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Mobility in Daily Life and Falls in Parkinson's Disease: Potential for Rehabilitation
Informed Consent Form

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OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 18978

CLINICAL RESEARCH CONSENT AND AUTHORIZATION
SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: *Mobility in Daily Life and Falls in Parkinson's Disease: Potential for Rehabilitation*

PRINCIPAL INVESTIGATORS:

Fay B. Horak, PhD, PT (503) 418-2602
Martina Mancini, PhD (503) 418-2602

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE

The purpose of the study is to learn more about the effectiveness of an exercise boot camp program to improve mobility and decrease falls in individuals with Parkinson's disease.

DURATION

Your participation in the study will last 62 weeks. Participation will consist of two study visits, two week long in-home activity monitoring collections, and, if randomized into the intervention group, 18 training sessions over six weeks. Visits will last up to three hours. We will ask you to track if falls occur over the next year, through the use of email or phone surveys.

PROCEDURES

If you decide to take part in this study, you will be randomized into one of two groups – one-on-one training sessions for up to six weeks or no intervention. Evaluations for the study visits involve:

- Gait, balance, and cognitive tests
- Clinical assessments of disease severity
- At home mobility monitoring using wearable sensors

RISKS

There is a small risk of falling and breach of confidentiality.

BENEFITS

You may benefit from the turning rehabilitation program.

CO1450

ALTERNATIVES

You may choose not to participate in this study, or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

IRB Approved: 9/6/2024
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Clinical Research Consent and Authorization Form

TITLE: *Mobility in Daily Life and Falls in Parkinson's Disease: Potential for Rehabilitation*

PRINCIPAL INVESTIGATORS	Fay B. Horak, PhD, PT	(503) 418-2602
	Martina Mancini, PhD	(503) 418-2602
CO-INVESTIGATORS	Patricia Carlson-Kuhta, Ph.D.	(503) 418-2602
	Laurie A. King, PhD, PT	(503) 418-2602
	Marian Dale, MD	(503) 494-7231
STUDY STAFF	Jacqueline Ellison, BS	(503) 329-3828
	Graham Harker, MPH	(503) 418-2601
	Solek Ashkinos	(971) 344-1714

FUNDED BY The National Institutes of Health (NIH) is funding this research study.

CONFLICT OF INTEREST *OHSU has a financial interest in, and Drs. Horak & Shah are employees of APDM, the company that makes the body-worn sensors used by this study. The nature of this financial interest and the design of the study have been reviewed by two committees at OHSU. They have put in place a plan to help ensure that this research study is not affected by the financial interest. If you would like more information, please contact the OHSU Research Integrity Office at coir@ohsu.edu.*

PURPOSE

You have been invited to be in this research study because you have Parkinson's disease and experienced falls in the past year. The purpose of this study is to learn more about the effectiveness of an exercise program to improve mobility and turning in the daily life of individuals with Parkinson's disease.

This study requires: 1) two study visits to the Balance Disorders Laboratory that will take about three hours each to complete, 2) wearing movement sensors during daily life for two, one- week periods, 3) if randomized into the active group, participating in 18 one-on-one exercise boot camp sessions with a personal trainer, and 4) tracking your falls for up to 12 months.

This study plans to enroll 60 participants with Parkinson's disease.

PROCEDURES

CO1450

Balance and Gait Testing. During the laboratory visits we will assess your balance and gait. You will undergo a brief clinical assessment of your mobility and Parkinson's symptoms. We will then place small (watch-sized) sensors placed on your arms, legs and torso that will record your movements during the walking and balance tasks. During the initial walking tests, you will also be asked to wear a headband which measures brain activity. This headband uses a technology called functional near-infrared spectroscopy (fNIRS) to measure changes in blood flow. Some participants will repeat some of the tests while using crutches equipped with sensors. Some balance tasks are on a movable surface. Trained research staff will be present to ensure your

safety while performing these tests. You will be asked to complete a number of walking trials of different lengths. The balance and walking tests will be video-recorded (optional – see participant options at the end of this form) for review by research staff. You will also complete several questionnaires about your activity level, thinking ability, and Parkinson's symptoms.

Wearing Sensors at Home. Participants will wear three sensors during daily activities for two one-week periods. Sensors are to be worn during your waking hours and charged overnight. At your first study visit we will instruct you on how to wear the sensors, how to charge the sensors at night, and how to mail the sensors back to the Balance Disorders Laboratory in a pre-paid mailing box.

Exercise Intervention. All 60 participants will be randomly assigned to one of two groups: a treatment group and a control group – 30 per group. Participants in the treatment group will attend 1-hour classes, 3 times per week for 6 weeks at the Balance Disorders Laboratory. These training sessions will be one-on-one with an exercise trainer and overseen by a physical therapist investigator. A ceiling-fixed harness system that is programmed to prevent falls during challenging exercise practice will be worn by participants during their training sessions. Physician clearance may be required for you to participate in the study to help ensure your safety to perform moderate level intensity exercise. Participants assigned to the control group will receive no intervention. These individuals will be asked to maintain their normal activity levels and routine for the seven weeks between study visits.

All participants will undergo testing at the beginning of the study (Week 0) and at the end of the study (Week 9 & 10).. For your testing sessions at OHSU we will ask you to complete a series of tests described below:

Procedures:	***Week 1*** Pre-intervention study visit (3 hours)	***Week 2*** Home monitoring (10h/day)	***Weeks 3-8***		***Week 9*** Home monitoring (10h/day)	***Week 10*** Post-intervention study visit (3 hours)
			Control Group: -No study requirements-	***Intervention Group: Exercise Sessions (60-min, 3x/ week)***		
Consent Discussion, Screening tests and medical history	X					
Clinical Examination of Parkinson's Symptoms	X					x
Gait, Balance, and Thinking tests	X					x
Home mobility-monitoring (7 days)		X			x	

Tracking Falls. We will ask you to record any falls that you may experience 12 months following the second study visit. You will be given a fall survey every 2 weeks, and also receive phone calls or email reminders.

Videos/photographs (optional). If you agree, during the balance and gait testing in the laboratory you will be videoed (with audio) or photographed. Also, while wearing the sensors at home, we will take a video (60 min or less) of your feet, while walking around your home and completing daily-living tasks. We will use the videos and photos to aid in data analysis, for educational materials, research presentations and publications. You will not be able to view the images before use and you may be recognizable in the images.

WILL I RECEIVE RESULTS FROM THIS STUDY?

We do not plan to share your test results with you or your primary care provider. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory. You may learn information about your health that is upsetting.

RISKS AND DISCOMFORTS

Falls. You may be at an increased risk of falling while performing the gait and balance tasks during the laboratory test session as well as during any exercise training sessions. We will minimize this risk by having an assistant with the you at all times who is experienced working with people who have gait difficulties. Additionally, a gait belt will be placed around your waist to aid in catching you, if you lose your balance. During training sessions participants will wear a ceiling-fixed body support harness that will support your weight if you fall.

Muscle soreness. The risk of muscle soreness from starting an exercise program is very high although the consequences are minor. You will likely have temporary muscle soreness after doing the exercises, especially when the exercise program is first started. A physical therapist investigator will make sure that the selection and progression of exercises are matched to your current fitness level and abilities in order to minimize this risk.

Musculoskeletal injury. There is a low risk of joint, tendon, or muscle pain, inflammation, or swelling during or after an exercise session. These injuries will be treated with cold, heat, and over-the-counter pain medication. If persistent or severe, you should see your primary care doctor for advice. The risk is reduced by use of well-trained trainers who will teach you how to exercise safely.

Exacerbation of chronic conditions. There is a low risk that existing chronic conditions such as chest pain and osteoarthritis will become worse by starting an exercise program. An experienced trainer leading the class will customize exercises as needed to minimize these risks.

Heart problems. There is a very low risk that exercise could result in a heart attack or irregular heartbeat. These problems can be serious or lead to death. Based on your health history, we may require a medical release form from your physician to clear you for exercising. Furthermore, the risk will be minimized by selecting exercises to fit your fitness level.

Discomfort. The fNIRS headband system can become uncomfortable if worn for extended periods. The study team will make every effort to minimize the time you spend wearing the system and will make adjustments to make sure it is as comfortable as possible when in use.

Emotional Distress**.** Some of the questions asked may be personal or embarrassing. You may refuse to answer them if you wish.

Breach of privacy/confidentiality. Although every attempt is made to keep subject information private, there is a chance of a breach of confidentiality. We will store the study data and images in a protected location to which only the researchers have access, and store the data without personal identifiers.

CONFIDENTIALITY

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, NIH, and the funder's representatives.
- The Office for Human Research Protections, a federal agency that oversees research involving humans.

Those listed above may also be permitted to review and copy your records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

If you sign a separate consent form to permit storage of your information for future research studies, then information from this study may be shared with other investigators for future research studies. All identifying information about you will be removed from the information before it is released to any other investigators.

We may continue to use and disclose your information as described above indefinitely.

COMMERCIAL DEVELOPMENT

Information and videos/photos about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information and videos/photos.

COSTS

There is no cost to you or to your insurance company to be in this study.

You will receive $100 for each study visit plus the subsequent week of mobility-monitoring (total of $200). If you are randomized into the Control group, rather than the exercise boot camp group, you will receive an additional $150 after the post-test sessions (total for Control group will be $350). This could be used to participate in community exercise classes after completion of this study.

We may request your social security number in order to process any payment for participation. You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

LIABILITY

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Martina Mancini at (503) 418-2602.

If you are injured or harmed by the study procedures, you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

PARTICIPATION

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Martina Mancini at (503) 418-2602.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. One part of the study is optional. You can choose not to participate in the optional part but still participate in the rest of the study.

If you do join the study and later change your mind, you have the right to quit at any time. You can choose to withdraw from the optional part of this study without withdrawing from the whole study. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to: Dr. Martina Mancini, OHSU, 3181 Sam Jackson Park Rd., OP-32, Portland, OR 97239, mancinim@ohsu.edu.

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your information, but the material will not be destroyed and we will continue to use it for research. You may be removed from the study if you are unable to complete the tests.

SIGNATURES

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this form.

PARTICIPANT OPTION

The optional parts of this study are described in detail throughout this consent form and listed here as a summary. Please read the options and place your initials next to your choice below. You can still participate in the main part of the study even if you choose not to participate in the optional parts.

	Yes, I agree	*No, I decline*
I agree to have video/photographs taken that may identify me.	_____ *Participant initials*	_____ *Participant initials*

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter:_____Date: _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and_____(state language).

See the attached short form for documentation.