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CONSENT FORM COVER PAGE

STUDY TITLE:
In-home cycling for individuals with Parkinson disease

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University of Wisconsin-Madison

Consent to Participate in Research

Title of Study: In-home cycling for individuals with Parkinson disease

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Invitation

You are invited to participate in a research study looking at how a home-based cycling program may affect performance of activities of daily living, walking speed, balance, falls, and overall activity level. This study is called, “In-home cycling for individuals with Parkinson disease,” and is being conducted by Dr. Kristen Pickett at the University of Wisconsin-Madison. You have been asked to participate because you are an individual with Parkinson disease who is currently not exercising due to lack of access to exercise classes.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to investigate possible ways to improve outcomes for underserved populations of individuals with Parkinson disease (PD). This research will study whether providing access to meaningful in-home physical activity via a telehealth approach improves activities of daily living, quality of life and balance.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 65 people will participate in this study all of whom will take part in the study here at the UW-Madison and in their home.

Funding for this study is provided by the Institute for Clinical and Translational Research and the Wisconsin Alumni Research Foundation (WARF), both here at UW-Madison.

What will happen in this study?

If you choose to participate in the study, you will be randomly assigned to one of the study groups. Depending on which group you are assigned to, you will either, immediately begin an in-home cycling program or be asked to wait for 6-months and then begin the cycling program. Regardless of the group you are assigned to, we ask that you do not begin any new exercise programs during the time you are enrolled in the study.

If you are asked to wait to begin the program, we want you to continue your regular routines just as you currently do. We will ask that you wear an activity tracker during this period so that we can better understand your current daily activity level.

During the cycling program, all participants will have a stationary recumbent cycle delivered to your home and properly fit to your individual needs. The team will ensure the stationary bike is set up in a safe and secure manner, and in an area free of clutter and dangerous obstacles.

Prior to beginning the cycling program, all individuals will be provided with an information sheet that clearly describes what part of the study you will be completing. When cycling, we would like you to aim for a moderate intensity level of activity. One way to understand your intensity level is by watching your heart rate. You can use your activity monitor on the bike to view your current heart rate. A moderate amount of physical activity should take you to between 50% and 70% of your maximum heart rate. Based on current recommendations[1], we will use the formula 220 – your age to calculate your maximum heart rate. Additionally, we will teach you to use a tool called a perceived exertion scale. This tool will also help you to know how hard you are exercising. We will ask that all individuals in the cycling groups start off with five minute exercise sessions, at the low end of the moderate intensity zone.

Some individuals will be partnered with a cycling partner. If you are assigned to the partnered social cycling group, the team will then set up a tablet computer that allows you to see and speak with a research partner, who will be your cycling partner. There will be scheduled cycling training sessions three times per week. These sessions will gradually increase in length of time and intensity level. The study team member working with you will help you to progressively increase your sessions. During the sessions, your partner will cycle with you and monitor the sessions by watching your activity tracker as well as information provided by the bike. Study team members will also ask about any falls that have occurred weekly. Your research partner will provide daily speed goals and encourage you to meet and maintain these goals. You will also be encouraged to exercise outside of the scheduled sessions. These unmonitored sessions, can be completed at your self-selected times. During these sessions no one will be monitoring you or your heart rate level.

Some individuals will be assigned to a solo cycling group. Solo cyclists will use a digitally displayed program on the bike to provide feedback about each session, but will be free to decide which

[1] Target Heart Rate and Estimated Maximum Heart Rate, Centers for Disease Control website https://www.cdc.gov/physicalactivity/basics/measuring/heartrate.htm

days and at what time they complete the cycling sessions. Over time, individuals in this group may elect to increase session durations up to 30 minutes per session. At the end of each week we will call you to ask about falls during the week, check-in on how things are going, ask about any problems you are having with the bike and give you your targets for the next week. Each week we will increase the goal amount or goal intensity of the sessions based on how things went the previous week. We will always be very clear about what the goals are at the end of each week.

Data from the activity trackers and the bike will be collected at all times during the study. Data from the bike will tell us how much, how long and at what times the bike was used. Date from the activity monitors will provide a continuous amount of data about your daily activity levels and heart rate. The activity monitors used for this study do not have the ability to tell us your location, therefore we cannot track your movements or tell where you are going. We are only able to see how many steps you take and your heart rate throughout the day.

All individuals in the cycling groups also will be asked to complete a daily activity log. This journal will allow us to see records of the exercise sessions and/or when a session was not completed. Additionally, we will ask that you give us information about how you are feeling during and after the sessions.

During the three-month interim between the end of the intervention and the final data collection, all participants will be able to keep their bike and may decide to continue cycling on their own. Some participants will be randomly assigned to continue with the help of a health coach. The coach will schedule sessions every other week to discuss goals and motivation for physical activity. These calls will last approximately 15-minutes.

Data collection for the study will occur at the UW-Madison Natatorium in the Sensory Motor Integration Lab (SMIL). Assistance with transportation to and from the lab can be provided. There will be three data collection points: once at the start of the program (baseline), once at the end of the intervention, and once at three months following the last day of the intervention. Individuals in the wait group will be assessed one additional time prior to the beginning of the 6-month waiting period.

During the data collection sessions, you will be asked to perform some walking and balance tests, perform a cooking task, answer some questions about what activities you perform daily and complete some questionnaires. Some of the topics covered in the questionnaires may be difficult to answer or may address sensitive topics. You may skip any question on the questionnaire or in the interview that you do not wish to answer. Questionnaire topics include depression, loneliness, perceived isolation, activities of daily living, falls, medical history and sleep quality. Data collection sessions will last approximately three hours.

As part of the study, we will collect video recordings during the data collection session in the lab. The videos are being collected to allow us to properly analyze your walking data and to ensure that the information from your interview session is properly recorded. Recordings will be kept indefinitely (banked), meaning we have no plan to destroy the recordings.
The recordings may be used for future research.

How long will I be in this study?

You will be part of the study for about 9 months if you are in the cycling groups and 15 months if you are asked to be in the 6-month wait group. The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

This study is not part of your health care.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What are my other choices if I do not take part in this study?

You do not have to be in this research study. If you decide not take part in the study, you have other choices.

For example:

- you may choose to investigate other means of participating activities involving exercise and social interaction.
- you may choose to take part in a different study, if one is available

Will being in this study help me in any way?

Exercise has been shown to improve cardiovascular health, mental health, overall quality of life, and decrease severity of PD symptoms. Participation in this study may benefit other people with Parkinson disease who live in underserved community areas. The project will help researchers learn more about how exercise, cycling, and telehealth can help individuals with PD with their activities of daily living, walking speed, balance, fall risk, and overall level of activity.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

What are the risks?

Home visits will occur as part of this study. If child or elder abuse or neglect is observed during a visit, members of the study team may be required by state law to report this to the appropriate authorities. This may include reporting to the local law enforcement or protective service agencies, resulting in legal or social risks to you or other members of your household. Your confidentiality cannot be guaranteed in cases of child or elder abuse.

Obtaining information on sensitive topics may cause anxiety, distress, embarrassment, feelings of sadness, or discomfort. The questionnaires you will complete in this study may show that you are experiencing symptoms of emotional distress such as depression or suicidal thoughts. If the questionnaires show that you are experiencing suicidal thoughts, we will immediately call 911. This will compromise your confidentiality and we will notify you immediately of this breach of confidentiality.

There are physical risks involved with participating in this study. Risks associated with data collection sessions include fatigue and falls that could occur during walking tests. During in-home exercise minimal risks include muscle soreness associated with beginning any exercise program. Moderate risks include falls, injuries, and skin irritation from the activity monitor. We do not anticipate any risks to you beyond the risks of daily life. To minimize the risks during the exercise intervention, a number of measures and precautions will be taken.

An information sheet will be provided to you to help you better understand which group you have been assigned. All individuals will have their maximum and target heartrate calculated. The calculation for target heartrate is 220 – participant age. Target heartrate will be calculated using a span of 50-85% of the calculated maximum (50 to 70% of maximum = moderate and 70 to 85% of maximum = vigorous exercise). These values will be provided to you on the information sheet as well as on the card on your bike. Weekly exercise goals will be established based on these criteria.

For individuals in the partnered cycling group, weekly goals will increase in duration and intensity as the study continues. You are not required to cycle on the days without scheduled cycling sessions, but you may choose to do so to work toward the goal of 150 minutes of exercise per week.The study team will gradually increase the duration of the cycling sessions for the first 12 weeks while verbally coaching you to keep their heart rate between 50 and 70% of your calculated maximum. The sessions during the first week will last 5 minutes. As you

exercise, it will take a greater speed to attain the desired heart rate. For the second twelve weeks, the research assistant will help you to monitor the average speed of the final session of the previous week and suggest an increase in the target speed to increase your heart rate. Heart rate monitoring will be done using a computer program that links your cycle and your activity tracker to the internet and allows us to view your data remotely. Additionally, we will ask you about your feelings about how much you are exerting yourself during the session. You will be provided with a card on the bike that helps you to answer these questions. Outside of these scheduled sessions and in the solo cycling group, you can use the reference card to monitor your heartrate. You will also be asked to complete a daily exercise log. A study team member will travel to your home to collect your logbook entries at four week intervals. These entries will be reviewed by the study team.

Researchers will also encourage and remind you to drink water frequently during exercise sessions and we will end a session if there is any indication of discomfort, exercise intolerance, a desire to stop, or a medical emergency. We will be collecting your emergency contact information as part of the baseline data collection and we will contact both emergency services as well as your contact, should the need arise. If 911 is activated, we will need to disclose your name, address and emergency contact information to the emergency response team.

If you are assigned to the solo cycling group, three sessions will be scheduled during the first week of the program. A study team member will call you 10 minutes after the scheduled completion time during the first week to see if any extra assistance with the bike or the journal is needed. Individuals in this group will be provided an information sheet to describe the cycling sessions, target heart rate, perceived exertion and the exercise journal. Individuals in the solo group will be self-directed as to when, how long and how hard you exercise. Heart rate and perceived exertion ranges will be established with you before beginning the study and you will be required to track this on your own during cycling sessions. A suggested progression is provided. All individuals in the solo group will be asked to complete the daily exercise journal. At the end of each week, a study team member will contact those in the solo cycling group via a telephone call to ask about falls and provide the individual with their average speed of the final session of the previous week.

There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

If necessary, we will provide transportation to and from the data collection sessions. In the event that you do not currently have internet service in your home, we will provide a mifi unit, which will allow you to access the internet via a wireless signal. This will be provided at no cost to you.

Will I be paid or receive anything for being in this study?

At the conclusion of the study, you will be given the option of keeping the recumbent bike, tablet computer (if applicable) and activity tracker or return the bike and tablet computer and receive $400 and keep the activity tracker (you will receive an additional $50 for the pre-test if you are assigned to the waitlist group).

If you choose to leave or we take you off the study before you complete the study visit, you will receive $50 for the pre-test if you are assigned to the waitlist group, $50 for the baseline assessment, $100 for each 2 months of the intervention you complete and $50 for the posttest.

What happens if I am injured or get sick because of this study?

Being injured during this research is very unlikely. However, accidents can happen.

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the Lead Researcher, Kristen Pickett, at (608) 890-2103 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the

Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections

Will information from this study go in my medical record?

- None of the information we collect for this study will be put in your medical record.

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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of such as child or elder abuse and neglect, or harm to self or others.

What will happen to my data after my participation ends?

We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data or samples for future research is called “banking.” The banked data will be kept in a secure location for use by researchers.

This is what will happen with your banked data:

- We will use the data in other research projects involving individuals with Parkinson disease.
- The banked data will be labeled with a code instead of your name.
- The research team will maintain a link between your data and your identifiable information kept by the study team.
- You can request to have your data removed from the bank by contacting the research team at any time.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Dr. Kristen Pickett at (608) 890-2103. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

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Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.

_____

Printed Name of Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent Date

****You will receive a copy of this form****