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

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UNIVERSITY OF CENTRAL FLORIDA

Title of research study: Technology-based fall risk assessments for older adults in low-income settings

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Key Information: The following is a short summary of this study to help you decide whether to be a part of this study. More detailed information is listed later in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an adult aged 60 years and older, with no marked cognitive impairment, participated in the first timepoint assessment of the Technology-based fall risk assessment for older adults in low-income settings study, and speak English.

You cannot participate in this study if you 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.

Why is this research being done?

Lack of physical activity is related to chronic conditions, increased falls, and reduced quality of life among low-income older adults. Limited data suggest that older adults who overestimate their fall risk and report fear of falling are less likely to participate in physical activity, and the association between fear of falling and physical activity intensity differs by fear severity.

This study aims to: 1) examine how many older adults need to be screened to recruit the sample, especially during the COVID-19 pandemic, and examine the acceptability of technologies and procedures for use among older adults in low-income settings.
2) examine the associations among fall risk appraisal, body composition, and physical activity, and 3) determine the dynamic relationships between fall risk appraisal, body composition, physical activity and behavioral changes related to fear of falling.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 9 days with two visits. Potential participants will be contacted via phone to schedule the first visit for obtaining consent and completing surveys and tests. We will meet at a meeting room and spend 105-158 minutes (total).

In the first visit, the consent process will take place at a private or quiet room in Kinneret Sr. apartments or at the UCF College of Nursing. We will explain all aspects of the study. Participation in this study is voluntary and you are free to decline to be in the study or to

withdraw from this study at any point without any negative consequence. If you need 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 you indicate that you are ready and want to take part in this research study, you will be asked to complete the questionnaires such as socio-demographic and fear of falling. You will be assessed your hand-grip strength and static balance performance. Then, you will complete a sit to stand test, a body composition test and then you will be asked your concerns and perception of using these devices

You will be asked to empty your bladder, remove socks, shoes, and metal objects (e.g., watches, jewelry) before the body composition testing. Also, you will be instructed to avoid exercise 6-12 hrs, eating 3-4 hrs, and drinking alcohol/coffee 24 hrs before the body composition test.

You will be asked to wear an activity monitoring device for 7 consecutive days.

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

Is there any way being in this study could be bad for me?

The risks to participants are minimal and do not exceed the risks associated with activities found in daily life. If you have a higher score (a score > 10 points) on the Patient Health Questionnaire-9, which uses for screening depression, the researcher will advise and recommend you seek a comprehensive assessment with your doctor. The cost for any treatment will be billed to you or your medical or hospital insurance.

Will being in this study help me anyway?

There are no benefits to you from taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include information about the associations among fall risk appraisal, body composition, and physical activity in low-income older adults.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Ladda Thiamwong, College of Nursing, at (407) 823-5091 or by email at ladda.thiamwong@ucf.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 407-823-2901or irb@ucf.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect the total number of 120 people will be in the study for timepoint 1 and 60 people for timepoint 2.

What happens if I say yes, I want to be in this research?

You will be asked to complete the questionnaires and tests which includes:

1. Demographic survey (such as ask about your age, fear of falling, fall risk, social network)
2. Assess your cognition using the Memory Impairment Screen (MIS)
3. Assess your depression symptoms using the Patient Health Questionnaire-9 (PHQ-9)
4. Assess your anxiety using the Geriatric Anxiety Inventory-Short form (GAI-SF).
5. *Assess your fear of falling using the Short Fall Efficacy Scale International (short FES-I) and behavioral changes related to fear of falling*
6. Assess your 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.

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

   You 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

8. Assess your dynamic balance performance test using the sit to stand test

   You will complete the sit to stand by full standing up from a chair as many as possible within 30 seconds

9. Assess your body composition using the Bioelectrical impedance analysis (BIA**)**

   You will be instructed and prepared for the body composition test. We will present a photo of wipe hands and feet using an InBody tissue (optional).

Fig. 2 Wipe hands and feet

We 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.

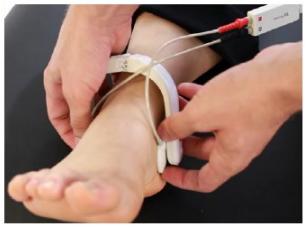

Fig. 3-4 Place the touch-type electrodes

You will then place the touch-type electrodes to their left and right ankles, middle fingers, and thumbs. You will hold this position for one minute and then remove the touch-type electrodes from your left and right ankles, middle fingers, and thumbs.

You will be asked to stand for 10-15 min before testing in standing position or sit for 10-15 min for seated position or lie down for 15 mins before testing in supine position.

Fig. 5 InBody S10

10. Assess acceptability of technologies and procedures using the evaluation form and the short version of Senior Technology Acceptance.

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

You 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. You will be instructed to remove the monitor only for imaging studies. Written instructions will be provided to you for the use of ActiGraph. You will be provided a phone number for the study team if you have questions about using the activity monitoring device.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can make appropriate plans for the data that has been collected from you. However, responses of participants that were submitted and the data recorded will not be excluded from the study data. The investigator can remove you from the research study without your approval.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your 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 your information include the UCF IRB and other representatives of UCF. Research records will be kept in a locked file in the PI's locked office; only the researchers will have access to the records.

We will maintain a computer encrypted, password protected master list that will contain identifiable data which links your subject ID codes with your information. Once this study is completed, the master list will be maintained for 5 years and then destroyed. The de-identified data will be kept indefinitely. The reason for keeping the de-identified data indefinitely is for scientific reproducibility and transparency.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What else do I need to know?

This research is being funded by the National Institute on Aging and LIFE@UCF.

If you are experiencing an emergency, call 911. If you believe you have been harmed as a result of participating in this study, it is important that you promptly tell the researcher(s) at the number listed above. UCF will assist you in obtaining necessary medical care. In general, this care will be billed to you or your insurance company. UCF has no program to pay for medical care for research related injuries.

If you agree to take part in this research study, you will receive $30 Walmart gift card at the end of the second day of the study. Also, you will receive your balance test and body composition results.

Please initial below if you do, or do not, want to participate in the future studies:

_____ I DO want to be contacted to participate in the future studies.

_____ I DO NOT want to be contacted to participant in the future studies