.2 NA

26.0 Multi-Site Research*

NA

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