Consent form for:

HM20015593 and NCT03883217

Optimizing Vibrational Therapy to Improve Gait and Balance in Parkinson's Disease

It was approved by the VCU IRB on 4/27/2021

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Optimizing Vibration Therapy to Improve Gait and Balance in Parkinson's Disease: a randomized, single-blind, placebo-controlled study

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

SPONSOR: Michael J. Fox Foundation

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 PDVibe2 device for this study. Resonate Forward, LLC will receive de-identified data related to 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

People with Parkinson's disease (PD) often experience walking problems that can interfere with the person's ability to conduct daily activities. Drug treatments for PD rarely improve walking problems. Researchers have found that vibration therapy may help improve walking problems. The purpose of this research study is to test the safety, comfort, and the effects of vibration (delivered by an experimental device called PDVibe2) on walking problems in persons with PD. The PDVibe2 was developed by Resonate Forward, LLC (RF) and is worn on the ankles and feet inside the shoes. The PDVibe2 was designed to administer vibrational therapy to the feet of the wearer in order to improve walking and balance. We think that the PDVibe2 will be safe, comfortable to wear, easy to put on, and may improve walking and balance. You are being asked to participate in this study because you have been diagnosed with Parkinson's disease, have walking problems, and may meet the study entry requirements.

The PDVibe2 is an investigational device, which means it has not been approved by the U. S. Food and Drug Administration (FDA). If you qualify for the study, you will be your own control. Which means you will walk with vibration therapy and with no vibration therapy. You will wear the

PDVibe2 during all your walking sessions. We will be evaluating whether the vibration therapy is more effective than walking alone (without vibration turned on). Though you may know whether you are receiving vibration or not (because you may feel it), the investigators assessing your walking and balance will not know whether you are receiving vibration therapy or not.

PROCEDURES

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

Initial Visit (Screening) will last approximately 2 hours. During this visit, you will:

- have a brief neurological and physical exam
- answer questions about your medical history
- have your weight, height, and leg length recorded
- walk for 2 minutes
- have your balance tested
- complete a few brief surveys
- be randomly assigned to a treatment sequence (vibration first 4 treatment sessions, or vibration second 4 treatment sessions)
- walk for 22 minutes with periods of rest in between
- discuss with the study staff any adverse events that occurred

Four walking sessions (sessions 1 – 4) will last approximately 1 hour each, They occur twice a day (at least two hours apart), on two consecutive days. During these visits, you will:

- have a brief neurological and physical exam
- walk for 22 minutes with periods of rest in between
- discuss with the study staff any adverse events that occurred
- complete a few brief questionnaires and balance testing after the 4th session

There will be a 2-week period before the next four walking sessions will start.

The second set of four walking sessions (sessions 5-8) will last approximately 1 hour. Twice a day (two hours apart), on two consecutive days. During these visits, you will:

- have a brief neurological and physical exam
- walk for 22 minutes with periods of rest in between
- discuss with the study staff any adverse events that occurred
- complete a few brief questionnaires and balance testing after the 8th session

The final Visit will occur approximately 6 – 10 days after your final treatment (8th session), it will last up to 2 hours. During this visit, you will:

- have a brief neurological and physical exam
- have your balance tested
- walk for 2 minutes
- discuss with the study staff any adverse events that may have occurred
- complete a few brief surveys and balance testing

Approximately 12 people will participate in this study.

If you decide to enter this study, you can still receive the usual treatments that you normally receive for your PD. You do not have to stop those treatments during the study. This includes exercise programs and the medications used to treat your Parkinson's disease as well as deep brain stimulation (if you have it).

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.

Please read, or have someone read to you, the rest of this document. If there is anything you do not understand, be sure to ask the study staff.

WHAT ARE THE BENEFITS FROM BEING IN THE STUDY?

There is some evidence that vibration therapy is effective in improving walking problems. 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.

If you are pregnant or may become pregnant during the course of this study, you should not participate since the safety of this device for an unborn child is unknown.

Possible Risks and Discomforts

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

- If you have a deep brain stimulator, there is a chance that the PDVibe2 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.

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

- 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 for you. You can take breaks at any time.
- There is a risk that you may fall when walking.
- If you have low blood pressure, you may feel lightheaded or dizzy from the walking. You can take breaks at any time.
- You may feel muscle fatigue or joint pain while walking. You can take breaks at any time.

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.

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.

The PDVibe2 may involve risks that are currently unknown or unforeseeable.

WHAT ARE THE COSTS?
The vibration device will be provided by Resonate Forward LLC at no cost to you. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?
Study participants are eligible for a $200 stipend to offset any expenses they incur while participating. You will receive $25 after completing visits 1-8. 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.

If the distance from your home to our clinic would make it difficult for travelling to and from the clinic, we may be able to pay for a local hotel for the night prior to treatment.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

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 not eligible for the study
- the sponsor has stopped the study

- you have not followed study instructions
- administrative reasons require your withdrawal

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 or the Federal Food and Drug Administration

A description of this 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.

Future Research Studies

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

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
- 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
- Research Collaborators
- Others as Required by Law
- Study Sponsor
- Data Safety Monitoring Boards
- Government/Health Agencies

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.

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

If you have any questions, complaints, or concerns about your participation in this research, contact:

Ingrid Pretzer-Aboff, PhD, RN, FGSA Adult
Health and Nursing Systems
1100 E. Leigh St.
Richmond, VA 23298
804-828-3340

Leslie Cloud, MD, MSc
Parkinson's Movement & Disorders Center
11958 W. Broad St
Henrico, VA 23233
804-356-7521

The researchers named above are the best persons to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
804-827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/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.

May we (the research team) use videos of you from this study in research conferences, while teaching students, and in other presentations? Please initial response.

_____YES _____only if you hide my face _____NO

May we (the research team) use photos of you from this study in research conferences, while teaching students, and in other presentations? Please initial response.

_____YES _____only if you hide my face _____NO

_____
Adult Participant Name (Printed)

_____ _____
Adult Participant's Signature Date/time

_____
Name of Person Conducting Consent Discussion (Printed)

_____ _____
Signature of Person Conducting Consent Discussion Date

_____ _____
Principal Investigator Signature (if different from above) Date