

Effects of Nordic Walking Exercise on Gait, Motor/Non-motor Symptoms,
and Exercise Biomarkers in Individuals with Parkinson's Disease

IRB PROTOCOL # 20-101-H

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DATE: 12/13/19



This research protocol has been approved by the Institutional Review Board at Grand Valley State University. Study No. 20-101-H Expiration: N/A.

Research Informed Consent Form

Research Project Title: Effects of Nordic walking exercise on gait, motor/non-motor symptoms, and exercise biomarkers in individuals with Parkinson's disease

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Study Collaborator: Julie Hall, MHS, MT (ASCP); Grand Valley State University

Study Sponsor: Grand Valley State University Center for Scholarly and Creative Excellence
Collaborative Research and Creative Activity Initiative

1. Introduction and Key Information

Key Information for You to Consider

- **Voluntary Consent.** You are being invited to take part in a research study. It is up to you whether you choose to join (participate) or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to join or discontinue joining.
- **Purpose.** The purpose of this research is to examine the effects of Nordic pole walking exercise on walking function, movement and non-movement Parkinson-related symptoms, and certain exercise-related chemical indicators (biomarkers) in people with Parkinson's disease.
- **Duration.** Your participation will be approximately 6 months.
- **Activities and Procedures.** The activities are 6 weeks of supervised Nordic pole walking training and 3 months of independent Nordic pole walking exercise. The evaluation procedures are four 1-hour test periods to assess your walking, movement and non-movement symptoms. Also, you will be asked to provide blood and saliva samples at eight scheduled times during the study to examine the changes in the chemical levels.
- **Risks.** There may be fatigue or a small risk of losing your balance during Nordic walking exercise. Blood taken from your vein may cause mild discomfort, pain, bruising, feeling of lightheadedness, and a rare risk of infection.
- **Benefits.** You will be given Nordic walking poles and training, and an electronic step counter (Fitbit Inspire) to wear free of charge. You will be coached to maximize the benefit of the exercise training to you personally. Your participation in this study may add to the understanding of the effects of Nordic walking exercise in persons with Parkinson's disease.
- **Alternatives.** Participation is voluntary, and the only alternative is not to participate.

2. Reason for Invitation

You are being invited to be in this research study because you have Parkinson's disease (PD). To voluntarily participate in this study, you:

- must have no change in your Parkinson's drug treatment and dose over the past month
- must have functional vision (are able to complete your daily activities inside and outside of the home with or without glasses)
- must be able to walk 500 feet on level surfaces without stopping, without help from another person
- must be able to go up and down 10 steps without help from another person, with or without a railing
- may not have any other neurologic conditions (such as stroke and brain injury)
- may not have muscle, joint, or heart conditions that limit your ability to safely walk independently for exercise
- may not have cognitive problems as measured on a memory test
- may not have recent deep brain stimulation-DBS (within last 3 months) or planned DBS in next 4 months
- may not have been previously trained in Nordic walking technique and are currently performing moderate intensity Nordic walking exercise at least 3 days per week

These criteria are to ensure both your safety to participate and the accuracy of this study.

3. Study Activities and Procedures

This study will take place over a period of six months and 12 people are expected to join. There are three parts in this study: exercise, study tests, and sample collection. The next picture is an overview of your participation in the study. The blue arrows show study tests and red arrows show sample collection. You will come to the Grand Valley State University Cook DeVos Center for Health Sciences building (GVSU CHS) in downtown Grand Rapids for testing and sample collection.



Exercise: If you volunteer in this study, you will join a 6-week supervised Nordic pole walking exercise training and a 3-month independent Nordic walking exercise program. The Nordic walking poles will be provided to you free of charge. Nordic walking training will be done outdoors in a small group, 3 times per week for the first 2 weeks and 2 times per week for the last 4 weeks, at a local community track with weather permitting. Training is designed to meet your abilities and supervised by the primary researcher. You will have one-on-one coaching on how to Nordic pole walk from a trained student researcher. Each Nordic walking exercise period is one hour: 10 minutes warm-up, 30-45 minutes of Nordic walking exercise, and 5 minutes of cool down period. There will be time to

take breaks during training as needed. During this training stage, you will also be asked to practice Nordic pole walking exercise 2 times per week on your own and have a weekly activity log to keep track of your exercise. We will provide an electronic step counter (Fitbit Inspire HR) free of charge for you to wear and to write down your walking distance and daily steps.

Following the 6-week training, you will be asked to continue your Nordic pole walking exercise independently for 3 months, at least 3 times per week, and fill out the weekly activity logs. You will also be asked to complete a monthly fall calendar to track any falls or near falls, so that researchers can ensure your safety with the independent exercise program. You will receive phone contact from the researchers twice monthly during this follow-up stage to ask how the Nordic walking exercise is going and see if you have any questions.

Study Tests: There will be four 1-hour test sessions (T0-A, T0-B, T1, T2; see picture) at GVSU CHS. At T0-A, you will be asked to provide information about your age, medical history and medications, activity level, and fall history. This information will be used by the researchers to guide exercise training and to describe research participants. All sessions will be done during the “on time” of your PD medication schedule, which is within 1 hour of taking your PD medication. You will also be asked to wear athletic shoes or nonslip soled shoes to ensure your safety during testing. In all sessions, we will measure 4 common walking and movement ability tests used by physical therapists and complete 2 questionnaires about your PD-related symptoms. The movement and walking tests will be measured by trained physical therapy student researchers, under the supervision of the primary researcher who is a licensed physical therapist. Additionally, the primary researcher will measure a wide range of common PD symptoms using the Unified Parkinson’s Disease Rating Scale, which is a standard test to assess movement and non-movement parts of PD. The movement part of this test will be videotaped so that it can be scored later by an independent qualified physical therapist. These videotape files will be destroyed when this study is completed. The researchers will tell you which test will be done, and give you instructions on how to do it.

Sample Collection: Your saliva and blood sample will be taken at the 8 times (see red arrows in picture) over a period of 6 months at GVSU CHS. We will measure the chemical changes caused by Nordic pole walking exercise in your samples. You will be scheduled for these appointments between 7:00-8:30 am and asked to refrain from eating any food for 30 minutes or doing any exercise prior to the sample collection. The researchers will give you instructions on how to collect your saliva samples in a collection tube. 3-4 ml of saliva (less than 1 teaspoon) will be collected each time. For blood collection, you will be seated and blood will be drawn by putting a needle into a vein in your arm by a trained person for blood draws. You will have 22 ml of blood taken each visit (for 8 visits). The total amount of blood taken for the whole study of 6 months will be 176 ml (12 tablespoons).

4. Possible Risks or Side Effects of Taking Part in this Study

There are minimal risks for participating in this study. These physical risks are similar to those you might encounter during any daily walking exercise. There is a small chance you might fall, just as there is any time you are walking; however, the trainers will be walking by your side to ensure your safety. You may get tired during exercise and can request a rest at any time. You will tell us if you

have any symptoms that concern you during the exercise and you will be closely monitored by the researcher and trainers. The risks of taking blood include temporary discomfort from the needle stick, possible pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and a rare risk of infection. Risks will be minimized by drawing blood with standard procedures. Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that the information could be lost or stolen. Number 10 in this form discusses what information about you will be used, protected, and shared.

5. Costs for Taking Part in this Study

There is no cost for you to join this study. Parking at GVSU CHS and at the local community track where Nordic walking training will take place will be free of charge. The only likely costs to you will be travel to and from these places. You will not be paid for taking part in this study. Your insurance will not be billed as testing in this study is for research purposes only.

6. What happens if I am injured?

If you are hurt as a result of taking part in this study, the researchers will assist you to find emergency care. In such an event, your insurance will be billed as usual. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance will be your responsibility. By signing this consent form, you are not waiving any legal rights or releasing the parties who are doing this study from liability for negligence.

7. Possible Benefits to You and Society

Although we cannot promise any direct personal benefits from participating in this study, you may learn how to use the Nordic walking poles for your own independent walking exercise. This study will provide helpful information about the possible health benefits of Nordic walking for persons with PD.

8. About Participating in this Study

Joining this study is voluntary and you may stop being in the study at any time. If you decide to stop joining in this study, this decision will not affect your medical care or any benefits that you have. If you stop joining, your permission will be asked to use information collected on you before you stop and you will be asked to return the Nordic poles and Fitbit monitor. If you choose to stop or not have your data or samples used for the study at any time or completion of the study, you should tell the researchers: Cathy Harro (616-331-5974) or Sok Kean Khoo (616-331-5916). However, after the direct link between your information and research data is destroyed, you are unable to withdraw from the study. You may be removed from this study if the researchers decide that it is in your best interest and continuing in the study would be unsafe for you. If you have other medical problems or side effects, the researchers will also decide if you may continue in the study.

9. Sharing of Results

We will verbally share your walking and PD movement/non-movement test results with you upon your request. We will share the results of the study as a whole with you once the study is done if you provide us your email.

10. Privacy and Confidentiality

Your name will not be shared with others or used in any reports on this study. You will be given a research number (ID) and we will have a list of all names and IDs kept in our locked file drawer in our research office. Once your ID-coded test information is collected, it becomes part of the research record for this study and will be stored in a locked filing cabinet or on a computer network with secure password. All hard copies of records will be kept locked up in the filing cabinet, and we will destroy them within 7 years of end of the study. For the highest level of federal protection, a Certificate of Confidentiality has been obtained from the United States Department of Health and Human Services in this study to help protect your privacy. This certificate prevents researchers from being required (subpoenaed) to disclose sensitive information that may identify you for use in the court in most cases.

Only certain people have the legal right to collect, use, and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigators and Collaborator (listed in page 1 of this form) and research students associated with this study
- the GVSU Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research study).

Additionally, a contract physical therapist from Mercy Health, Dr. Katie Dabkowski, will view a video recording of one of your movement tests to score the test. In this case, the video file will be labeled by your research ID only and no other information will be shared.

Your samples will not be used to test for your DNA makeup/changes and your research records will not be released without your permission unless required by the law or a court order. If information about this study is published or presented at scientific meetings, your name and other personal information will not be used.

11. What will Happen with your Blood and Saliva Samples?

Your blood and saliva samples will be labeled with your research ID so that they will not contain information that could directly identify you (de-identified). All samples will be stored at a -80 °C freezer in a secure key card access laboratory at GVSU CHS. We will measure the chemical level changes in your samples in the laboratory. The research records will be stored on a computer network with secure password and the individual research results from your samples will not be provided to you. Your samples will not be used to make a profit and this study does not include whole genome or exome sequencing (test for DNA makeup or changes).

12. After the Study is Over

Your samples will be destroyed after 7 years. Within the 7 years, the researchers may re-test your samples with new tests directly related to the purpose of this study and will not be performed without further IRB approval. Your samples will not be tested for your DNA makeup or changes. Your samples do not have any information that can be linked to you (de-identified) and will not be used to make a profit. You have the right to ask for your samples to be destroyed at any time by contacting Cathy Harro (616-331-5974) or Sok Kean Khoo (616-331-5916).

The researchers will also keep your research data for 7 years. However, your name and other information that can directly identify you will be deleted from the data (de-identified). Your de-identified research data may be deposited in a public repository supported by the National Institutes of Health as required by some scientific publications. You have the right to ask for your data to be destroyed at any time by contacting Cathy Harro (616-331-5974) or Sok Kean Khoo (616-331-5916).

13. Names of Contacts for Questions About the Study

If you have any questions about taking part in this study, or in the event of a research related illness or injury, please contact: Cathy Harro (616-331-5974), Sok Kean Khoo (616-331-5916), or Michael Shoemaker (616-331-3509). If you have any questions about your rights as a research participant, you may contact: Office of Research Compliance and Integrity at Grand Valley State University (616-331-3197) or e-mail: rci@gvsu.edu

Documentation of Informed Consent

By signing this consent form, you certify you have read this form, your questions about the study or this consent form have been answered, and you are voluntarily agreeing to take part in the study. You are giving authorization for researchers to collect self-reported health information relative to this research. You may ask more questions or choose to stop participating in the study at any time without penalty or effect on your medical care or benefits. You have been advised that the researchers in charge of this study may discontinue your participation in this study if it is felt to be in your best interest.
A signed copy of this consent form will be provided to you.

Signature of Study Participant

Date

Printed Name of Study Participant

Signature of Person Obtaining Informed Consent

Date

Printed Name of Persons Obtaining Informed Consent