Moving Mindfully for Freezing of Gait

NCT05923229

Consent Form

05/17/2023

Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Moving Forward: Interventions for Managing Freezing of Gait in Parkinsons

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Research Team Contact: Martha Hessler 314-286-1478

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Kerri Rawson and Gammon Earhart to examine two interventions for managing freezing of gait (FOG) among people with Parkinson disease. Participants will be randomized to an educational program about FOG or a mindfulness-based walking program. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to examine the feasibility and benefits of two interventions for managing FOG. One is an educational program about FOG and the other one is a mindfulness-based walking therapy (MBWT) program.
- As a voluntary participant, you will be randomized to one of the two interventions. Both programs are 14 weeks long and begin in mid August 2023.
- If you are randomized to the educational program, you will be asked to read and comment on weekly materials at home about FOG and strategies to manage FOG. You will also track your falls, freezing episodes, classes related to Parkinson symptoms, and medical care such as changes in medication or medical visits. Participation will take about 1-2 hours a week.
- If you are randomized to the mindfulness-based walking therapy program, you will be asked to participate in in-person classes 2 hours a week and one 4 hour silent retreat in a group setting. You will also have daily home practice. The home practice will include reading about mindfulness in a book we provide, practicing mindfulness exercises via recordings, incorporating mindfulness exercises you learn into your daily activities, and tracking falls, freezing episodes,

classes related to Parkinson symptoms, medical care, and time practicing mindfulness. Home practice will take between one to two hours a week.

- You were selected because you are a person with Parkinson disease who experiences freezing of gait.
- You will be in this study for 9-10 months (this includes a follow-up period).

Both groups will:

- Participate in a video (e.g. Zoom) or phone screening (approximately 30 minutes) that will consist of cognitive and freezing of gait questions.
- Attend a pre-evaluation session, post-evaluation session, and follow-up evaluation session (approximately 2-3 hours each) that will consist of motor and cognitive activities.
- Complete questionnaires (approximately 45 minutes) that we send home with you after each evaluation session about your mood, motor and non-motor symptoms, mindfulness, and quality of life.
- Participate in telephone interviews after each evaluation session (approximately 30 minutes) to discuss freezing of gait.
- Record any falls or injuries, freezing episodes, classes related to managing Parkinson symptoms (i.e., Rock Steady Boxing, APDA exercise classes, etc) and your usual care received from your medical team (i.e., neurologists, physical or occupational therapists, changes in medication, etc).

Participants randomized to the educational program will:

- Read weekly materials about freezing of gait that will include information about the latest research, technology, strategies for FOG, and article reviews.
- Provide commentary about the reading materials weekly.

Participants randomized to the mindfulness-based walking therapy program will:

- Attend an orientation session (approximately 2 hours), attend in-person group meetings once a week for twelve weeks (approximately 2 hours), and attend a half-day mindfulness retreat around week nine (approximately 4 hours).
- Wear a sensor (actigraph) around your ankles and on your hip that records information about your movement for three days after each evaluation.
- Record time spent practicing mindfulness at home.

- Instead of participating in this study, you could continue to receive the same treatment you are currently receiving from your medical providers.
- You will need to come to Washington University School of Medicine – 4444 Forest Park Avenue, St. Louis, MO for the in-person group meetings and evaluations.
- You may or may not benefit from this study.

- The main risks to you are feeling tired from reading the materials and participating in the discussions. You may also stumble or fall during the meetings or evaluations, but will be fitted with a gait belt and a research team member will be close by to help reduce these risks. More detail about risks is provided below.
- You will be paid up to $150 for participating in this study. You will not have costs for participating in this study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

The rest of this document provides more details about the study.

WHAT WILL HAPPEN DURING THIS STUDY?

Participation in the study will include randomization to one of two interventions being evaluated for management of FOG. Both interventions are fourteen weeks long and include three evaluation sessions.

The in-person part of these evaluation sessions will include motor tests such as walking for two-minutes, balance testing, walking through the building, and a motor exam to measure Parkinson-related symptoms. The evaluation will also include cognitive testing on an iPad. We will also send home a binder that has several questionnaires about mood, quality of life, and Parkinson symptoms, and do a phone interview to discuss your freezing of gait episodes. The evaluation sessions will occur prior to the intervention (pre-evaluation), after the intervention (post-evaluation), and fourteen weeks after the post-evaluation (follow-up evaluation). These evaluations will take approximately two to three hours for the in-person part and one to two hours for the phone interview plus questionnaires. The evaluations will take place in-person at Washington University School of Medicine, 4444 Forest Park Avenue, St. Louis, MO.

If you are randomized to the FOG educational program, you will receive a binder that has fourteen weeks of reading materials. Each week the materials will cover a different topic related to FOG, such as the effects of medication on FOG, potential brain mechanisms related to FOG, and new technology for FOG. The materials will also include facts about FOG, strategies to manage FOG, and the latest research about FOG. We will ask that you read the materials and comment about them in the binder. We will also provide you with a weekly calendar to track falls, freezing episodes, medication changes, and any medical care received or classes related to Parkinson's. We anticipate that this at-home education program will take about an hour or two of your time per week. Using your preferred method, we will call, text, or email you each week to remind you about your weekly assignments. We will also have you email or mail (we will provide self-addressed stamped envelopes) us the weekly calendars.

If you are randomized to the mindfulness-based walking therapy program, you will be asked to attend weekly in-person group meetings. The group meetings will take place in-person at Washington University School of Medicine, 4444 Forest Park Avenue, St. Louis, MO. In total, there will be fourteen weeks of in-person classes. The first week will include an orientation to the program. Then there will be twelve weeks of classes that will include learning about mindfulness, mindfulness exercises, and mindful walking exercises. Around week nine, we will have a half-day retreat to review what we have learned. Participation in the mindfulness-based walking therapy program will include home practice and

incorporating some of the mindfulness exercises into your daily life. We will provide you with an iPad during the study that has mindfulness recordings to listen to at home. We will also ask that you track your falls, freezing episodes, medication changes, and any medical care received or classes taken related to Parkinson's and to track your mindfulness practice. Lastly, we will also ask that you wear a sensor (actigraph) for three days around your ankles and on your hip that will record information about your movement after the pre-evaluation, post-evaluation, and follow-up evaluations. We will show you how to wear it and give you instructions during the evaluations.

Medical records may need to be reviewed to confirm diagnoses, combordities, and medical treatments.

If you tell us that you are thinking about hurting yourself or others, the research staff may give you referrals for treatment or work with you to contact your personal doctor or therapist to discuss your thoughts of harming yourself. We may need to work with you on a plan that might include getting you to a medical facility for safety. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) or St. Louis Behavioral Health Response at 1-800-811-4760 (https://bhrstl.org/crisis-hotline/).

WILL YOU SAVE MY RESEARCH DATA TO USE IN FUTURE RESEARCH STUDIES?

The data we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and the general public. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These future studies may provide additional information that will be helpful in understanding Parkinson disease and freezing of gait or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. Should this occur, there are no plans to provide financial compensation to you. There are no plans to provide financial compensation to you should use of your data occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data you give up any property rights you may have in the data. We will protect the confidentiality of your information to the extent possible.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

It is your choice whether or not to let researchers share your data for research in the future. If you say "yes," you can change your mind later. If you say "no," you can still fully participate in this study.

Please place a mark next to your choice:

_____Yes, use my data in other research studies.
Initials

_____ No, do NOT use my data in other research studies.
Initials

AUDIO RECORDING/VIDEO RECORDING/ PHOTOGRAPHS

One aspect of this study involves making audio recordings and/or video recordings of you. The recordings will be of the motor testing during the evaluations to help ensure we score things properly. We may also record some of the group meetings so that we can review them to ensure we did not miss any important information during the meetings. Only members of the study team will have access to these videos, and all videos will be archived in password-protected files indefinitely when the study is completed.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your voice recording.

While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately forty people will take part in this part of the study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for nine to ten months.

There will be a video or phone interview in June or July to do some initial screening and start tracking falls, freezing episodes and medical care. Then you will be asked to attend the pre-evaluation session in July or early August, the post-evaluation session in December, and the follow-up evaluation session in Feb or March. Between mid-August and the end of November will be the active intervention 14-week period. Identifiable data will be destroyed with the project is closed.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Mild

- Fatigue – You may feel tired while reading, during the classes or during the evaluations. Rest

breaks will be provided as frequently as possible during evaluations. You may also inform a member of the research team, and we will help you to take a break from the study or discontinue the study if necessary.

- Discomfort during the group learning experiences – You may feel uncomfortable or embarrassed during the discussions. You will be encouraged to share only experiences that you are comfortable sharing.
- Stumbling during locomotion – You will be closely attended by a trained research team member during walking exercises and evaluations in the laboratory. We will be prepared to assist you if you may stumble. We will also fit you with a gait belt to facilitate assistance if needed.
- Falling – You will be closely attended by a trained research team member to ensure safe conditions in the laboratory and during evaluations. If you appear unsteady or tired you will be encouraged to sit down.
- Physical discomfort – You may experience physical discomfort such as muscle soreness while engaging in mindfulness exercise that require movement. You will be encouraged to not move in ways that cause discomfort.
- Technological burden – You may be asked to use an iPad which you may consider burdensome. We will train you on how to use the iPad to try to reduce this burden.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

We also hope that, in the future, other people might benefit from this study because we will be using feedback and experiences from this study to inform future interventions to help with freezing of gait.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN). You may also need to provide your address if a check will be mailed to you. You should receive a check within eight weeks of our last meeting.

You will be paid $50 for each evaluation you attend, for up to $150 in total compensation.

WHO IS FUNDING THIS STUDY?

National Center for Complementary and Integrative Health (NCCIH) is funding this research study. This means that Washington University is receiving payments from NCCIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NCCIH for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain

information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Center for Complementary and Integrative Health (NCCIH)
- Hospital or University representatives to complete University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, all notes and recordings will be stored in the laboratory in a manner compliant with all HIPAA requirements. This includes records being kept in a secured laboratory that is locked when research team members are not present, being stored on password-protected computers in a locked office, and/or on secure networks in full compliance with HIPAA guidelines for security of protected health information. Cognitive testing is stored within the NIH Toolbox app on a password-protected iPad that is kept in the secured laboratory. The data is only labeled with an ID code. It is then uploaded into REDCap.

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 Web site will include a summary of the results. You can search this Web site at any time.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you or your health condition.

- Reminders of group meetings

- Reminders of reading assignments at home to prepare for group meetings or other supplemental FOG education materials such as short video links
- Reminders of tracking falls, freezing episodes and usual care
- Reminders of in-person evaluation appointments
- Study information, such as consent updates

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address or telephone number. To avoid this, we will send a test message to ensure we have the correct email address or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

iPads and actigraphs will need to be returned upon withdrawal.

CAN SOMEONE ELSE END MY PARTICIPATION IN THIS STUDY?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be in your best interest for you to continue.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Martha Hessler at 314-286-1478. If you feel that you have been harmed in any way by your participation in this study, please contact Kerri Rawson at 314-273-1053.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)