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| **Title of research study** | **Feedback Device to Increase Arm Swing During Walking** |
| **Investigator and department** | *The principal investigator for this project is Dr. John Jeka, PhD, Professor and Chair of the Kinesiology Department at Temple University.* |
| **Why you are being invited to take part in a research study** | *We are inviting you to participate in this research project because you are a person with Parkinson’s disease (PD), or a person without PD who is interested in contributing to research about PD.* |
| **Participant Rights**  **Who can I talk to?** | *If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team at*  John J. Jeka, PhD  Professor and Chair  Temple University  Department of Kinesiology  Pearson Hall Rm 230  1800 N. Broad Street  Philadelphia, PA 19122  Phone: 215-204-4405  Fax: 215-204-4414  Email: [jjeka@temple.edu](mailto:jjeka@temple.edu)  W. Geoffrey Wright, PhD (Co-Investigator)  Department of Physical Therapy  Department of Bioengineering  Temple University, Philadelphia, PA, 19140  215-707-9519  [wrightw@temple.edu](mailto:wrightw@temple.edu)  Elizabeth Thompson, DPT, NCS (Graduate Student Investigator)  Department of Physical Therapy  Department of Kinesiology  Temple University, Philadelphia, PA 19122  215-204-0448  [eliz.thompson@temple.edu](mailto:eliz.thompson@temple.edu)  Peter Agada (Laboratory Technician and Investigator)  Department of Kinesiology  Temple University, Philadelphia, PA 19122  215-204-0448  [tuf30575@temple.edu](mailto:tuf30575@temple.edu)  Hendrik Reimann, PhD (Post-Doctoral Investigator)  Department of Kinesiology  Temple University, Philadelphia, PA 19122  215-204-0448  [tuf79669@temple.edu](mailto:tuf79669@temple.edu)  Roshita Rathore (Graduate Student Investigator)  Department of Kinesiology  Temple University, Philadelphia, PA 19122  215-204-0448  [tuf73641@temple.edu](mailto:tuf73641@temple.edu)  *This research has been reviewed and approve by an Institutional Review Board. You may talk to them at (215) 707-3390 or e-mail them at:* [*irb@temple.edu*](mailto:irb@temple.edu) *for any of the following:*  *• 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 subject*  *• You want to get information or provide input about this research*  *You are also encouraged to ask the research team any questions you may have, including before, during, or following the time that this consent form is discussed with you.* |
| **Why are we doing this research?** | *People who have Parkinson’s disease (PD) may have trouble walking and moving their limbs. Giving them reminders about the right way to move can help, but it is very difficult to get those reminders when there is no doctor or physical therapist around. This research study is being conducted to understand more about how people with PD interpret sensory information when they are walking, and why they sometimes need reminders during walking. This research study is also being conducted to test a wireless, portable device that will detect a person’s arm swing while walking and give reminders (through a vibration or “buzzing”) of how to move the right way.*  *We are including both people with PD and people without PD in our study. This way, we can compare any differences in responses to learn more about how PD affects walking and movement.* |
| **How long will the research last?** | *For the first part of the study, you will participate in 2 sessions that will last about 2 hours each.*  *For the second part of the study, you will be asked to participate in 7 evaluation/training sessions with study staff, lasting 60 minutes per session. Six of the sessions will be conducted over a period of 2 weeks. You will then be asked to use the study devices when you walk for exercise at home, 30 minutes per day, 5 days per week for 6 weeks. After the period of home exercise, you will return for the final evaluation session with study staff.* |
| **How many people will be studied?** | *We expect about 180 people will be in this research study.* |
| **What should I know about this research?** | * *Someone will explain this research to you.* * *Whether or not you take part is up to you.* * *You can choose not to take part.* * *You can agree to take part and later change your mind.* * *Your decision will not be held against you.* * *You can ask all the questions you want before you decide.* * *If you agree to participate, you may change your mind at any time without penalty or loss of benefits to which you are otherwise entitled.* |
| **What happens if I say yes, I want to be in this research?** | Evaluation and training sessions for the experiment will be performed at the Virtual Environment and Postural Orientation (VEPO) lab at Temple University. In some cases, walking trials with the cuing device may be help at Willingboro library, Willingboro, NJ, for people unable to travel to Philadelphia. You should plan to wear shorts, t-shirt or sleeveless shirt, and comfortable walking shoes. If you agree to participate, you will participate in 2 testing sessions for the first part of the experiment, with each session lasting 2 hours. For the second part of the experiment, you will participate in up to 7 evaluation/training sessions (lasting 1 hour each) and a 6-week home walking program. The 6-week home walking program will involve walking for 30 minutes per day (with rest as needed) for 5 days a week.  All participants will be asked to complete the Mini-Mental Status Exam, a 30-question questionnaire designed to detect cognitive problems, to ensure you will be able to follow the study directions.  You will be assessed by a rehabilitation professional experienced with treating persons with PD. This professional will give you tests to examine how well you are moving. If you have PD, you will be given the Hoehn and Yahr scale, the Timed up and Go (TUG) test, the miniBESTest, the Activities-specific Balance Confidence Scale (ABC), the Functional Gait Assessment (FGA), the Parkinson’s Disease Questionnaire – 39 item (PDQ-39), and a part of the Unified Parkinson’s Disease Rating Scale (UPDRS). If you do not have PD, you will just be asked to complete the TUG test, ABC, FGA, and miniBESTest. All participants will also be given a test to assess the sensation in your arms and legs using cotton swabs or thin bristles.  We will videotape all of your walking.  You will have adhesive markers attached to your skin with tape, to allow us to better see your movements on the videotape. You will also have adhesive sensors attached to your skin with tape to measure the activity in your muscles. For some trials, you will have electrodes attached to your skin on the back of your neck, which will deliver a small current while you are walking that may give a tingling sensation.  You will be asked to walk short periods of time on a treadmill, wearing a harness for safety.  You will be asked to walk certain distances (up to 2 minutes) on indoor and outdoor surfaces like tile, pavement, hardwood, or a treadmill. You may be asked to walk on an unobstructed path or on a path with one 7-inch tall obstacle which will be visible to you. We will attach a small device to each arm (about the size of a wristwatch) by a fabric strap like a wristband, a small pouch or belt around your waist, and may ask you to wear another wristwatch-like device on your legs. The devices and videos will help us measure the length of your steps and your arm swing as you walk. Some of the devices will also have small vibrators inside them to give you cues for how to move as you walk. You will be asked to walk with the cues and without the cues. You may be asked to walk short distances repeatedly during the testing session. You will be given as much rest as you need in between walks. For the home walking program, you will be loaned a pair of sensors to wear on your wrists, and a device to gather and store the data, as well as to track your walking through a password-protected program.  ***Sessions will be recorded using a video recorder to learn more about your walking. We may be interested in using these recordings to teach students or present the research to others, but this is optional; your selection of “yes” here indicates your permission for us to use the videos in education or presentations..***  ***Yes\_\_\_ No\_\_\_***  ***I agree that my session(s) may be used to present the research to others.***  If you are a person with PD, you will be asked to participate while ON your anti-parkinsonian medication. |
| **Is there any way this research could be bad for me?** | *No identifiable psychological, social, or legal risks exist for participating in this study.*  *There may be some potential physical risks, including loss of balance and possible fatigue in feet, legs and back, and a potential risk of falling and injury. The measures in place to minimize this risk include having a member of study staff walking next to you during all the walking tests, and using a gait belt around your waist that the spotter can hold onto if you become unsteady. Whenever a study staff member is not walking with you, you will have a harness for safety and to prevent falling. There is also a potential risk of skin irritation at the site where the study device is attached by its band, or where the markers or electrodes attach to your skin. To minimize this risk, your skin will be examined before and after applying the device.*  *There may be some potential privacy risk in this study. We take all possible steps to minimize the risk of disclosing your identity or information. Please see the section below, “What happens to the information collected for this research?” for more information about this.* |
| **Will being in this research help me in any way?** | *You are not expected to receive any direct medical benefits from your participation in this study. However, your participation may help researchers understand how cues can change a person’s movement patterns. We hope that, in the future, other people might benefit from this study through more effective techniques to help them improve movement. If you complete each session, you will be paid $40 for each study session.* |
| **What happens to the information collected for this research?** | *To the extent allowed by law, we limit the viewing of your personal information to people who have to review it. We cannot promise complete secrecy. The IRB, Temple University, Temple University Health System, Inc. and its affiliates, and other representatives of these organizations may inspect and copy your information. If you are a person with PD, you will also need to sign a separate “Authorization to use and disclose your protected health information” to be a part of this research. If you are a person with PD, we will ask you for information regarding your PD diagnosis and current medications you are taking. This information will be kept in a secure location, such as a locked office and encrypted, password protected electronic data storage. We may publish the results of this research. However, we will keep your name and other identifying information confidential.*  *Any potential loss of confidentiality will be minimized by storing data in a secure location such as: locked office and encrypted, password protected electronic data storage. All subjects are identified using an alpha-numeric (letters and numbers) identification system (such as “Subject1.”) Videotaped testing sessions will be used for educational purposes and seminar presentations of the study findings and will be destroyed after 5 years. All data will be destroyed in 10 years.*  *If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of Temple University or governmental authorities if you or someone else is in danger or if we are required to do so by law.* |
| **Is there anything else I should know about this research study?** | *Dr. Jeka, the principal investigator, has equity interests with Bertec, Inc., the company that holds joint ownership of the Armsense device. Further, Armsense, the device used in this study and developed by the principal investigator, has a US patent pending. This interest is considered a financial conflict of interest. If you would like more information, please use the contact information given in the Participant Rights section of this form.* |
| **Statement of Consent** | *Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.*  *If you agree to participate, please sign your name below.* |
| **Signature and Date** | **NAME OF SUBJECT[Please Print]** |
| **SIGNATURE OF SUBJECT** |
| **DATE** |
| **NAME OF RESEARCH STAFF Conducting Informed Consent** |
| **SIGNATURE OF RESEARCH STAFF** |
| **DATE** |