

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

Effects of Task-Specific Step Training on Reactive Balance

NCT05734443

Informed Consent Form

March 24, 2025

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

Title of research study: Validation and application of wearable sensors for capturing responses to losses of balance

IRB #: 21-1072

Principal Investigator: Michael Madigan, 540-231-3543, MLM@vt.edu

Other study contact(s):

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Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Falls are a leading cause of injuries. This study aims to develop new methods for preventing falls. There are two goals of this study. The first goal is to validate the use of small wearable sensors on your body to measure any naturally-occurring losses of balance during your daily life. The second goal is to compare three different types of exercise on your balance during laboratory testing and during your daily life.

You will be asked to use three small wearable sensors every day for 2-3 weeks. You will be asked to visit our lab 1-2 times for instructions on how to use the wearable sensors and for balance testing. You may also be asked to complete 6 balance training sessions at our lab (2 sessions per week for 3 weeks).

Please know that your participation in the study is voluntary, and that you can withdraw from the study at any time without penalty.

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

We invite you to take part in a research study because you:

- are 65-80 years old
- you are willing to wear 3 small watch-sized sensor daily for two or three weeks (one on each foot and one on your chest)
- you do not have a leg amputation
- you do not weigh over 250 pounds
- you pass a health screening

What should I know about being in a research study?

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

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

Why is this research being done?

This research is being done to develop new methods for preventing falls. It will help validate the use of small sensors to detect losses of balance during your daily life, and help evaluate three new balance training interventions.

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

Your participation in this study will last approximately 5-7 weeks. More specifically, if you are not assigned to complete balance training, your participation in the study will last approximately 5 weeks. If you are assigned to complete balance training, your participation in the study will last approximately 7 weeks. Balance training will be performed twice a week for three weeks.

All subjects will be asked to use some small wearable sensors every day for 2-3 weeks. You will be asked to visit our research lab to receive instructions for using the wearable sensors, and while we test your balance. All subjects will also be asked to visit our lab once to test your balance.

More detailed information about the study procedures can be found under, **“What happens if I say yes, I want to be in this research?”**

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

During balance testing, you could fall. We will require you to wear a safety harness during these tests. During balance training, you could stumble. The investigator and a spotter will always be nearby to provide assistance in the event you need it. Therefore, the potential risks associated with this study are considered minimal.

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”**.

Will being in this study help me in any way?

There are no benefits to you, and we cannot promise any benefits to others, from your taking part in this research. However, we hope this research will help be able to measure losses of balance during daily life outside of any research lab, and we hope it will help us develop a new balance training exercise.

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

Participation in research is completely up to you. You can decide to participate or not to participate. You can leave the research at any time, for any reason, and it will not be held against you.

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

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

Who can I talk to?

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Madigan (PI) or other study personnel using the contact information given on the first page.

This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or irb@vt.edu if:

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

How many people will be studied?

We plan to include 60 people in this research study.

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

1. Upon arrival at the lab, the study and procedures will be summarized, an informed consent form will be provided and explained, and all questions will be answered. If you agree to participate, you will be asked to sign the informed consent form.
2. You will be asked to use 3 small wearable sensors every day for 2-3 weeks. One will be worn on top of each foot (using pouches either secured to your laces or using pouches on socks if you are not wearing shoes) and one on your sternum using a lightweight shoulder harness. You may be asked to visit our lab so we can provide you with instructions on how to use these sensors. You will be asked to put these sensors on your body in the morning when getting dressed, wear them for at least 10 hours during your usual daily routine, and remove them at night and charge them while sleeping. We will provide you with instructions on their charging and use. We will also ask you to wear a voice recorder on your wrist to record a brief description of any event when you lose your balance while using the wearable sensors. At the conclusion of the study, or if you withdraw early, we will set up a time to meet to obtain these sensor back from you.
3. You will be asked to visit the lab while we test your balance. During this test, we will ask you to either bring with you appropriate clothing for testing, or we will provide this clothing for you. You will then be asked to change into these clothes in a nearby restroom. During the balance test, you will wear a safety harness and repeatedly walk back-and-forth along a walkway. You may be exposed to trips or slips while walking. If you are tripped or slipped, simply react naturally and try to recover your balance and continue walking. To

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

help us measure your balance and body movements, we will place reflective markers (small balls approximately 1 cm in diameter) on your body on your shoes, ankles, knees, hips, shoulders, elbows, wrists, and head band. You will also be asked to wear the same wearable sensors worn above. Reflective This balance testing session will take about 2 hours to complete.

4. You may be asked to participate in balance training. If so, this training will take place twice a week for three weeks at a day and time convenient to you. Training will take place either in our lab on VT Campus in Whittemore Hall Room 556, or at our lab in the mall on University City Boulevard. Training will involve some combination of stepping exercises, standing balance exercises, and strength exercises. You will not be able to choose whether or not you complete balance training, or which type of training you are asked to complete. Both will be determined by chance, like flipping a coin. You will have a 50% chance of being assigned to balance training, and a 50% chance of being assigned to no balance training. If you are assigned to balance training, you will have a 33% chance of being assigned to non-treadmill training, treadmill training, or strength and balance training. Each training session will take about 45 minutes to complete.
5. You may be asked to undergo a DEXA scan. If a DEXA scan is performed for this study, the scan will take place in a lab in the Human Integrative Physiology Lab in the Garvin Innovation Building in the Corporate Research Center (1872 Pratt Drive, Suite 1575). A member from our research team will meet you at this location to escort you through the testing. During this scan, you will be asked to lay down on the scanner and simply stay still while the scan is performed. The scan will expose you to 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.

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

You can leave the research study at any time, for any reason, and it will not be held against you. If you stop being in the research study, already collected data may not be removed from the study database.

Can I Be Removed From The Research Without My OK?

You can be withdrawn if you fail to follow the investigator instructions during sessions or miss scheduled sessions or do not use the wearable sensors as requested.

What Are My Responsibilities If I Take Part In This Research?

Your responsibilities if you take part in this research are to 1) attend the scheduled sessions, 2) notify the investigators if you are going to have to miss a session, 3) follow the investigator instructions during all sessions, and 4) follow the investigator instructions when using the wearable sensors.

Is there any way being in this study could be bad for me? (Detailed risks)

If you are asked to complete a DEXA scan, you 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

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

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.

Balance testing will expose you to the risk of a fall. We will minimize this risk by requiring you to wearing a safety-harness to catch you in the event you lose your balance and start to fall.

Balance training will also expose you to the risk of a fall. We will minimize this risk by have the investigator and spotter near you during training to provide you with balance assistance if needed.

There is a small risk the markers placed on your skin could cause skin irritation. To minimize this risk, we will use a brand of tape that is meant for use on human skin and has not caused such irritation in our prior studies.

Clothing will be washed after use. Shoes will be sprayed with disinfectant and deodorizer.

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.

If necessary, please contact the investigators regarding these risks.

Please note that there are no funds available from the researchers or Virginia Tech in the event you experience a research-related injury.

What happens to the information collected for the research?

We will obtain contact information from you (such as your name, phone number, or email address) for communicating with you about scheduling. We plan to only allow the investigators to use this information. We will make every effort to limit the use and disclosure of your personal information, including research study data, only to people who have a need to review this information. However, we cannot guarantee complete confidentiality. Organizations that may inspect and copy your information include the IRB, Human Research Protection Program, and other authorized representatives of Virginia Tech.

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

A description of the parts of this work considered to be a clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The results of this study may be presented at conferences, during seminars, in academic papers, or in other reports. None of your contact information will be revealed in any of these.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action,

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document research documents and information.

What else do I need to know?

You will be compensated for your time and effort \$50 cash at the end of each week of using the wearable sensors, \$20 cash immediately following your balance testing session, and \$10 cash for each balance training session at the end of each week of training. If you live greater than 25 miles away from Blacksburg, an extra \$10 per session will be provided to offset high gasoline prices.

Parts of this research are funded by the National Institutes of Health.

The researchers would like to take photographs and/or videos during the study for documentation and presentation purposes. We will only take these photographs and/or videos if you give your permission to do so. Indicate your decision below by initialing in the space provided.

_____ I give my permission for photographs/videos to be made of me during this study, and these can be used for BOTH research documentation and presentations as well as other non-research purposes (e.g., websites, social media). In either case, these photographs/videos will not be de-identified. If you select this option, you will also be asked to complete an accompanying media release form.

_____ I give my permission for photographs/videos to be made of me during this study, and these can be used for research documentation and presentations. In this case, these photographs/videos will not be de-identified.

_____ I do not give my permission for photographs/videos to be made of me during this study.

Photographs/videos of you during this study will be shared amongst the research team using secure links to a Google Drive, or via a USB drive.

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Take Part in a Research Study

Verbal Consent Block

Verbal consent will be required from you prior to our screening process. The initials and date of the investigator below documents your verbal consent.

Initials of investigator

Date

Written Consent Block

Your signature documents your permission to take part in this research. We will provide you with a signed copy of this form for your records.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent