

COVER PAGE

CONSENT FORM

Official Title: Walking and mHealth to Increase Participation in Parkinson Disease

NCT Number: NCT03517371

Document Date: May 14, 2022

Title of Project: Walking and mHealth to Increase Participation in
Parkinson Disease (WHIP-PD)

Principal Investigators: Dr. Terry Ellis, PhD, PT

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.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- If you decide to be in this study, you will sign a copy of this form and we will give you a copy of this form to take home with you.

Background

Walking and exercises to improve walking capacity reduce disability and enhance quality of life in people with Parkinson disease. However, sometimes people have difficulty participating in exercise over the long-term on their own.

Little is known about the most effective ways to help people with Parkinson disease engage in regular exercise and become more physically active.

You are being asked to participate in a research project so that we can study different ways to help people with Parkinson disease become more active and exercise regularly.

This study is funded by the National Institutes of Health.

Purpose

The purpose of this study is to compare the benefits of 2 different ways to help people with Parkinson disease exercise regularly in order to improve physical activity levels, walking ability and quality of life.

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What Happens in this Research Study

You will be one of about 220 subjects asked to participate in this study. The study is taking place in 2 primary locations: Boston University and Washington University in St. Louis. This study may be offered at other locations outside of Boston University that may be closer to you. You may be able to participate in the location that is most convenient for you.

If you agree to participate in this study, you will be asked to participate in up to 8 exercise training sessions over the first 6 months and 4 evaluation sessions over 12 months. These visits may be held at the Center for Neurorehabilitation, Sargent College, Boston University or at one of the alternate locations more convenient to you. There may also be an option to complete portions of the assessments at your home or remotely, via videoconference. One evaluation session will occur before you participate in the exercise program, others will occur at 3 months and 6 months. The last one will take place after you complete the exercise program at 12 months. Additional visits with the physical therapist are available to you if you have a medical issue that impacts your ability to continue doing your study exercise program or if you have difficulty using the technology and you are in the mobile health group.

First Evaluation Session: Screening, Interview, Baseline Visit

The initial evaluation session will take place at the beginning of the study. First, we will make sure you meet the criteria necessary to participate safely in the study. We will conduct some screening tests. The screening tests will include asking you questions about your medical history. We will also assess your memory and Parkinson's symptoms. If you don't meet the eligibility criteria to ensure safe participation, then you will not be able to continue in the study and the interview would be completed.

If you do meet the eligibility criteria, then we will ask you to do some additional walking and balance tests and participate in an examination of the symptoms of Parkinson disease such as tremor, slowness and stiffness. We will video record a portion of these tests to help us score them accurately. You will have the option of agreeing or refusing to have these tests video recorded. We will also ask you to answer some questions about your quality of life, your physical activity and non-motor symptoms of Parkinson disease such as fatigue, mood and apathy. You can skip any questions that you do not want to answer or a test that you do not want to perform.

At the end of the session, you will be asked to wear a small, lightweight monitor (about the size of a pager) that measures your Parkinson's symptoms. You will be asked to wear the monitor 24 hours per day for 7 days (except while you are bathing, showering, or swimming). During this time, you will be asked to perform your usual daily activities. The monitor is worn at the ankle and fastens with a Velcro strap; it has no buttons, switches, or dials; you simply need to remember to keep it on. You'll be shown how to

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put in on and take it off and you'll be allowed to try it out to make sure it is comfortable. You will be provided with a pre-paid shipping box to send the monitor back to us at the end of the 7 day period.

The entire evaluation session will take about 3 hours if the entire session is done in person at a research site. If portions of the assessment are done remotely (filling out forms at home or completing forms over the phone with an assessor), you will be at the research site or have an assessor at your home for around 45 minutes to one hour. You will be allowed to rest, have a drink and a snack during this time if you wish. If there is not an option for in-person visits at a research site or at your home due to COVID19 restrictions, there is an option for a test kit to be sent to you for walking tests at the 3, 6 and 12 month assessment periods. You would be provided with detailed instructions about performing the walking tests and would need to have the assistance of another person in your household to perform the home walking tests. This is an option in the event that in-person visits are not advised or you are not comfortable with an in-person visit. It is not required for your continued participation in the study.

During the COVID19 Pandemic, we will take precautions to ensure that you are as safe as possible during your visit. By doing some of the assessment remotely, we will limit the in-person time and therefore limit exposure. Other measures to both ensure your safety and comply with university and state guidelines include:

- Use of surgical masks by participants and research staff during all visits at all times.
- Maintaining of social distancing when possible, use of personal protective equipment (PPE) when not able to maintain 6 feet apart (may include gowns, gloves, face shields).
- Screening of all staff and participants prior to in person contact using CDC symptom checklist
- Sanitization of all equipment or surfaces

Exercise Program: Up to 8 Physical Therapy Sessions

If you agree to participate in the study, you will be randomly assigned to one of two exercise programs. Random assignment is like flipping a coin. You won't be able to choose which program you prefer as this study requires a random assignment to groups. You will be informed about which group you are assigned to at the end of your first evaluation session or afterwards by phone. If by phone, one of the research team members will call you to let you know. The exercises in both exercise programs are similar but are delivered differently. In one condition, the exercises are provided using video which are accessed through a smartphone/tablet application or "app." In the other condition, the exercises are provided using printed pictures with instructions. The number of in-person visits that you have with the physical therapist to learn your exercise program will be about the same in both exercise programs.

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About 1-2 weeks after you finish the first evaluation session, you will begin the exercise sessions with a physical therapist. You will be asked to participate in up to 8 physical therapy sessions. Six of the physical therapy sessions will be spread out over the first 3-months. These sessions may be held in person (at Sargent College, Boston University one of our alternate locations or at your home). These visits may also be done remotely via videoconference. You and your physical therapist will decide together where the visits will be conducted and if they will be in person or remote. Your therapist will consider university and state guidelines with respect to COVID19, safety of doing exercises independently and your access to technology when considering where to conduct these visits. Two additional physical therapy sessions will be provided (one at 3 and the other at 6 months) to monitor your progress and make any necessary changes to your exercise program. Each of these sessions will last approximately 1 – 1.5 hours. A licensed physical therapist will teach you the exercises, how to do them correctly and how often to do them. The exercise program includes walking, strengthening and stretching exercises that you can do at or near home. You will be asked to gradually increase the amount of walking and the number of sets and repetitions you do for the strengthening, and stretching exercises over 12-months. You will be asked to do the exercises 5 times per week over 12 months. In the event that your personal or borrowed device is not functioning correctly or you are having difficulty using it, you may need an additional 1-2 visits with study personnel to help address your technological issues. You may also have additional visits with the physical therapist if you have a medical condition that arises during the study that impacts your ability to continue to do the exercise program.

Mobile Health Exercise Condition:

If you are randomly assigned to the mobile health exercise condition, you will view your exercises in an exercise application or “app,” called Wellpepper, on your phone or computer tablet. This will allow you to easily access the exercises at a time and place convenient for you. If you don’t have a phone or tablet that you would like to use, we will loan you a computer tablet containing the “app” to take home with you, and to return to us at the end of the study. If you don’t have wireless internet in your home, we will enable the device that we give you with wireless service for 1 year, at no cost to you, so you can access the “app” from home.

During the physical therapy sessions, the physical therapist will teach you how to perform some exercises. The therapist will video record you performing the exercises and upload the videos for you to access through the Wellpepper “app”. You’ll be able to watch the videos of the exercises and listen to the instructions from the therapist through the Wellpepper “app” on your phone or tablet. This will help you to do the exercises with proper form when you get home. The exercise videos are stored in a virtual private cloud that is secured by “Wellpepper,” the company who developed the “app.” These videos are only accessible through the app, they are not stored on your personal device or on a device loaned to you. To keep your videos secure, Wellpepper

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will require you to set up an account with an email and a unique password that you create. You can decide how much information that you put in the app. For example, you can enter your full name or use your first name only. You could use a current email account to access the “app” or you could have a new one created for you, just for use in this study. Your account information and exercise videos will be destroyed at the end of study.

During the physical therapy sessions, the physical therapist will ask you about the things that motivate you to exercise and the barriers that might prevent you from exercising. The physical therapist will work with you to develop strategies to overcome these barriers so you can engage in exercise more successfully. Your physical therapist will work with you to set up exercise goals. We may ask you if we can video record part of these sessions so that we can ensure the sessions are being conducted in the same manner across therapists. You will have the option of agreeing or refusing to have the session video recorded.

You may receive automatic reminders when to do the exercises. The “app” provides visual feedback so you can see your progress over time. There is a message feature you can use to communicate with your physical therapist if you have any questions or concerns. Your physical therapist will be able to adapt the exercises remotely over 12-months, based on how you are doing. The exercises will take approximately 30-45 minutes to complete during a session. You will be asked to complete at least 5 exercise sessions each week over the 12 month period.

Printed Exercise Condition:

If you are randomly assigned to the printed exercise condition, you will be given an exercise program printed on paper to take home with you. This will include pictures of the exercises and instructions on how to do them correctly. The exercises will take approximately 30-45 minutes to complete during a session. You will be asked to complete at least 5 exercise sessions each week over the 12 month period. You will be given a journal to keep track of when you do your exercises and walking. We will ask you to bring these completed journals to your assessment visits.

Second Evaluation Session: 3 months

You may be asked to come back to Boston University to participate in a study visit about a quarter-way through the exercise program (about 3 months after your first visit). Portions of this assessment may be done remotely or at your home. We will conduct the same tests of walking, balance and Parkinson’s symptoms as we did during the first evaluation. We will ask you some questions about whether you have had any changes in your medical condition and in your medicines since your last visit. We’ll also ask you questions about your quality of life, your physical activity and non-motor symptoms of Parkinson disease such as fatigue, mood and apathy. This session will take about 2–2.5 hours if done entirely at Boston University or another site. Portions of this assessment

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may occur remotely or at your home. If portions are done remotely, the in-person time (either at a research site or at your home) will be limited to about 45 minutes.

Third Evaluation Session: Mid-way through the Exercise Program

You may be asked to come back to Boston University to participate in a study visit about mid-way through the exercise program (about 6 months after your first visit). Portions of this assessment may be done remotely or at your home. We will conduct the same tests of walking and balance and Parkinson's symptoms as we did during the first evaluation. We will ask you some questions about whether you have had any changes in your medical condition and in your medicines since your last visit. We'll also ask you questions about your quality of life, your physical activity and non-motor symptoms of Parkinson disease such as fatigue, mood and apathy. This session will take about 2–2.5 hours if done entirely at Boston University or another site. Portions of this assessment may occur remotely or at your home. If portions are done remotely, the in-person time (either at a research site or at your home) will be limited to about 45 minutes.

Final Evaluation Session: After the Exercise Program

You may be asked to come back to Boston University to participate in a final study visit. This will occur within about 1-2 weeks after completing the exercise program. Portions of this assessment may be done remotely or at your home. We will then conduct the same tests of walking, balance and Parkinson's symptoms as we did during the first evaluation. We will ask you some questions about whether you have had any changes in your medical condition and in your medicines since your last visit. We'll also ask you questions about your quality of life, your physical activity and non-motor symptoms of Parkinson disease such as fatigue, mood and apathy. This session will take about 2–2.5 hours if done entirely at Boston University or another site. Portions of this assessment may occur remotely or at your home. If portions are done remotely, the in-person time (either at a research site or at your home) will be limited to about 45 minutes.

At the end of the second, third and final evaluation sessions, you will be asked to wear the same monitor that you wore after the first evaluation session. You will be asked to wear the monitor 24 hours per day for the next 7 days (except while you are bathing, showering, or swimming). During this time, you will be asked to perform your usual daily activities. We will give you a stamped envelope with our address on it so you can mail the monitor back to us after the 7 days.

Risks and Discomforts

There are some minor risks and discomforts if you decide to participate in this study. The evaluation sessions are long, around 2 to 3 hours, but you can take as many breaks as you need in order to feel comfortable. There is also a small risk that you could feel some fatigue, muscle pain or other discomfort or

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experience a fall during the assessment process. However, the evaluation sessions are not vigorous and are being conducted by experienced professionals, so the risk of injury during these sessions is very low.

As with any exercise, this walking, strengthening and stretching program may cause you injury. For example, you could have sore muscles, you could fall and harm your skin, joints or bones, or you could have shortness of breath or chest pain. These things are possible. Your risk of injury will be less if you wear good walking shoes and if you follow the exercise instructions to make sure you are doing the exercises with good form.

The risks of any problems occurring during the exercise sessions are minimized because all exercise sessions will be prescribed by licensed physical therapists who have experience working with people with Parkinson Disease. They will make sure that you are performing the appropriate exercises given your abilities and that you are doing the exercises safely.

We want to know if you end up with an injury of any kind, so please contact us if your health condition changes, you need medical attention, are hospitalized or experience a fall. If your health condition changes or you have a fall, we will ask you to record this on a calendar that we will provide you. When you call us to tell us about the health condition or fall, we will ask you questions because we want to make sure the exercise program is safe for you. You may stop taking part in this study at any time and for any reason. To tell us about an injury, change in medical status or a fall, please call the following phone number: 617-358-6157.

There is a risk of loss of confidentiality while using the “app”; however, safeguards have been put into place to protect your information.

There may be some risk of contracting COVID19 when doing any in person visits. We have outlined steps above to limit exposure time and protect you from possible exposure through use of screening, protective equipment and sanitization measures. We will follow all state and university guidelines directing whether in person care is advised based on changes in community infection rates and/or new information about disease transmission.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

Potential Benefits

Study participants in both groups might experience benefits from participating in

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this study, as both groups will receive up to 8 physical therapy visits that include a walking, strengthening and stretching exercises. The exercise program has the potential to result in improved community mobility and participation in life activities among persons with PD. However, it is possible that you may not receive any benefit from participating.

Alternatives

The alternative is that you would not participate in this research study.

Subject Costs and Payments

There are no costs to you to participate in this study. However, you will be responsible for providing your own transportation to and from the study site. You will receive free parking for all evaluation and exercise training sessions. The physical therapy sessions will be provided to you at no cost. You will also receive a \$25.00 Amazon gift card after completing each of the 4 assessment sessions. The gift card will be given to you at the end of each assessment visit.

Confidentiality

Any information you are asked to provide for this study will be confidential. Only the people working on the study will have access to the information collected. All of the information gathered will be kept in a locked cabinet in a locked office or on a secured password protected computer. The information collected from each participant will be given a unique code (your name won't be used). We will keep a master list which matches your name to the unique code and only a few select study investigators will have access to this list. When we report the results of this study, we will not include your name. No one will know you were part of the study or which of the information came from you. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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.

Wellpepper has taken many steps to protect your confidentiality. The information collected through the Wellpepper "app" is converted to a code so only the researchers in this study will have access to the information. To keep your videos secure, Wellpepper will require you to set up an account with an email and a unique password that you create. At the end of the study, information stored by Wellpepper will be retained by the researchers in this study and not by Wellpepper. Your account information and exercise videos will be destroyed at the end of the study.

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This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not share or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. Your information will not be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and 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 (such as to report elder abuse or communicable diseases) or if you have consented to the disclosure.

Researchers may need to provide information that may identify you if it is needed for auditing or program evaluation from personnel of the United States federal or state government agencies or by the National Institutes of Health which is funding this project. Your information may also be viewed by organizations dedicated to research oversight, such as the Boston University Institutional Review Board or the Office for Human Research Protections. 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.

Research Participant Preference on Communications

The BU Center for Neurorehabilitation uses email and text communication for various items including, but not limited to, research appointment reminders and explanation of research procedures.

It is important for you to understand that regular email and text are convenient but are generally not encrypted, and protected health information is therefore at risk of being intercepted. BU uses an encrypted email program to communicate securely, but it is less convenient as it requires you to log in to a separate site to obtain each message. We give you the choice below of secure email, non-secure email, or non-secure text. If you choose the more convenient non-secure email or text, please note you are taking on the risk of interception, and you release Boston University from any liability for following your stated preference. If you contact us by non-secure email or text, we will assume you have made that choice.

EMAIL Communication Preference

Please provide your email communication preference below (check your preferred option):

Please communicate with me using Data Motion secure internet based-email, to the email address provided:

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Please use regular email to the following address:
 I do not wish to communicate by email

Right to Refuse or Withdraw

Participating in this study is voluntary. You have the right to refuse to take part in the study. If you decide to be in this study and then change your mind, you can withdraw from the study at any time. Your decision will not affect your ability to receive health care here or at any other place.

Also, it is possible that the researcher may take you out of the study without your permission. This may happen because the researcher thinks it's in your best interest, you can't make the required study visits or other administrative reasons.

Emergency Care and Compensation for Injury

If you are injured as a result of taking part in this research study, we will assist you in getting medical treatment. However your insurance company will be responsible for the cost. Boston University does not provide any other form of compensation for injury.

Statement of Consent:

Signing this form means that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Please feel free to ask questions at any time, now or in the future, regarding the research or your participation in it. The Principal Investigator in the Center for Neurorehabilitation, Sargent College, Boston University will be happy to answer any questions that you might have:

Dr. Terry Ellis, PhD, PT, Principal Investigator
 Assistant Professor
 Director of the Center for Neurological Rehabilitation
 College of Health & Rehabilitation Sciences: Sargent College
 Boston University
 617-353-7571

You may obtain further information about your rights as a research subject by calling the Institutional Review Board for Human Subject Research of the Boston University Charles River Campus, at 617/358-6115. If any problems arise as a result of your

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participation in this study, including research-related injuries, please immediately call the Principal Investigator, Terry Ellis, at Boston University, at 617-353-7571.

Participant's name

Participant's signature

Date

I have fully explained to _____ the nature of the above described research study and any risks involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedure or the risks and benefits if any should occur during the course of the study.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

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