Effects of Task-Specific Step Training on Reactive Balance

NCT05734443

Study Protocol and Statistical Analysis Plan

March 24, 2025

Suzie Lee
[Date]

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)" to prepare a study protocol outlining your research plan.*
- *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as "N/A." For example, a simple survey might have many sections with "N/A." For subsections (e.g., 1.x or 8.x) you can mark as "N/A"if you are certain that the subsection is not applicable.*
- *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
- *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate "Amendment: Date" before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

PROTOCOL TITLE:

Include the full protocol title.

Validation and application of wearable sensors for capturing responses to losses of balance

PROTOCOL NUMBER:

Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP).

21-1072

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21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

VERSION NUMBER/DATE:

Include the version number and date of this protocol. Versions should start at 1.0.

Version 1.0 December 14, 2021

Version 2.0 April 28, 2022

Version 3.0 May 18, 2022

Version 4.0 July 3, 2022

Version 5.0 October 3, 2022

REVISION HISTORY:

Use this table to keep track of changes. Add more rows as needed.

Revision #	Version Date	Brief Summary of Changes (i.e., the different sections)	Consent Change?
1	April 28, 2022	Changes to Research Protocol and Informed Consent form requested by HRPP.	yes
2	May 18, 2022	Changes to Research Protocol and Informed Consent form requested by HRPP.	yes
3	July 3, 2022	Changes to Research Protocol and Informed Consent form requested by HRPP.	yes
4	October 3, 2022	Clarified in section 19.3 how de-identified data will be shared with external collaborators.	no

Table of Contents

1.0	Study Summary	4
2.0	Objectives	5
3.0	Background	5
4.0	Study Endpoints	8
5.0	Study Design and Statistical Analysis Plan	9
6.0	Setting	10
7.0	Study Intervention(s)/Investigational Agent(s)	12
8.0	Procedures Involved	16
9.0	Data and Specimen Long Term Storage and Use	22
10.0	Sharing of Results with Subjects	24
11.0	Study Timelines	24
12.0	Inclusion and Exclusion Criteria	24
13.0	Vulnerable Populations	27
14.0	Number of Subjects	28
15.0	Recruitment Methods	29
16.0	Withdrawal of Subjects	30
17.0	Risks to Subjects	31
18.0	Potential Benefits to Subjects	34
19.0	Data Management and Confidentiality	34
20.0	Provisions to Protect the Privacy Interests of Subjects	36
21.0	Provisions to Monitor the Data to Ensure the Safety of Subjects	38
22.0	Compensation for Research Related Injury	38
23.0	Economic Burden to Subjects	39
24.0	Consent Process	39
25.0	Process to Document Consent in Writing	43
26.0	Resources Available	44
27.0	Multi-Site Research	45

1.0 Study Summary

Study Title	Validation and application of wearable sensors for capturing responses to losses of balance
Study Design	A three-group posttest-only design.
Primary Objective	To validate the use of wearable sensors for capturing responses to losses of balance (LOBs). During laboratory testing, we will use both wearable sensors and a laboratory-based optoelectronic motion capture system to measure responses to LOBs after laboratory-induced trips and slips. During real-world testing, we will use wearable sensors to measure responses to LOBs after any naturally-occurring trips or slips during the real-world daily lives of participants. Participants for this primary objective are referred to as "non-balance training participants."
Secondary Objective(s)	Responses to LOB measured during both laboratory testing and real-world testing will be used to compare between three types of balance training. Participants for this secondary objective are referred to as "balance training participants."
Study Population	Adults age 65-80
Sample Size	60 total including 30 non-balance training participants and 30 balance training participants.
Research Intervention(s)/ Investigational Agent(s)	Data will be obtained using 1) a laboratory-based optoelectronic motion capture system to measure responses to LOBs (i.e. body movements) after laboratory-induced trips and slips, 2) wearable sensors to measure responses to LOBs after laboratory-induced and any naturally-occurring real-world trips and slips, 3) a wearable voice recorder to describe any real-world trips or slips. For balance training participants, each participants will complete one of three different research interventions: non-treadmill training (NT); treadmill training (TT); or strength training (ST). All interventions will be performed two times per week for three weeks. In this document, balance training participants will be referred to as NT participants, TT participants, or ST participants (depending upon which intervention they complete).
Study Duration for Individual Participants	The study duration for individual participants will be 5-7 weeks, not including screening.
Acronyms and Definitions	LOB - Loss of balance PBT - perturbation balance training NT - Non-treadmill training TT - Treadmill training ST - Strength and balance training

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives of this study:

The primary objective is to validate the use of wearable sensors for capturing responses to losses of balance (LOBs). During laboratory testing, we will use wearable sensors and a laboratory-based optoelectronic motion capture system to simultaneously measure responses to LOBs after laboratory-induced trips and slips. During real-world testing, we will use wearable sensors to measure responses to LOBs after any naturally-occurring trips or slips during the real-world daily lives of participants.

The secondary objective of this study is to compare the effects of three balance training exercises on responses to LOBs measured in the laboratory and in the real-world during daily life.

2.2 State the hypotheses to be tested:

Hypotheses for our primary objective that will involve non-balance training participants:

Hypothesis 1: LOB response measures obtained from the wearable sensors after lab-induced trips and slips will exhibit statistical agreement with the same measures obtained simultaneously from a laboratory-based optoelectronic motion capture system.

Hypothesis 2: Real-world LOB responses will show greater variety than laboratory-induced LOB responses.

Hypotheses for our secondary objective that will involve balance training participants:

Hypothesis 3: NT and TT participants will exhibit improved LOB responses after lab-induced trips and slips compared to ST participants.

Hypothesis 4: NT and TT participants will exhibit statistically-equivalent LOB responses after lab-induced trips and slips.

Hypothesis 5: NT and TT participants will exhibit improved LOB responses after any naturally-occurring real-world trips and slips.

3.0 Background

3.1 Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study:

Falls are the leading cause of injuries among older adults. An estimated 60% of falls among community-dwelling older adults are due to LOBs induced by tripping or slipping [Berg 1997]. Laboratory studies have shown that these falls generally result from an age-related decline in balance recovery ability after an LOB [Pavel 2007; van Dieen 2005]. However, technical challenges with capturing the kinematics of these events outside the lab has resulted in at least two knowledge gaps that limit progress in fall prevention research. First, there is a need to validate the use of wearable sensors (that can be used outside the lab in the real-world) by comparing their measurements with a gold-standard laboratory system. Second, it is unclear if gait and tripping/slipping events differ meaningfully between the laboratory and real-world. Laboratory trips and slips are contrived, highly-controlled, and often not unexpected, and likely result in more stereotypical LOB responses. Real-world trips and slips are typically unexpected, have more variable etiology and environmental contributions, and as a result likely elicit more variable LOB responses. Accordingly, there is a critical need to evaluate the use of wearable sensors to capture responses to LOBs both in the laboratory and in the real-world.

Multiple studies report a reduction in real-world fall risk after perturbation-balance training (PBT) [Rosenblatt 2013; Grabiner 2012; Bhatt 2012]. These studies speculate that this reduction in fall risk is due to improved responses to LOBs. An LOB is defined as an event when the postural control of the body that resists gravity (balance) is momentarily lost, and is then followed by either successful recovery of balance without a fall, or a fall. To our knowledge, no studies have shown a direct training effect of PBT on responses to real-world LOBs. Until a real-world effect is demonstrated, PBT studies reporting a reduction in falls may be confounded by concomitant changes such as in activity intensity, safe/risky behavior, and the daily living environment rather than true PBT-induced improvements in balance.

Accordingly, evaluating responses to real-world LOBs and their context (i.e. the circumstances surrounding the LOB) are critical in evaluating the effectiveness of PBT. Prior studies have been limited to participant recall to obtain information on fall context despite well-documented inaccuracies in self-reporting [Perry 2012; Zecevic 2006]. Rather, we propose to track body movements during responses to real-world LOBs and their context using wearable sensors and voice recorders.

The study proposed in this IRB application will compare two types of PBT (NT and TT) to an alternative training (ST) among adults age 65-80. This study may link training-induced improvements to improvements in real-world LOB responses, a truly novel and innovative link that has previously not been possible.

Berg, W.P., H.M. Alessio, E.M. Mills, and C. Tong, Circumstances and consequences of falls in independent community-dwelling older adults. Age Ageing, 1997. 26(4): p. 261-8.

Rosenblatt, N.J., J. Marone, and M.D. Grabiner, Preventing trip-related falls by community-dwelling adults: a prospective study. J Am Geriatr Soc, 2013. 61(9): p. 1629-31.

Grabiner, M.D., M.L. Bareither, S. Gatts, J. Marone, and K.L. Troy, Task-specific training reduces trip-related fall risk in women. Med Sci Sports Exerc, 2012. 44(12): p. 2410-4.

Bhatt, T., F. Yang, and Y.C. Pai, Learning to resist gait-slip falls: long-term retention in community-dwelling older adults. Arch Phys Med Rehabil, 2012. 93: p. 557-564.

Pavol, M.J. and Y.C. Pai, Deficient limb support is a major contributor to age differences in falling. J Biomech, 2007. 40(6): p. 1318-25.

Perry, L., D. Kendrick, R. Morris, S. Dinan, T. Masud, D. Skelton, S. Iliffe, and T. ProAct65+ Study, Completion and return of fall diaries varies with participants' level of education, first language, and baseline fall risk. J Gerontol A Biol Sci Med Sci, 2012. 67(2): p. 210-4.

van Dieen, J.H., M. Pijnappels, and M.F. Bobbert, Age-related intrinsic limitations in preventing a trip and regaining balance after a trip. Safety Science, 2005. 43: p. 437-453.

Zecevic, A.A., A.W. Salmoni, M. Speechley, and A.A. Vandervoort, Defining a fall and reasons for falling: comparisons among the views of seniors, health care providers, and the research literature. Gerontologist, 2006. 46(3): p. 367-76.

3.2 Describe any relevant preliminary data:

Preliminary data on PBT from our group is cited below. In short, these data show PBT improved LOB responses after lab-induced trips and slips.

In Bieryla et al. (2007), we showed beneficial effects of TT on laboratory-induced trips. In Allin et al. (2019), we showed beneficial effects of slip training on laboratory-induced slips. In Allin et al. (2020), we showed beneficial effects of TT on laboratory-induced trips and slips.

Bieryla KA, Madigan ML, Nussbaum MA. Practicing recovery from a simulated trip improves recovery kinematics after an actual trip. Gait & Posture, 2007, 26(2), 208-213.

Allin LJ, Nussbaum MA, Madigan ML. Two novel slip training methods improve the likelihood of recovering balance and avoiding a fall after a laboratory-induced slip. Journal of Applied Biomechanics (2019) 35(1): 37-43.

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

Allin LJ, Brolinson PG, Beach BM, Kim S, Nussbaum MA, Roberto KA, Madigan ML. Perturbation-based balance training targeting both slip- and trip-induced falls among older adults: a randomized controlled trial. BMC Geriatrics (2020) 20:205.

3.3 Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge:

This study will address two major knowledge gaps in the literature.

First, there is a need to validate the use of wearable sensors (that can be used to capture responses to LOBs in the real-world) to measure responses to LOBs with simultaneous measures obtained from gold-standard laboratory-based equipment.

Second, PBT studies aiming to reduce the risk falls have almost exclusively used specialized treadmills to apply perturbations during training. While this type of training has shown beneficial effects on responses to laboratory-induced LOBs, the cost of these specialized treadmills may present a barrier to widespread adoption of this training by some individuals or organizations. This study will evaluate an alternative PBT not requiring a specialized treadmill that would alleviate cost as a barrier to its use, and measure the effects of this training on responses to LOBs after both laboratory-induced trips and slips, and naturally-occurring trips and slips.

4.0 Study Endpoints

*4.1 Describe the primary and secondary **study** endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing

Study endpoints for all participants will include:

1) measurements of body movements during responses to LOBs after lab-induced trips and slips

2) two or three weeks of using wearable sensors to measure body movements during responses to LOBs after naturally-occurring trips and slips during daily life

3) during the two or three weeks of using wearable sensors, participants will also use a digital voice recorder to record a description of the context of each real-world LOB. Specifically, participants will be asked to make a short recording

after each LOB to describe (1) what they were doing at the time (e.g., "I was walking across my living room"), (2) how they lost their balance (e.g., "I tripped over my dog"), (3) why they lost their balance (e.g., "my dog ran in front of me to bark at the mailman"), and (4) the results of LOB (e.g., "I fell, or did not fall, as a result").

*4.2 Describe any primary or secondary **safety** endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

No safety endpoint is included while using wearable sensors in the real-world during daily life because the use of the wearable sensors does not increase risk above that normally experienced during every day life.

During balance training (among balance training participants), safety endpoints will include number of times the spotter is needed to provide support to the participant during training, and the number of times the participant is fully supported by the harness during measurements of responses to lab-induced LOBs.

5.0 Study Design and Statistical Analysis Plan

5.1 Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy):

For our primary objective, a one-group repeated-measures design will be used to validate the use of wearable sensors to capture responses to LOBs. Subjects will use wearable sensors for three weeks to capture responses to naturally-occurring trips and slips during daily life. Subjects will then complete a laboratory session to capture lab-induced LOB responses simultaneously from the wearable sensors and a gold-standard optoelectronic motion capture system.

For our secondary objective, a three-group posttest-only design will be used to compare the effects of three balance training exercises on responses to LOBs after laboratory-induced trips and slips, and two weeks of naturally-occurring real-world trips and slips. Subjects will first complete three weeks of their assigned training. Subjects will then

complete a laboratory session to capture lab-induced LOB responses simultaneously from the wearable sensors and a gold-standard optoelectronic motion capture system. Subjects will then use wearable sensors for two weeks to capture responses to naturally-occurring trips and slips during daily life.

5.2 Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures):

Hypothesis 1: LOB response measures obtained from the wearable sensors after lab-induced trips and slips will exhibit statistical agreement with the same measures simultaneously obtained from a gold-standard laboratory-based motion capture system.

To address Hypothesis 1, a Bland-Altman analysis will be used to evaluate level of agreement between the two systems. This approach will reveal any measurement bias between the two systems, and provide bounds for these differences.

Hypothesis 2: Real-world LOB responses will show greater variety than laboratory-induced LOB responses.

To address Hypothesis 2, a repeated-measures ANOVA (with a random effect for subject) will first be used to compare means of key kinematic measures of LOB responses between environments (real-world vs lab). Second, we will compare statistical variability by examining the model residuals between real-world and lab environments using hypothesis testing (essentially Levene's test) and interval estimation to quantify potential differences in variability.

Hypothesis 3: NT and TT participants will exhibit improved LOB responses after lab-induced trips and slips compared to ST participants.

To address Hypothesis 3, response variables will be compared between NT, TT, and ST participants using a one-way ANOVA with group as the independent variable and covariates included as needed. A significant effect of group will be followed by post-hoc analysis using Dunnett's test to determine whether NT, TT, or both differ from ST.

Hypothesis 4: NT and TT participants will exhibit statistically-equivalent LOB responses after lab-induced trips and slips.

To address Hypothesis 4, agreement of response variables between NT and TT participants will be evaluated using statistical equivalence test.

A comparison between the three balance training exercises on LOB responses after any naturally-occurring real-world trips will be done qualitatively and thus not have an explicit hypotheses to be tested.

6.0 Setting

6.1 Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where the team will perform the research procedures.*
- *Describe the composition and involvement of any community advisory board(s).*
- *For research conducted in other locations, describe:*
  - *Site-specific regulations or customs affecting the research at those locations.*
  - *Local scientific and ethical review structure at those locations. Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

All participants will be recruited from the Virginia Tech, NRV, and Roanoke Valley communities.

Sessions involving laboratory-induced trips and slips for all participants will take place in our research lab on the VT campus (556 Whittemore Hall). Also during this session, the investigators will train the participants on the use of the wearable sensors and voice recorders.

Balance training sessions for balance training participants, including all three types of balance training, will be performed in our research lab on the VT campus (556 Whittemore Hall) or our research lab leased by VT in the University City Boulevard Mall.

When the two or three weeks of using wearable sensors is complete, the investigators will meet up with the participant to retrieve the sensors from the participant. This meeting will take place either in our research lab on the VT campus or in the University City Boulevard Mall.

Other interactions between the investigator and each participant will occur over the phone to provide any troubleshooting or address any issues with wearable sensor use. At least two telephone calls will be made (one at the end of the first day of sensor use and one at the end of the third day of sensor use), with additional calls up to daily calls possible as needed.

7.0 Study Intervention(s)/Investigational Agent(s)

7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:

- *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

Study Investigational Agents

The wearable sensors will be commercially-available inertial measurement units (https://apdm.com/wearable-sensors/) are the size of a matchbox and are specifically designed for wearing to measure body movements. They come with specialized straps to secure then on the body where desired. Three sensors will be worn by each participant including one on the top of each shoe using small pouches that are secured to the shoes using the shoe laces, and one sensor on the sternum using a light-weight shoulder harness worn under clothes.

The portable voice recorder (Sansa Clip Zip MP3 player) is a commercially-available device.

These sensors are self-contained, do not require any wires for connectivity, and will be used in a manner consistent with their approved use.

The laboratory-based equipment used to measure responses to LOBs will be an optoelectronic motion capture system. This system includes 13 cameras and a CPU unit for data collection. Reflective markers (approximately 1 cm in diameter) are placed on the participant at selected anatomical locations to measure body movements and responses to LOBs.

No microwaves, X-rays, DEXA scans, general anesthesia, or sedation will be used as a part of the intervention. However, DEXA scans will be used as a part of screening participants.

Study Interventions

To address our secondary objective, balance training participants will be assigned to one of three balance training exercises/interventions including TT, NT, and ST. No drugs are used in this study. Each training session for TT, NT, and ST will be one-on-one with the investigator, approximately 30-45 minutes in duration, and two sessions will be completed each week for three weeks. A description of each session of each type of training follows.

Each TT session will involve a trip training protocol with a specialized treadmill (Aviles et al., 2019). TT perturbations will be induced while participants are standing on a modified treadmill (Freemotion 800, Freemotion Fitness, Logan, UT). The treadmill belt will then be accelerated posteriorly, varying in speed from 0.5 to 2.4 mph, to induce a forward LOB within about 40 msec. Participants will be instructed to react naturally and try to establish a stable gait after perturbations and an initial step over an obstacle. The treadmill belt speed will be maintained until one of two conditions are met: (1) participant established a stable gait for several strides, or (2) participant received substantial support from a fall protection harness or spotter(s) standing next to him/her. Based upon the performance of participants, the treadmill speed will progressively be increased during each session to continue challenge participants and to maintain variability over the course of training. Perturbations in the reverse belt direction (i.e., 0.5 mph anteriorly) will also be included intermittently to reduce anticipation. A slender, lightweight rectangular foam block (7.5 cm x 7.5 cm cross section) will be placed within 3-7 cm in front of the toes before each trial to elicit a step over an obstacle, similar to that needed during an actual trip. Given the suddenness of these perturbations, participants will wear a fall protection harness supported by an overhead gantry to protect knee or hand from contact with the treadmill in the event of an unsuccessful attempt to recover balance. Each TT session will involve exposure to up to 40 treadmill perturbations with a rest break after every 10 perturbations.

Each NT session will involve four phases of voluntary/volitional stepping exercises. Each session will begin with a three-minute warm-up of walking on a treadmill and light stretching. Phase 1 – Rapid Stepping will involve volitional stepping exercises from bilateral standing where a participant will start to fall forward and then take quick steps to recover balance. This exercise will be performed first without tripping obstacle, and then with a slender, lightweight rectangular foam block (7.5 cm x 7.5 cm cross section) placed in front of the toes before stepping. Phase 2 – Trunk Control will involve similar stepping exercises as Phase 1, but with explicit instructions and emphasis on arresting trunk motion and controlling trunk posture to be vertical at touchdown of the first recovery step. Phase 3 – Lean Release will involve similar exercises as Phases 1 and 2, but with the addition of an "unexpected" forward LOB. The participant will lean slightly forward while being supported by a trainer with their hands on the participant's shoulders and arms fully extended in front of the participant. Without warning, the trainer will release the participant, and the participant will take recovery steps to recover balance. Phase 4 – Simulated Trip will self-induce a slow-motion trip and practice stepping over the obstacle and continue walking. The participant will stand 15-30 cm away from the tripping obstacle, swing their foot forward to purposefully trip on the obstacle, then elevate the

obstructed foot over the obstacle to recover balance, and continue walking. We will encourage participants to take a long initial recovery step and control trunk posture to be vertical at touchdown of the first recovery step. To prevent a fall in the event of an unsuccessful balance recovery during any of the four phases of NT, the investigator and spotter will be nearby to provide support if needed. The investigator will also demonstrate each phase before asking the participant to complete them, and if necessary assistance will be provided during initial attempts by the participant. Each NT session will be individualized to each participant's capability and rate of improvement to continuously challenge the participant while not asking them to overexert themselves.

Each ST session will involve general balance and strength exercises adapted from the Otago Exercise Program (Campbell et al., 1997). Otago has shown its effectiveness in reducing fall risk in community-dwelling older adults, and thus it is chosen among many other general exercise interventions to increase the level of evidence for demonstrating efficacy. In addition, similar to NT or TT, it can be performed individually. Each ST session will involve strength and balance exercises with varying ankle weights or difficulty of the balance exercises (e.g., holding onto a wall or no support), which will be progressively increased based upon the performance of participants. Strength exercises will include controlled squatting, lunges, knee bends, hip extensions, leg side raises, and toe raises. Resistance will be provided with ankle weights. Balance exercises will involve standing with feet side-by-side at decreasing distance, standing with one foot in front of the other, and standing on one foot. Difficulty will progress by increasing angle weights and increasing difficulty of standing position (e.g. feet side by side and moving them closer together, one foot in front of the other and increasing the distance between them, and asking subjects to move their body while in these challenging feet positions). The progression of difficulty will be based on the investigators perception of the improving ability of the participant.

Aviles, J., Allin, L. J., Alexander, N. B., Van Mullekom, J., Nussbaum, M. A., & Madigan, M. L. (2019). Comparison of treadmill trip-like training versus tai chi to improve reactive balance among independent older adult residents of senior housing: a pilot controlled trial. The Journals of Gerontology: Series A, 74(9), 1497-1503.

Campbell, A. J., Robertson, M. C., Gardner, M. M., Norton, R. N., Tilyard, M. W., & Buchner, D. M. (1997). Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. BMJ, 315(7115), 1065-1069.

7.2 List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use:

N/A

7.3 List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher's recommendation for each of those devices:

Commercially-available inertial measurement units (https://apdm.com/wearable-sensors/) are the size of a matchbox and are specifically designed for wearing to measure body movements. They come with specialized straps to secure then on the body where desired. Three sensors will be worn by each participant including one on the top of each shoe using small pouches that are secured to the shoes using the shoe laces, and one sensor on the sternum using a light-weight shoulder harness worn under clothes.

The portable voice recorder (Sansa Clip Zip MP3 player) is a commercially-available device.

The above sensors are self-contained, do not require any wires for connectivity, and will be used in a manner consistent with their approved use.

All participants will be used these devices, and will be provided detailed instructions on the use of the sensors. None of these devices alter behavior in any way and thus do not increase risk beyond that during daily life. None of these sensors using any kind of radiation.

The laboratory-based equipment used to measure responses to LOBs will be an optoelectronic motion capture system. This system includes 13 cameras and a CPU unit for data collection. Reflective markers (approximately 1 cm in diameter) are placed on the participant at selected anatomical locations to measure body movements and responses to LOBs.

7.4 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

For our primary objective, a one-group repeated-measures design will be used to validate the use of wearable sensors to capture responses to LOBs. Non-balance training participants will use wearable sensors for three weeks to capture responses to naturally-occurring trips and slips during daily life. Subjects will then complete a laboratory session to capture lab-induced LOB responses simultaneously from the wearable sensors and a gold-standard optoelectronic motion capture system.

For our secondary objective, a three-group posttest-only design will be used to compare the effects of three balance training exercises on responses to LOBs after laboratory-induced trips and slips, and two weeks of naturally-occurring real-world trips and slips. Balance training participants will first complete three weeks of their assigned training. Subjects will then complete a laboratory session to capture lab-induced LOB responses simultaneously from the wearable sensors and a gold-standard optoelectronic motion capture system. Subjects will then use wearable sensors for two weeks to capture responses to naturally-occurring trips and slips during daily life.

8.2 Provide a description of:

- *All research procedures being performed*
- *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study*

population separately. For complex studies, you are encouraged to include a figure or chart.

Recruitment and Informed Consent
- Interested participants will respond to our recruitment strategies and contact the investigators.
- The investigators will telephone interested participants and follow the telephone script included in the application to first screen participants for inclusion criteria. If participants satisfy the inclusion criteria, the investigator will continue the telephone conversation and administer the health questionnaire described in an attachment to this application. De-identified information from this health questionnaire will then be reviewed by a health professional with specialist training for the geriatric population. This specialist will be a board certified physician or board certified specialist in geriatric physical therapy.
- If the participant passes the health questionnaire, then a DEXA assessment for osteoporosis will take place. This assessment will be based upon a DEXA scan performed for this study, or DEXA scan completed within the last year.
- If a DEXA scan is performed for this study, the scan will take place in the Human Integrative Physiology Lab, led by Dr. Kevin Davy. Dr. Davy does not have a role in the current work, but his lab will be providing this service to the PI for a fee. The Human Integrative Physiology Lab is in the Garvin Innovation Building in the CRC (1872 Pratt Drive, Suite 1575). A member from the research team involved in this IRB application will meet the subject at this location to provide a lead. Trained staff in this lab will conduct the scan.
- If the participant passes the DEXA scan, she/he will have completed our screening process.
- A copy of the informed consent form will be delivered to the participant, and the first visit will be scheduled (at least 24 hours after delivery of the informed consent form.
- The investigator will meet the participant in our research lab. The investigator will confirm the inclusion criteria and ask if they have any questions about the informed consent form. All questions will be answered. If the participant still wants to participate, they will sign the informed consent form, and be provided a copy for them to keep.

Group Assignment and Training
- Participants will be randomly assigned to be either a non-balance training participant or a balance-training participant. Balance training participants will then be assigned to either TT, NT, or ST.
- If the participant is assigned to balance training, this training will be completed twice a week for three weeks. Each training session will be approximately 45 minutes in duration. The details of each type of training is described in detail in section 7.1.
- NT, TT, and ST will all be customized to participants' capabilities, and training difficulty will progressively increased based on participants' capabilities. For NT, difficulty will be increased by 1) adding the obstacle to training during all four phases, 2) leaning the participant farther forward during Phase 3, and asking subjects to walk faster during Phase 4. For TT, difficulty will be increased by increasing the maximum speed of the treadmill perturbations. For ST, difficulty will be increased by using heavier ankle

weights and using more challenging balance postures. The progression of difficulty will be based on the investigators perception of the improving ability of the participant.
- If the participant is assigned no training, then no such training will be performed.
- All participants will then complete the two types of LOB response measurements described below.

Measure LOB responses in the laboratory:
- Each participant will complete a lab session to assess their response to an LOB after lab-induced trips and slips. This session will take place in our research lab on the VT campus (556 Whittemore Hall). During these sessions, participants will wear a safety harness supported overhead to prevent impact with the floor in the event of an unsuccessful balance recovery. First, the appropriate size will be selected from a range of sizes we have in the lab. Second, the investigator will assist the participant in donning the harness, securing all straps and connections, and inspecting and confirming the overall fit. The PI (Madigan) has extensive experience with the harnesses, and will train the student investigators in their use.
- Participants will also wear reflective markers so researchers can measure their movements with a laboratory motion capture system. As we have done for years, these markers will be affixed to clothing and skin at selected anatomical landmarks using double-sided tape. Youngjae Lee will place markers on participants. Markers will be place bilaterally on the shoes at the toes and heels, ankles, knees, hips, shoulders, elbows, wrists, and on a headband worn around the head.
- Participants will first complete a minimum of 10 walking trials along a 12-meter-long walkway at a self-selected speed. Instructions will be to “walk as if you have somewhere to go, and if tripped or slipped, recover your balance and continue walking.” All participants will wear the same model of rubber-soled shoes and a safety harness affixed to a ceiling-mounted track that spans the length of the walkway. After initial walking trials, trips and slips will be induced during randomly-selected trials with walking trials and rest breaks interspersed. As in our prior work, trips will be induced using a tripping obstacle that is initially concealed and level with the walkway. Upon proper placement of the foot relative to the obstacle while walking, the obstacle will be activated and quickly rise and result in a trip shortly after mid-swing. In an effort to add variety to the LOB responses, three trip obstacle heights from prior tripping studies will be used including 5, 7.5, and 10 cm. Slips will be induced using the same methods and distraction efforts as in our preliminary studies. While the participant is facing away from the walkway and distracted, a contaminant or slipping hazard applied over a 0.9 × 0.9 m targeted section of the walkway to induce an unexpected slip at heel strike during the next trial. In an effort to add variety to the LOB responses, three different contaminants or slipping hazards will be used including vegetable oil, soapy water, and a carpet mat on a polished vinyl floor.

Measure naturally-occurring LOB responses in the real-world:
- Participants will be briefed on how to wear and use the wearable sensors, and the investigator will give the sensors to the participants for them to wear over the subsequent three weeks (no balance training participants) or two weeks (TT, NT, and ST participants) during their daily lives. Participants will be asked to wear the sensors for at least 10 hours a day.

- The wearable sensors will be worn at the locations described in 7.3 above, and require no input from the participant. The voice recorder will be worn on the wrist like a watch. Participants will be asked, if they experience any kind of loss of balance, to describe to the voice recorder 1) what they were doing when they lost their balance (e.g. carrying groceries in from the car), why they lost their balance (e.g. did not see a stick in the sidewalk), and how they responded (e.g. recovered balance by taking steps or grabbing a railing).
- The investigator will telephone the participant at the end of the first day of sensor use and help troubleshoot any issues. This will also telephone the participant at the end of the third day of sensor use to help troubleshoot any issues. If necessary, telephone calls will be made at the end of every day for additional support.
- After the participant has worn the sensors for two or three weeks, another meeting will be scheduled so the participant can return the sensors to the investigators.

8.3 Describe:

- *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
- *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
- *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
  - *Screening questionnaires*
  - *Survey(s), including online surveys*
  - *Demographic questionnaire(s)*
  - *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
  - *Focus group guide(s)*
  - *Other documents used to collect data*

Safeguards intended to reduce the risk of adverse outcomes include:
a) using our medical screening process to exclude individuals at an increased risk of adverse outcome during training or laboratory testing;
b) having subjects complete warm-up exercises of walking on a treadmill and stretching prior to balance training and testing;
c) the balance training used here was designed to be completed by adults 65-80 years;
d) the balance training is tailored to each participant's capabilities;
e) rest breaks will be provided as needed by the participant
f) the same balance testing methodology employed here has been used in several of our prior studies without adverse outcome;

g) an investigator and a spotter will be nearby participants to provide balance assistance, if necessary during balance training; and
h) participants will wear a safety harness to prevent a fall to the floor during balance testing. The PI (who has extensive experience using the harnesses) will train the relevant study team member(s) in selecting the proper size safety harness, appropriately tightening all safety harness straps and connections, and setting the proper length of the lanyard that connects the harness to the overhead support. The harnesses we will be using are rated for individuals up to 310 lb, and we will limit our recruitment to individuals up to 250 lb.

No safeguards will be used during the two or three weeks of wearable sensor use since this phase of the study does not involve risk greater than that experienced during daily life.

All devices used in this study (lab-based motion capture system, wearable sensors, and voice recorders) will be used in the same manner as their approved use. Also, the use of these sensors does not influence behavior and therefore does not affect risk.

8.4 What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection:

Participant anthropometric and demographic information will be collected and recorded in a computer file on a password-protected and VT-managed computer. In this file, participants will only be identified by a numeric code, and not personally-identifiable information will be recorded.

Data collected during the laboratory testing session will include body motion during trip and slip LOB responses obtained simultaneously from two systems. The first system is the wearable sensors (https://apdm.com/wearable-sensors/) with individual sensors worn on each foot and one on the sternum using a shoulder strap under the clothing. The second system is the lab-based optoelectronic motion capture system (Qualisys, Inc) and reflective markers (small balls approximately 1 cm in diameter) placed at specific locations on the body. Data from these systems will be recorded as a computer file on a password-protected and VT-managed computer. In these files, participants will only be identified by a numeric code, and not personally-identifiable information will be recorded.

Video recordings and photographs of participants during perturbations will be obtained to assist with data analysis and for possible use in presentations. Participants will need to provide permission, on the Informed Consent Form, for us to use these in presentations. These videos and photos will be kept on a password-protected and VT-managed computer.

Data from the wearable sensors during real-world LOB response tracking will be automatically stored onboard the sensors themselves until downloaded by the study

team when returned to the study team after the two or three week data collection. Participants will be asked to charge the sensors nightly, and will be given the charger and detailed instructions and training on how to do that from the study team. When downloaded by the study team, the data file is in the form of a de-identified Excel file that is ready for analysis, and these files will be kept on a password-protected and VT-managed computer.

Data will be collected by the voice recorder by having participants press a record button on it, having participants speak into the recorder the information requested by the study team, and then pressing a button to stop. These recordings include a time/date stamp, and will be downloaded for analysis by the study team when returned to the study team. These files will be kept on a password-protected and VT-managed computer.

8.5 Who will transcribe or code audio and/or video recordings?:

Youngjae Lee will transcribe voice recordings. No other transcriptions will be performed.

8.6 Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets <u>all</u> the following criteria for alteration of consent (deception is considered an alteration of informed consent):

- *The research involves no more than minimal risk to the subjects*
- *The alteration will not adversely affect the rights and welfare of the subjects*
- *The research could not practicably be carried out without the alteration/deception*
- *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

Incomplete disclosure will be used in that we will not describe some details of parts of the laboratory session for balance testing. In particular, we will not disclose 1) whether participants will be slipped or tripped; 2) when during their multiple walks along our laboratory walkway they will be slipped or tripped; and 3) exactly how we will cause them to slip or trip.

This is necessary so that our testing involves unexpected slips and trips.

At the end of the laboratory session that involves exposing participants to slipping and tripping, we will provide a debriefing by reading the attached debriefing script.

8.7 If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur:

The study does not involve long-term follow-up.

9.0 Data and Specimen Long Term Storage and Use

9.1 If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed:

We will store data for the foreseeable future. Computer files will be kept on password-secured and managed Virginia Tech computer systems, while any paperwork will be kept locked in a restricted access office. The data access will be controlled by the PI, and access will be restricted to the research personnel.

9.2 For specimens, list the data to be stored or associated with each specimen:

N/A

9.3 Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens:

Data will be made available to other researchers, with requests made via direct communication (email or phone). De-identified data files will be shared in response to other investigators direct request. Other researchers seeking access to the data associated with this research must seek their own separate IRB/HRPP approval/determination prior to accessing the data.

9.4 Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed:

Identifiers will be a number ranging from 1 to the total number of participants enrolled. The key to make them identifiable will be kept in a separate computer file on a password-secured and managed Virginia Tech computer system. Only the study investigators will have access to the code. It will be destroyed 1 year after the completion of the project because at that time there will be no reason to need to contact study participants.

9.5 Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:

☒	*Name*
☐	*Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)*
☐	*Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)*
☒	*Phone numbers*
☐	*Fax numbers*
☒	*Electronic mail addresses (e-mail)*
☐	*Social Security numbers*
☐	*Medical record numbers*
☐	*Health plan beneficiary numbers*
☐	*Account numbers*
☐	*Certificate/license numbers*
☐	*Vehicle identifiers and serial numbers, including license plate numbers*
☐	*Device identifiers and serial numbers*
☐	*Web Universal Resource Locators (URLs)*
☐	*Internet protocol (IP) address numbers*
☒	*Biometric identifiers, including finger and voice prints (audio recording)*
☒	*Full face photographic images and any comparable images (including video recording)*
☐	*Student record number or identification number*
☐	*User name for online or computer accounts*

☒	*Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)***:** Age

10.0 Sharing of Results with Subjects

10.1 Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject's primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects:

Results will not be shared with participants.

11.0 Study Timelines

11.1 Describe:

- *The duration of an individual subject's participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
- *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
- *The amount of time expected for the investigators to complete this study including primary data analyses.*

Duration of participant's participation: about 7 weeks

Time expected to enroll all study participants: 18 months

Amount of time expected for investigators to complete study: 24 months

12.0 Inclusion and Exclusion Criteria

12.1 Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management:

Screening will involve four phases. Participants will only proceed to the next phase if they pass preceding phases. The below Inclusion/Exclusion criteria apply to both non-balance training participants and balance training participants.

Phase 1
Inclusion criteria will be screened over the phone by an investigator (YL):

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

1. How old are you? [must be 65-80 to be eligible]
2. Are you willing to wear 3 small watch-sized sensors daily for two or three weeks (one on each foot and one on the chest) [must be yes to be eligible]
3. Have you had a lower limb amputation? [must be no to be eligible]
4. Do you weigh over 250 pounds? [must be no to be eligible]
5. Administer the Telephone Interview for Cognitive Status [must score 25 or higher to be eligible]

Phase 2
If the prospective participant passes phase 1, then the investigator will administer a health questionnaire during the same phone conversation. A copy of this health questionnaire is included with this application. No responses on this questionnaire will automatically make a participant ineligible. Rather, all responses to this questionnaire will be reviewed holistically by the health care specialist. No personally-identifiable information will be collected with this questionnaire. While it is rare for an individual age 65-80 to become pregnant, we will still include a question within the health questionnaire to ascertain pregnancy status.

Phase 3
The results of each health questionnaire will be reviewed by a health care specialist certified for clinical treatment of the geriatric population. No personally-identifiable information will be collected with this questionnaire. The health care specialist will then either:
1) accept the prospective subject for the next step of screening (see below);
2) decline the prospective subject for participation;
3) telephone the prospective subject for further evaluation and subsequent adjudication. If this occurs, personally-identifiable information may be collected directly by the interviewer.

Phase 4
Osteoporosis Screening
The prospective participant must not have clinical osteoporosis as indicated by bone mineral density of the lumbar vertebra and proximal femur of $t < -2.5$ obtained from Dual Energy X-ray Absorptiometry (DEXA). This assessment will be based upon a DEXA scan performed for this study, or DEXA scan completed within the last year.

Participant must pass all four phases to be eligible to participate.

12.2 Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

Phase 1 - Inclusion criteria screened over the phone:
1. How old are you? [must be 65-80 to be eligible]
2. Are you willing to use wear 3 small watch-sized sensors daily for two weeks (one on each foot and one on the chest) [must be yes to be eligible]
3. Have you had a lower limb amputation? [must be no to be eligible]
4. Do you weigh over 250 pounds? [must be no to be eligible]
5. Administer the Folstein Mini-Mental Status Exam [must score 25 or higher to be eligible]

Phase 2 - Health questionnaire (see attached to this application)

Phase 3 - Review of health questionnaire by health professional.

Phase 4 - Osteoporosis screening. The prospective participant must not have clinical osteoporosis as indicated by bone mineral density of the lumbar vertebra and proximal femur of $t < -2.5$ obtained from Dual Energy X-ray Absorptiometry (DEXA). This assessment will be based upon a DEXA scan to be scheduled for this study, or one they have had completed within the last year.

12.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
- *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
- *Prisoners (including all incarcerated individuals)*
- *Adults not capable to consent on their own behalf*

Minors will be excluded

Pregnant women will be excluded based upon self report.

Prisoners will be excluded

Adults not capable to consent on their own behalf will be excluded

13.0 Vulnerable Populations

13.1 If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:

- *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
- *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
- *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
- *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the "CHECKLIST: Minors (HRP-416)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information in this protocol.*

Employees of Virginia Tech may be included. If so, it will be emphasized that their participation is entirely voluntary.

No other vulnerable populations listed above will be included.

14.0 Number of Subjects

14.1 Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow):

60 participants will be enrolled. This number is based upon a formal sample size analysis described here:

30 non-balance training participants will be recruited for our primary objective. Given that this objective is for validation, no formal effect sizes could be determined. Rather, we estimated 30 participants for this objective to be a reasonable number based upon our available resources and the number of expected LOBs estimated from prior work [Handelzalts et al. 2020].

30 balance training participants will be recruited for our secondary objective and be based upon Hypothesis 3: NT and TT participants will exhibit improved LOB responses after lab-induced trips and slips compared to ST participants.

The sample size was determined using data from lab-induced trips among community-dwelling older adults aged 65 years or older (Pavol et al., 2001). The effect size index (i.e., Cohen's $d = 1.45$) was determined using the difference in mean trunk angle from vertical at the time of recovery foot ground contact between fallers and non-fallers (17.4°) and the combined standard deviation (12°). The difference in means was considered the minimal clinically important difference based on the anchor-based method (Rai et al., 2015). Using G*Power (Faul et al., 2007) for an independent t-test with 80% power and a one-sided Type I error (or alpha) of 5%, a sample size of seven participants per group is needed. In an effort to be conservative and account for any participants withdrawing from the study, 10 participants per balance training group (TT,NT,ST) will be recruited.

Handelzalts, S., N.B. Alexander, N. Mastruserio, L.V. Nyquist, D.M. Strasburg, and L.V. Ojeda. Detection of Real-World Trips in At-Fall Risk Community Dwelling Older Adults Using Wearable Sensors. Front Med, 2020. 7: p. 514.

14.2 If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites:

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

Not a multi-site study.

14.3 If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures:

N/A

14.4 If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately:

30 participants will be assigned to be non-balance training participants

30 participants will be assigned to be balance training participants, with 10 completing each of the three types of training under investigation (TT, NT, ST).

Other than these differences in balance training, all other testing will be the same for all participants.

15.0 Recruitment Methods

15.1 Describe when, where, and how you will recruit potential subjects:

All participants will be recruited from the Virginia Tech, NRV, and Roanoke Valley communities.

All participants will be recruited using participant lists from the VT Center for Gerontology, email listservs to VT and the VT Life Long Learning Institute, emailing advertisements to senior centers and senior living communities, newspaper advertisements, word-of-mouth, and visits to local community organizations.

15.2 Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym):

University or community members

15.3 Describe the methods that you will use to identify potential subjects:

Please see question 15.1.

15.4 Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.

- *For flyers, attach the final copy of printed flyers.*
- *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
- *For email recruitments, please include the subject line.*
- *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*
- *Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

Flyers are included with this application. This same language will be used in recruitment emails (subject line = Research volunteers needed) and newspaper advertisements.

Compensation is provided for time and effort. Participants will be compensated $10 for each balance training session, $20 for each balance testing session, and $50/week of wearing the sensors. For participants traveling to Blacksburg from at least 25 miles away, an extra $10 per session will be provided to offset high gasoline prices. Payment will be provided weekly.

If a participants withdraws from the study early, then they will be paid $10/hour for time completed, and $50 per week completed of wearing the sensors (as long as they completed at least one half of the week prior to withdrawing).

All payments will be made in the form of cash.

16.0 Withdrawal of Subjects

16.1 Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent:

Participants can be withdrawn if they fail to follow the investigator instructions during sessions or miss scheduled sessions.

16.2 If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention):

N/A

16.3 Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires):

All sessions and data collections will be terminated when a participant withdraws from the study. Partial withdraw will not be accommodated, meaning that participants cannot withdraw from some of the procedures but remain involved in others.

17.0 Risks to Subjects

17.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate "No risk" or "N/A." Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate "The investigators are not aware of any risks from participation in this study." or "No more than risks than are found in everyday life." The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:

- *Physical (e.g., potential for pain, discomfort, infection)*
- *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
- *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
- *Legal (e.g., potential for disclosure of illegal activity, negligence)*
- *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security)*
- *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

There are potential risks for participants in the proposed work.

1. During a DEXA scan, participants will be exposed radiation. The amount of radiation is less than 2 days' exposure to natural background radiation (NBR). By comparison, a chest X-ray uses the equivalent of about 3 days' exposure to NBR, and a flight from UK to USA is equivalent to approximately a week's exposure to NBR (https://www.nhs.uk/conditions/dexa-scan/#:~:text=The%20amount%20of%20radiation%20used,a%20week's%20exposure%20to%20NBR).

2. During balance training or testing, there is a risk of muscle strains, joint strains, other soft tissue injury, or broken bones. The risk of these outcomes is considered low given our safety measures described in 17.2.

3. During balance training or testing, there is a risk of participants overexerting themselves. This risk is considered low given our safety measures described in 17.2.

4. During balance testing, the physical risk of skin irritation and bacterial exposure related to the reflective markers, lab-provided rubber soled shoes and clothing, as well as the safety harness, are very low (but not zero). We are not aware of a single incident of this in the PI's 20 years of conducting human subjects research.

5. After balance training or testing, there is the potential for participants to experience muscle or joint soreness. This risk is no different than participation in physical exercise, and is mitigated by the safety measures described in 17.2.

6. During the two-weeks of using wearable sensors, there is no more risk than is found in everyday life for losses of balance or falls because these sensors do not affect balance or fall risk.

7. In the event the wearable sensors are lost, stolen, or damaged during the course of the research, participants will not be held financially responsible for their replacement.

17.2 Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)

To minimize the risks described above in 17.1, the following safety measures will be used:

a) using our medical screening process to exclude individuals at an increased risk of injury;

b) having subjects complete warm-up exercises prior to balance training and testing including walking on a treadmill and stretching;

c) the balance training used here was designed to be completed by adults 65-80 years;

d) the balance training is tailored to each participant's capabilities;

e) rest breaks will be provided as needed by the participant

f) the same balance testing methodology employed here has been used in several of our prior studies without adverse outcome;

g) an investigator and a spotter will be nearby participants to provide balance assistance, if necessary during balance training; and

h) participants will wear a safety harness to prevent a fall to the floor during balance testing. The PI (who has extensive experience using the harnesses) will train the relevant study team member(s) in selecting the proper size safety harness, appropriately tightening all safety harness straps and connections, and setting the proper length of the lanyard that connects the harness to the overhead support. The harnesses we will be using are rated for individuals up to 310 lb, and we will limit our recruitment to individuals up to 250 lb.

i) several measures will be taken to minimize the risk of skin irritation or bacterial exposure related to the reflective markers, lab-provided rubber soled shoes and clothing, as well as the safety harness, are very low (but not zero). These measures will include: a) using disinfecting wipes after each participant's testing, b) removal of adhesive material after each participant's testing, and c) using tape specifically designed to use on human skin.

j) to minimize the exposure to radiation during DEXA scans, we will only use qualified study personnel to perform the scanning, and inform participants of the radiation exposure prior to scanning.

17.3 If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device:

N/A

17.4 If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant:

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

N/A

17.5 If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships):

N/A

18.0 Potential Benefits to Subjects

18.1 Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB's risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document:

Participants who receive a DEXA scan will benefit from receiving this test at no cost. It can detect osteoporosis.

Balance training participants may benefit from balance training by improving their balance. However, this has not been formally evaluated at this time.

18.2 If applicable, specify that there are no anticipated direct benefits for participants:

N/A

19.0 Data Management and Confidentiality

19.1 Describe procedures that you will use for quality control to ensure validity of collected data:

We have extensive experience implementing similar procedures and training in prior studies, and will leverage that experience during the planning and execution of this study. We will also adequately pilot test the protocols described here prior to enrolling any participants, including sufficient practice to ensure we are thorough and consistent with our procedures.

19.2 Describe any existing data or biospecimens you will obtain as part of this study. Include:

- *Variables or samples to be obtained*
- *Source of the data or specimens*
- *Your authorization to access or receive the data or biospecimens*
- *Whether the data or biospecimens are publicly available*
- *Whether the data or specimens you receive will contain identifiers*

Participants who have had a DEXA scan within the last year will be asked to obtain a copy of the scan results from their physician. In particular, we will review the bone mineral density of the lumbar vertebra and proximal femur. This must not be $t < -2.5$, which is an indication of clinical osteoporosis.

19.3 Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.:

Any paper-based records will be kept in our restricted-access research lab or the PI's office, and only be accessible to personnel involved in the study.

Data computer files will be de-identified (will only use participant numbers) and be maintained on password-protected computers/networks or students investigator's personal computers. If the latter, it will be required that that they meet Virginia Tech security requirements for low risk data described here: https://security.vt.edu/resources.html . Personally-identifiable data (name, email, and phone number for corresponding with participants) will only be stored on password-protected computers managed and secured by Virginia Tech.

De-identified data to be used for Phase 2 of the screening process and data analysis will be shared with external collaborators using a VT Google Drive with access limited to recipients.

For DEXA scanning, the study team will use pseudonyms (subject numbers) rather than identifiable information. The results from this test will be a hard-copy print out provided to the investigator. These data will not be transmitted via email.

19.4 For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center):

N/A

19.5 Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).

- *What information will be included in the long term storage of data or specimens?*
- *How long will the data or specimens be stored?*
- *Where and how data or specimens will be stored?*
- *Who will have access to the data or specimens during long term storage?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens be shared or transported?*
- *When and how will personal identifiers be destroyed?*

We will keep data for the foreseeable future for potential use in subsequent studies, presentations, and pilot data for proposals. Paper-based records will be kept in a secured location only accessible to the principal investigator. Computer-based files will be password protected and only available to personnel involved in the study. Personal identifiers will be destroyed one year after the completion of the study by deleting these files and ensuring they are completely removed from paper-based records and the computer.

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that you will take to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained):

Personal data over the phone will only be obtained for scheduling purposes, and will not be shared with anyone outside of the research group. All other data will be collected

in a private room for performing research interventions. Interviews and data collection will only be administered by research personnel involved in the project.

Participants will also be provided access to a nearby restroom to change into appropriate attire for their balance testing session.

20.2 Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research):

We will make it clear that participants can discontinue their participation without penalty. We will ask participants how they are doing and feeling throughout testing, and give plenty of encouragement. We will keep them well-informed throughout each session so they are aware of what is going on and what to expect.

When possible, sensors will be fit and applied by a member of the study team that is the same sex as the participant.

We will also develop an illustrated step-by-step instructional packet on the wearable sensors usage for participants to use at home.

20.3 Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan:

If a participant opts to use the results of a DEXA scan they had within the last 12 months, rather than having a new scan performed for this study, will be asked to obtain a copy of this prior scan from their physician.

20.4 Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:

- ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
- *Sexual discrimination and/or sexual violence that involves a student*

- *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
- *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
- *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

N/A

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety monitoring is <u>required</u> when research involves greater than minimal risk and is sometimes appropriate for other studies.

21.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
- *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the safety data and with what frequency.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

The only potential safety-related concerns will occur during the experimental sessions and balance training sessions with the participants. We will use the strategies described above to minimize these risks, and keep in constant communication with the participant during experimental sessions regarding testing protocol and any potential risk.

22.0 Compensation for Research Related Injury

22.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any:

There are no available funds available for research-related injuries. This will be made clear to participants on the informed consent form.

22.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research:

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare:

Potential economic burdens include: transportation, missed work, and childcare.

24.0 Consent Process

24.1 Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.

Describe the following:

- *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
- *Please review "SOP: Informed Consent Process for Research (HRP-090)" for recommended procedure. Describe your process, being sure to include:*

- *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that you will take to minimize the possibility of coercion or undue influence*
- *Steps that you will take to gauge or ensure the subjects' understanding*

Upon contacting the investigators, the study protocol will be explained to participants via telephone. This will allow participants to ask questions pertaining to the study. During this telephone conversation, we will ensure comprehension by asking participants if they understand everything we've said about the study. We will also ask for verbal consent from all participants to continue with the protocol, and document this verbal consent on the consent form.

Participants will then be screened using the 4-phase process described elsewhere in this application. If/when the participant passes this screening process, they will be provided the informed consent form (via email or physical mail), and a date and time for their first session will be scheduled. Participants will be provided at least 24 hours to review the informed consent form prior to their first session.

Written consent will take place either prior to their DEXA scan (if they are required to complete one because they do not have one over the last year) or at the start of the first session (if no new DEXA is required). Either way, and upon arrival to meeting location, the participant will be given a paper copy of the informed consent to look over and will be asked if they have any questions about the form prior to signing. As much time as necessary will be dedicated to the consent process. We will make sure participants understand their participation is entirely voluntary. We will ensure participants understand throughout the consent process by recruiting English-speaking adults, asking them if they have any questions, and if they understand the consent form.

Youngjae Lee will be obtaining consent from participants.

Because our procedures involve several visits to the lab for some participations, we will ask subjects weekly how they are doing with the study and procedures, and answer any questions they might have. If necessary, we will remind them that their participation is entirely voluntary.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*

- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

Non-English speaking participants will not be recruited

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

N/A

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*

- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals' authority to consent to the minor's general medical care.*
- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

Only participants 65-80 years old will be eligible for this study.

Adults Unable to Consent

- *Describe the process you will use to determine whether an individual adult is capable of consent.*
- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
  - *For research conducted in the Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "legally authorized representative."*
  - *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
- *Describe the process for assent of the subjects.*
  - *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
  - *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
  - *Describe whether and how you will document assent.*

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

Only university or community-dwelling adults of sound mind will be recruited.

25.0 Process to Document Consent in Writing

25.1 Consult "SOP: Written Documentation of Consent (HRP-091)" for recommended procedures, and describe whether and how consent of the subject will be documented in writing:

We will require written consent from each participant prior to testing.

25.2 If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins):

Considering that a verbal consent process will be used for the phone screening, we would like to request a waiver of written documentation of the consent process. For this waiver, we are expected to explain how the two criteria below have been met.

1. The research presents no more than minimal risk of harm to subjects.

The screening process that will be completed before obtaining written documentation (a questionnaire completed over the phone) presents no more than minimal risk of harm to subjects. If we need to complete a DEXA scan on any subjects, we will obtain written consent from these subjects prior to this scan.

2. The research involves no procedures for which written consent is normally required outside of the research context.

The research procedures we plan to complete prior to written consent (a questionnaire completed over the phone) do not normally require written consent outside of the research context.

25.3 If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review "CHECKLIST:

Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You should use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script:

See attached.

26.0 Resources Available

26.1 Describe the resources available to conduct the research. For example, as appropriate:

- *Describe the PI's availability to supervise the research.*
- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

The PI (Madigan) will have adequate availability to supervise this research, and dedicate the required amount of time to this project.

The PI will ensure all persons assisting with the research are adequately informed and trained regarding the protocol and duties. In particular, the PI will observe multiple pilot training sessions, take written notes and provide verbal feedback during these sessions, and debrief students with his notes after the pilot session is complete. This will be repeated until the PI is confident in the competence level of the student(s).

Training and testing sessions will take place in the Virginia Tech Occupational Ergonomics and Biomechanics Lab. This lab is well-equipped with high-precision measurement tools and safety equipment used to assess gait, including all the equipment required for the current study. All personnel using laboratory equipment will be trained on how to use the equipment prior to testing.

21-1072 Validation and application of wearable sensors for capturing responses to losses of balance

27.0 Multi-Site Research

Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.

N/A