University of Wisconsin Eau Claire

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Informed Consent Form
Fall 2025

Study Title: Combining vibrotactile coordinated reset fingertip stimulation with resistance training to improve functional and clinical outcomes in individuals with Parkinson's Disease

Study Dates: September 2, 2025 – May 15, 2026

Principal Investigator Details
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Introduction: You have been invited to engage within a research study conducted by Dr. Nicholas Beltz, Associate Professor, Department of Kinesiology, University of Wisconsin- Eau Claire. The research you will take part in would help us answer the question, "Does the addition of vibrotactile coordinated reset (vCR) gloves to a resistance training program improve muscular strength, endurance, flexibility, fall risk, gait speed, and Unified Parkinson's Disease Rating Scale scores in individuals with Parkinson's Disease?"

Purpose of the Research: The primary purpose of this research is to examine the impact of combining 12-weeks of resistance training and vCR on changes in Parkinson's Disease symptoms and physical function.

Potential Benefits: By participating in this study, you will have access to a set of vCR gloves at no cost. The collected data will be useful to determine the utility of vCR in helping maintain functional outcomes in individuals with Parkinson's Disease. You may also experience improvements in your muscular fitness, balance, gait speed, and flexibility by participating in the resistance training program.

Inclusion/Exclusion Criteria: You will need to be a participant in the UWEC Parkinson's Exercise Program at UW-Eau Claire. The program takes place during the academic year, Tuesday/Thursday from 9:30-11am for 12-week sessions. You must have diagnosed Parkinson's Disease, confirmed by your primary care provider. You will not be able to participate in the study if you have additional diagnoses of neurological disease, cardiovascular disease, orthopedic issues that preclude safe participation in exercise, use a pacemaker device, or are currently receiving deep brain stimulation therapy.

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Vibrotactile Coordinated Reset (vCR) Gloves: The vCR gloves are worn on the hands with small motors embedded within the glove fingertips, with exception to the thumb (see picture below). The motors are connected to a small box contained within a pouch that is worn around the torso. While worn, the motors in each fingertip vibrate in a randomized pattern at a specific frequency and duration. Student researchers assembled the gloves in the Biomedical Engineering laboratory and were overseen by UWEC faculty Drs. Elizabath Glogowski and Marc Mc Ellistrem. During and after glove assembly, the research team evaluated each glove for quality assurance, and the unit was determined safe for use. Please refrain from all activities that could expose the gloves or battery pack to water or make them excessively dirty (washing dishes, laundry, gardening). Exposing the gloves to excessive moisture may compromise the integrity of the device but the wearer of the glove is not at risk of injury through electrical stimulation. If worn properly, there will be no risk for the glove wire exposure as they are in a protective sheath and sewn onto the outside of the glove. The gloves can be safely cleaned with disinfecting spray. You will be asked to bring the gloves to the Parkinson's Exercise Program for regular cleaning and maintenance. These gloves are not approved by the Food and Drug Administration to treat or prevent any disease. Similar studies have been conducted at Stanford University and Rice University to examine the impact of vCR gloves.

Research Procedures: Involvement in this study will require participation in the Parkinson's Exercise Program (PEP) during the 2025-2026 academic year. Parkinson's Exercise Program sessions are hosted twice per week for a total of 12-weeks each semester.

<u>Study Design</u>

- Participants will be randomly assigned to a group prior to starting the Fall 2025 PEP
    - Group 1 will engage in resistance training only during the Fall 2025 PEP.
        - Resistance training sessions during PEP will consist of two sets of 8-10 exercises using a combination of resistance training machines and free weights. Resistance

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training sessions will be total-body, in nature.
    - Group 2 will engage in resistance training and wear vCR gloves twice per day for 2hr each session (morning and evening).
- There will be a 10-week break between Fall and Spring PEP, in which participants will not engage in resistance training or receive vCR stimulation.
- Groups will switch treatments upon starting the Spring 2026 PEP.

Physiological Testing Sessions

Throughout the study, each participant will complete four separate physiological testing sessions: at the beginning and end of the Fall 2025 and Spring 2026 semesters. The first physiological session will begin with a verbal explanation of the study procedures, informed consent, and health history questionnaire. You can ask questions throughout the entire process.

Each physiological testing session (~30 mins) will involve the following:

- Hand Grip Dynamometry: You will stand, grasp a handle, and squeeze the handle tightly for three seconds. You will repeat this procedure using each hand.
- Chair Stand: You will repeatedly stand and sit in a chair, as many times as possible for 30 seconds.
- Arm Curl: While hold a 5-lb (female) or 8-lb (male) dumbbell, you will complete as many repetitions of a bicep curl as you can in 30-seconds.
- Flexibility: While seated in a chair, you will reach your hand to your toe. You will repeat the test with each leg.
- Fall Risk Assessment: You will stand on a platform in a comfortable position. You will compete two 40-second trials, one with your eyes open and the other with your eyes closed.
- Gait Speed: At a comfortable and self-selected pace, you will walk ten meters on a track in a straight line and timed with a stopwatch.

If you agree to participate, your email will be shared will Mayo Clinic so that the Mayo research team can contact you. While at Mayo Clinic, you will be asked to complete a neurological assessment regarding your Parkinson's Disease called the Movement Disorder Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS). This assessment will be held at Mayo Clinic and administered by a Mayo Clinic Neurologist at four points: at the start of the project in Fall 2025, at the end of the Fall 2025 semester, at the beginning of the Spring 2026 semester, and at the end of the Spring 2026 semester. Each study visit will take up to 60

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minutes to complete.

Possible Risks:
Subjects may experience muscular soreness, an expected and normal response to resistance training. There may be physical discomfort (e.g., pinching, numbing, skin indentations, etc.) associated with wearing the vibrotactile glove and study personnel will be vigilant for this possibility.

Please refrain from all activities that could expose the gloves or battery pack to water or make them excessively dirty (washing dishes, laundry, gardening). Exposing the gloves to excessive moisture may compromise the integrity of the device but the wearer of the glove is not at risk of injury through electrical stimulation. If worn properly, there will be no risk for wire exposure as they are in a protective sheath and sewn onto the outside of the glove. The research team will be evaluating the patient response to the glove on a weekly basis in the Parkinson's Exercise Program to monitor adverse events to glove wearing.

Trained researchers and technicians will minimize risk by administering proper testing protocols and resistance training sessions. The research team will maintain vigilance for the presence and worsening of symptoms while wearing the device. The research team strongly advises that you report any adverse events to your primary care provider. Any adverse events will be documented, and the subject will be instructed to contact their primary care physician.

Confidentiality and Privacy:
Data will be coded to maintain confidentiality; thus, no data will be personally identified with you. Your name will not appear in any presentation or publication coming from this research.

During the study, we will protect confidentiality of research subjects and data by assigning identification numbers to each participant. We will ensure confidentiality by only allowing one student to collect data at a time. Sharing data will only be within the research group. Only necessary information that will contribute to our research hypothesis and question will be tested and reported. At the end of the research our data will be locked in a drawer for five years post research. Data collected at the Mayo Clinic will be de-identified by assigning identification numbers to each participant. De-identified data collected at the Mayo Clinic will be shared with the UWEC team through an encrypted network.

Contact Information:
If you have any questions, please direct them to:
Nicholas Beltz, PHD, ACSM-RCEP
Associate Professor in Kinesiology

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This research study, including this informed consent form, has been reviewed and approved by the University of Wisconsin – Eau Claire Institutional Review Board for the Protection of Human Subjects (Proposal ID: 202541265). This board ensures that research studies involving human participants are ethical and follow appropriate federal and state regulations. Any questions or concerns about your rights as a participant in this research should be directed to:

Dr. Michael Axelrod
Committee Chair, Institutional Review Board for the Protection of Human Subjects
University of Wisconsin – Eau Claire
715-836-5020
axelromi@uwec.edu

By signing the informed consent, you agree to participate in this research study. You acknowledge understanding the study's procedures, what will be asked of you, and the potential risks coming from the study. You understand and meet the inclusion criteria of the study. You understand that there will be no financial compensation for your participation. You also understand that participation is voluntary and is not a requirement of receiving benefits or services from the University of Wisconsin-Eau Claire or any other organization. The research team strongly recommends that you notify your primary care provider and/or healthcare team responsible for treating your Parkinson's Disease that you are participating in this research study. Your right to participate in the Parkinson's Exercise Program will not be impacted should you choose to withdraw from the study. If you agree to participate, you may choose not to answer any given questions, and you may withdraw your consent and discontinue your participation at any time. If you choose to participate in this study, there are additional rules that we will follow to protect your private health information (PHI). Your PHI is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA), which is a federal law passed to protect the privacy of your Protected Health Information. By signing this document, you agree to participate in this research study. You are also authorizing the research team to use and disclose your Protected Health Information for this research study. This includes your health history, current and future medication, and data collected from the

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research procedures including tests, interviews, and questionnaires. By returning your completed informed consent form, you are giving your consent to take part in this study.

Participant Printed Name: _____ Date: _____

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____