CHAPMAN UNIVERSITY
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Smartphone-based assessment of ON and OFF walking periods in patients with Parkinson's disease in real-world environments (PD)

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM
Lead Researcher
Dr. Niklas Ignasiak, BSPT, MS, PhD
Assistant Professor
Physical Therapy
714.516.5503 | ignasiak@chapman.edu

Other Researchers
Dr. Vincent Berardi, BS, MS, PhD
Assistant Professor
Psychology
714.516.5883 | berardi@chapman.edu

Christopher Watkins
PhD student
Computational Sciences
Watki115@mail.chapman.edu

STUDY LOCATION(S): private home

STUDY SPONSOR(S): Chapman University

No one on the study team has a disclosable financial interest related to this research project.

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research project is to develop a device which can provide rhythmic feedback to patients with Parkinson's disease in order for them to maintain appropriate walking speed and a regular walking rhythm. Often times patients experience fluctuations of their walking ability throughout the day, depending on the time when medication was taken last (sometimes called being "ON" or "OFF"). The ultimate goal of the project is to develop a smartphone application which will identify slow and unsafe walking performance during OFF periods based on recordings of a smartphone sensor and then to automatically trigger a vibrating wrist-band which would give feedback to the patients when needed. In the current study, the first step is to collect walking data using a smartphone throughout a day while patients continue their normal everyday routines. This data is needed to train the device to identify when somebody is walking and when this walking becomes slow and unstable.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We expected 40 people will be in this research study. Of those participants we aim to include 20 patients with Parkinson's disease and additional 20 non-Parkinson subjects. All study procedures will be done at your house or outside of it. We are using a smartphone and another mobile device to record the walking, so that we can collect data where it is most convenient for you. The principle is that we ask you to wear the devices while you continue your normal daily routines.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?

1. You will be visited at home by a researcher and outfitted with a smartphone which is to be carried in a belt holder that we provide. Furthermore, we ask you to wear six small sensors (sizes of a matchbox) which we will attach to both feet, wrists, around the pelvis and the upper body. Setting up of all sensors will take about 15 minutes.
2. Then we ask you to perform several short (1-2 minutes) bouts of walking depending on your preferences in- or outdoors. In between the walking you will be able to sit or lie down and rest. Recording of all walking bouts will take about 45 minutes in total.
3. Afterwards the researcher will leave but we ask you to continue wearing the smartphone and all sensors for about 4-6 hours. Furthermore, we ask you to fill out a patient diary in which you indicate your ability to walk on an hourly basis.
4. At the end of this period a researcher will return to you (exact times can be arranged at your convenience) and you will be asked to again perform several short walking bouts (1-2 minutes) with rest periods for about 45 minutes.
5. At the end we will take the smartphone and the sensors off, collect the diary and the study is terminated.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if:

- you have been diagnosed with Parkinson disease
- your Parkinson-related symptoms change over the course of a day and are depending on when you have been taken your medication
- you are comfortable to allow a researcher to visit you at home
- you are at least 18 years of age

Exclusion Requirements
You cannot participate in this study if:

- you are unable to walk for 1-2 minutes when having not taken your medication

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?

There are no known harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risks and/or discomforts associated with the procedures described in this study include:

- Injury: there is a small risk of falling when performing the walking bouts.
- Invasion of privacy: there is a small chance you might feel uneasy to allow a researcher into your home.
- Change of daily routine: there is a small chance that it is inconvenient for you to accommodate the two visits a researcher.
- Wearing of sensors: there is a small chance that you will be bothered by being requested to carry the sensors of for 4-6 hours.
- Breach of privacy and confidentiality: As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Participant Benefits
You will not directly benefit from participation in this study.

Benefits to Others or Society
Upon successful completion of the study we hope to be able to finally develop the device, which would be serving as complementary treatment and assistive device for patients with Parkinson's disease. The device will operate in everyday situations and focuses on times when medication is not effective anymore and therefore fills a void when patients have limited access to other support.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation
You will receive $ 50 upon completion of this study. If you decide to withdraw from the study before its end or you are withdrawn by the research team before entering the study, you will receive no compensation.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you become ill or get injured as a result of this study you should seek medical treatment through your doctor or treatment center of choice. The University and/or researchers are not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

If you experience any side effects, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

HOW WILL MY PERSONAL INFORMATION BE KEPT?

Subject Identifiable Data

All identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The collection of personal data (name, telephone number, street address) is required to arrange for the data collection visit. At the end of the form you can choose if you wish that your identifiable information will be removed at the end of data collection or alternatively if you wish that we retain this data in order for the research team to contact you when another study is planned that you might be eligible for.

Data Storage

Research data will be maintained in a secure location at Chapman University. Only authorized individuals will have access to it. Temporarily, data (without identifiable information) will be stored electronically on a password protected laptop computer.

Data Retention

The researchers intend to keep the research data indefinitely, but this will not include your name or other personal identifying information. You can choose if you wish us to keep your contact information for contact purposes at a later time point. If you choose to do so, this data will be kept for approximately 10 years.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized Chapman University personnel, and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Study records provided to authorized, non-Chapman University entities will not contain identifiable information about you; nor will any publications and/or presentations without your separate consent.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Dr. Niklas Ignasiak, BSPT, MS, PhD
Assistant Professor
Chapman University, Department of Physical Therapy
Rinker Health Science Campus, 9401 Jeronimo Rd, Irvine, CA 92618
Telephone: 714.516.5503
eMail: ignasiak@chapman.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 714-628-2833 or irb@chapman.edu if:

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

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form or participate in this study until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form or you may save a copy of this information to keep for your records. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Chapman University.

Contact information repository:

You can choose if you wish us to keep your personal contact information in order to contact you at a later time point for participation in another study.

_____**Yes**, I wish my contact information not to be deleted after study termination.

_____**No**, I wish my contact information to be deleted after study termination

Signature of Participant | Date

Your signature below and/or study participation indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

I agree to participate in the study.

Subject Signature | **Date**

Printed Name of Subject

Researcher Signature | **Date**

Printed Name of Researcher

CHAPMAN UNIVERSITY
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the Chapman University IRB staff at 714-628-2833 or irb@chapman.edu.