Protocol Title: SCH: Context-aware Freezing of Gait mitigation in real-world setting

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: HM20020085 Context-aware Freezing of Gait mitigation in real-world setting

VCU INVESTIGATORS: Ingrid Pretzer-Aboff, PhD and Leslie J. Cloud, MD, MSc.

SPONSOR: National Institute of Neurological Disorders and Stroke at the National Institute of Health.

The Principal Investigator (Dr. Pretzer-Aboff) is a founder, a member of the Board of Directors, and has an ownership interest in Resonate Forward, LLC, which is providing the PDVibe3 device for this study.

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

People with Parkinson's disease (PD) may experience a walking problem called freezing of gait (FoG) that can interfere with the person's ability to conduct daily activities. FoG has been described as feeling like your feet are glued or stuck to the floor. Drug treatments for PD rarely improve FoG. Researchers have found that vibration therapy may help improve FoG. The purpose of this research study is to test the safety, tolerability, and effectiveness of using a wearable device (UG motion sensor, that is the size of a watch) that will recognize FoG and then send a signal to another small watch-like device (PDVibe3) to deliver a vibration stimuli to

your feet. We believe the vibration stimulus (which feels like a phone on vibration mode) will help reduce FoG in persons with PD. We are also interested in how your mood and sleep may impact your experiences of FoG. You are being asked to participate in this study because you have been diagnosed with Parkinson's disease, have FoG, and may meet the study entry requirements.

The PDVibe3 is an investigational device, which means it has not been approved by the U.S. Food and Drug Administration (FDA). The UG motion sensor is also an investigational device.

What will happen if I participate?

Usual care for your disease or condition involves taking medications to help with Parkinson's. In this study, you will receive usual care. We ask that when you arrive, you have taken your medication, and to bring extra medicine with you should your next dose be due while you are at the study site.

You will be randomly assigned (like the flip of a coin) to receive a dose of vibration, which may be high, low, or somewhere in between.

You will be photographed and videotaped during walking sessions, but your face will be blurred so that the recordings will not be identifiable. If you choose to participate in the interview portion of this study, it will be audio recorded only.

PROCEDURES

The study visits will take place at the Parkinson's Movement and Disorders Center.

Initial Visit will last up to 2 hours. During this visit, you will:

- Complete a short cognitive exam
- Answer questions about your medical history
- Complete a few brief surveys asking you about your sleep and mood, fatigue, your balance, falls, freezing of gait, sleep, mood, quality of life, and your activities of daily living and anxiety
- Be given instructions on how to use the Agtigraph GT9X Link device (which collects data about your sleep)
- Wear the Actigraph GT9X Link device on your wrist for up to 14 consecutive, 24-hour days
- Complete a sleep diary when wearing the Actigraph GT9X Link device
- Provide a saliva sample
- Wear the UG motion sensor (which detects FoG) on each ankle
- Wear the PDVibe3 on each ankle

- Walk five, 5-meter scenarios without vibration therapy. The five scenarios include:
    a. Walk through a narrow passage
    b. Walk and turn 540 degrees
    c. Walk toward a chair
    d. Walk while performing a verbal task
    e. Walk through a door before it closes
- Complete a 10m WT

Walking session will last approximately 4 hours each. During this visit, you will:

- Return the sleep diary and Actigraph GT9X
- Complete a couple surveys asking you about your sleep and mood
- Wear the UG motion sensor (which detects FoG) on each ankle
- Wear the PDVibe3 (which provides vibration) on each ankle
- Provide 2 saliva samples, once before walking and once after walking
- Walk five, 5-meter scenarios without vibration and then with vibration therapy. The five scenarios include:
    a. Walk through a narrow passage
    b. Walk and turn 540 degrees
    c. Walk toward a chair
    d. Walk while performing a verbal task
    e. Walk through a door before it closes

Qualitative Phone/Zoom Interview will last up to 1 hour. During this interview, you will:

- Participate in an interview about your experiences with FoG

You will be able to take breaks at any time if you feel tired.

Approximately 16 individuals will participate in this study.

This study will not use your saliva samples to sequence all or part of your DNA.

WHAT ALTERNATIVE TREATMENTS OR PROCEDURES ARE AVAILABLE?

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. As non-research alternatives, PD gait and balance disturbances can be treated by a physical therapist and/or medication. Laser canes and service dogs have also been found to be helpful for some people. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for Parkinson's disease.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is some evidence that vibration therapy is effective in improving freezing of gait. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study team learn things that may help other people in the future.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Your condition may not get better or may become worse while you are in this study.

Possible Risks Associated with Device

Occasional (Between a 1-10% chance that this will happen)

- You might have some discomfort from wearing the Actigraph GT9X Link on your wrist. We will adjust the device to your comfort level.
- You may feel some discomfort such as a tingling sensation from the vibration and/or discomfort from the straps that are used to attach the device to your feet. We will adjust the device to your comfort level.
- Completing the surveys, assessments and walking may be somewhat tiring or frustrating for you. You can take breaks at any time.
- There is a risk that you may fall when walking. Risks of falls will be minimized by the use of safety belts worn around your waist, and spotters who will walk next to you. Canes and walkers are allowed.
- If you have low blood pressure, you may feel lightheaded or dizzy from the walking. You can take breaks at any time.

Rare (Less than a 1% chance that this will happen)

- If you have a deep brain stimulator, there is a chance that the PDVibe3 may turn it off. As a result, you may feel a brief increase in your Parkinson's symptoms. If that occurs, the study doctor will be there to return it to normal working status for you.

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. The walking assessments for this research task will be conducted in a VCU/VCUHealth space so there is the potential risk for invasion of privacy and loss of confidentiality. This potential risk will be minimized by limiting interactions with individuals outside of the study team during the task.

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

If you are or may become pregnant, you will be excluded from the study since the UG Motion Sensor and PDVibe3 might involve risks to the embryo or fetus that are currently unforeseeable.

WHAT ARE THE COSTS?

There is no cost to participate in this study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $25 by a gift card and/or an e-gift card after completion of each of up to 3 study visits, for a total compensation up to $75.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Please be aware that the investigative team and the University may receive money for the conduct of this study. There are no plans to share any money or profits with you if the use of your data results in inventions or discoveries that have commercial value.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

If you withdraw from the study, data that has already been collected about you will remain part of the study database and may not be removed.

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services National Institute of Health or the Federal Food and Drug Administration

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site 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.

Future Studies

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

- History and physical exam
- Diagnosis
- Photographs, videotapes

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor
- Research Collaborators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Ingrid Pretzer-Aboff, PhD, RN, FGSA Adult Health and Nursing Systems 1100 E. Leigh St. Richmond, VA 23298 804-828-3340	and/or	Leslie Cloud, MD, MSc Parkinson's Movement & Disorders Center 11958 W. Broad St Henrico, VA 23233 804-356-7521

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date