Participant Consent Form

SNACK PD: "Exercise snacks for people with Parkinson Disease: a pilot randomized controlled trial"

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Sponsor: Parkinson Canada

Contact number for study information and questions:
Tel: 250-862-4181 (8:00 am to 4:00 pm) Email: parkinson.research@ubc.ca

Welcome to the consent form for the study "Exercise Snacks for people with Parkinson Disease: a pilot randomized controlled trial". This study is often referred to as SNACK PD for shorthand.

Please read the consent form carefully before signing the consent. All participants will receive a copy of the consent form to keep for their records.

If at any time you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598. Please reference the study number (H24-02753) when calling so the department can better assist you.

1. Invitation

- You are being invited to take part in this research study because you have been diagnosed with Parkinson's Disease (PD).
- This research study will be conducted in-person at 1) The Humphreys Family Movement Disorder Clinic and UBC Okanagan and 2) through self-management within your own home or work environment.
- Regular contact with the study team will occur either by phone, email at both scheduled time points and on an as needed basis.

- Participation in this research study requires the use of a personal phone, computer, or tablet with internet connectivity.

2. Your Participation is Voluntary

- Your participation is completely voluntary; it is up to you to decide whether or not to take part in this study. This information letter will tell you about the risks and benefits of this study.
- If you wish to participate, please review and sign the Consent Form located at the end of this document. There are 2 identical copies of this consent form; please sign both copies as one is for yourself and the other gets entered into study records.
- If you decide to take part in this study, you are free to withdraw at any time, without need to give any reasons for your withdrawal.
- If you are not willing to participate in the study, you will not lose the benefit of any medical care, education, or other services to which you are entitled or are currently receiving.

3. Who is conducting this study?

Dr. Daryl Wile is the Principal Investigator (PI) for this study. Dr. Wile is appointed with the Southern Medical program at the University of British Columbia Okanagan (UBCO) and the clinical neurologist for the Humphreys Family Movement Disorder Clinic at Kelowna General Hospital.

4. Funding

This study is funded by a Pilot Project Grant from Parkinson Canada**.**

5. Background:

Physical activity helps people with PD, but many people living with PD are insufficiently active. Reasons include lack of time, low motivation, no access to exercise equipment and unpredictable symptoms. “Exercise snacks” are 1–2-minute bouts of vigorous exercise done periodically throughout the day. We believe exercise snacks are well suited to people with PD and want to test this approach.

6. What is the purpose of the study?

This study will see if people with PD can stick to a program of Exercise Snacks, and if this helps their walking ability, and quality of life. We will recruit 40 participants to do one of two styles of Exercise Snacks. We will take what we learn and use it to design a larger clinical trial.

7. Who can participate in this study?

- Adults (19 years of age or older) with Clinically Established PD
- Medically cleared to exercise by their physician
- A score of ≤ 3 on the modified Hoehn & Yahr scale (this means signs of PD can be on one or both sides, and mild balance difficulty is permitted. People should be able to walk on their own)
- Have access to a computer, tablet, or smartphone with internet connection.

8. Who should not participate in this study?

- If you have a physical disability preventing exercise
- If you can't walk without help
- If you are in another clinical trial that would interfere with this study.
- If you have a scheduled event (e.g., medical or surgical procedure, travel in the next 3-4 months) that would interrupt participation in the study.

9. What does the study involve?

- To start, you will go through some questionnaires about your exercise and activity history and your illness.
- We will set up a visit to the UBC Okanagan Campus. This will take about 90 minutes. You will go over some balance and walking testing and then you will try examples of the different types of exercise in the study.
- We will ask for a recent clinic appointment note from your treating neurologist for information about your PD including when it started, and what medicine you take.
- We will record how your neurological exam for PD has recently looked (within 6 weeks; this is called the MDS-UPDRS III score). We can take this score from your recent clinic appointment note, if available. If a recent score is not available, Dr. Wile will obtain a new score as part of the research study at the baseline appointment scheduled at UBC Okanagan Campus.
- We will randomly assign you to one of the two different exercise types (like the flip of a coin). These are different in terms of how intense the exercise is, but both exercise types are designed for people with PD. We will show you how to use the Seven Movements online exercise platform (see below) to see example videos and rate the intensity and enjoyment of the exercise each time you do one.
- Participants will be encouraged to bring their personal devices (e.g., laptop, tablet, phone) to the baseline assessment to ease orientation to the Seven Movement platform. This allows the study team to provide individualized support for technical learning challenges that may arise. Bringing one's personal devices will be optional. The study team will offer loaner devices, if needed, for the duration of the intervention, ensuring no participant is excluded due to device access or compatibility issues.
- You will go over the exercises you will do with a kinesiologist (an exercise specialist) to be sure they make sense and are safe for you. We will also check your heart rate and blood pressure on this visit.
- You will be asked to wear a wearable device, Actigraph LEAP, on either wrist at the start of the study and end of the study, for a total of 10 days each. This device does not send information wirelessly. The data it collects about your activity level and heart rate stays on the device until you give it back to the study team. Your name or identity are not stored on the watch and it does not track your location (there is no 'GPS' on the device). Returning the device to the study team will be at no cost to yourself. The study team keeps the data on a protected computer.
- After the visit to UBC Okanagan you will start the exercises the next Monday. Every week, you will have two different options to do, and each one takes two minutes. Your goal is to do 10 per week, or two per day with two days off each week.
- You can decide when and where you want to do the exercises based on when you feel able. The exercises are simple, and don't need special clothing, preparation, or equipment.
- We will call you to check in during week 1, 2, 4, 8 and 10 and ask if you have any questions or safety concerns.

- After 12 weeks, we will see you again at UBC Okanagan to do walking and balance tests and surveys about the study experience. This visit should take 30-60 minutes.

9.1 Study Monitoring

Participants will undergo monitoring through the following processes:

1. **Informal Check-in Calls**: Study coordinators will make phone calls on the Tuesday of Weeks 1 and 2 to check in with participants.
2. **Interim Safety Review Calls**: Formal safety review calls will take place on the Tuesday of Weeks 4 and 8. During these calls, participants will discuss their experiences with the exercises completed so far.
3. **Scheduling Call**: In Week 10, a call will be made to schedule the final study visit, which will occur within two weeks after the study completion.
4. **Ongoing:** At any point throughout the study the research team will be fully accessible to you by phone or email or in-person, if necessary, should you have any questions, concerns or you are in need of support.

9.2 Time Commitment:

Screening w/ Dr. D. Wile	1 x 15 min = **0.25 hours**
Onboarding & baseline measurements	1 x 90min = **1.5 hours**
12-week active trial period	2 min exercise snacks, twice daily, 5 days per week, for 12 weeks = ~4 hrs total
Participant check-ins (variable)	Minimum 6 x 15 min per = 1.5 hours
Post-study baseline measurements /discussion	1 x 30min = 0.5 hours
Post-study Questionnaire	1 x 30 min = 0.5 hours
TOTAL *(appx)*	**8.25 Hours**

10. What are the risks to myself?

This study was created with help from experts in PD exercise so the exercises should work well for most people. To keep everyone safe, we start with a safety check based on Canadian exercise guidelines. Participants can decide when they feel safe and ready to do their sessions.

The risks are like what people experience exercising in daily life, such as getting tired, dizzy, or having sore muscles. It's a good idea to have someone nearby to help if needed.

When wearing Actigraph LEAP device if you have any skin irritation or discomfort, you can take it off for a break. We would like you to wear it as much as possible for the five day periods we will go over with you - these happen for five days before the study, five days twice during the study, and after the study.

Joining the study is optional, and you can stop anytime.

If any medical concerns come up during the study, Dr. Wile is overseeing the study and will offer an appointment at the Humphreys Family Movement Disorder Clinic. If you're already a patient, your chart will be updated. If you're not already a patient, a letter about this medical concern will be sent to your family doctor with advice on what to do next.

11. What are the potential benefits of participating?

This study might help people with Parkinson's Disease who are:

- Unable to do longer exercises.
- Unable to do exercises that need special equipment.
- Unable to consistently exercise at a scheduled time.
- Struggling with variable or unpredictable physical ability and motivation to exercise during the day.

12. What if new information becomes available that may affect my decision to participate?

You will be advised of any new information that may affect your decision to participate. You may be invited to sign an updated consent form in that case to participate in the study.

13. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the greatest extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the study team know.

14. How will my taking part in this study be kept confidential?

- Your confidentiality will be upheld. Research records that identify you may be inspected in the presence of the Investigator or their designate, and by representatives of the Research Ethics Board for monitoring purposes. No information or records that disclose your identity will be published without your consent, nor will information or records be released without your consent unless required by law.

- As a participant in this study, you will be assigned a unique study number. This number will not include any personal information that could identify you, such as your Personal Health Number, Social Insurance Number, or initials. Only this unique number will be used on any research-related information collected about you throughout the study, ensuring your identity remains confidential.

Information that identifies you will be retained solely by the Principal Investigator and/or their designate. The list linking your name to the unique study number will not be removed or released without your consent, except as required by law.

- Your rights to privacy are protected by federal and provincial laws, which mandate safeguards to ensure your privacy is respected. You also have the legal right to access the information about you provided to the sponsor and, if necessary, the opportunity to correct any inaccuracies in this information. Further details about these laws can be requested from your study team.

- The de-identified research data collected during the study may be published or deposited in a publicly accessible location at the time of publication. This data may include demographic information (e.g., age, sex, years of education). At no point will identifying information, such as your name, birth date, or address, be included in such data. While this practice enhances the transparency of the research and allows for broader access to the data, it means that other researchers may analyze the data for purposes beyond those outlined in this consent form. Once data is made publicly available, you will not have the option to withdraw your data. The potential risk of being identified through publicly available data is currently considered low, although it is difficult to ascertain definitively.

- Any hardcopy documents will be securely stored in a locked filing cabinet of a locked office of study personnel at UBC Okanagan.

- Electronic files will be encrypted and stored within a password protected software platform, Redcap, provided by UBC Advanced Research Computing (ARC) for data capture. The ARC REDCap platform meets the requirements of UBC Information Security Policy SC14 and associated Standards, and has undergone a Privacy Impact Assessment (PIA01956).

- Access to study files will be limited to the Principal Investigator, Co-investigators, and research coordinators.

15. What happens if something goes wrong?

- By signing "**Yes, I consent to participating in the study**" on this consent form, you do not give up any of your legal rights and you do not release the study team, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and by the study sponsor [University of British Columbia].
- If you have any concerns, please contact Dr. Daryl Wile (principal investigator) for further information at daryl.wile@ubc.ca

16. What will the study cost me?

- There are no direct costs associated with participating in this study.

- Any costs that participants could incur associated with parking for visiting UBC Okanagan will be covered by the study.
- If there are any unexpected receipts related to costs of the study, participants will be asked to retain them and provide them to the research team at the end of the study period to receive reimbursement.
- To participate in this study, you will require an internet connection. Some internet service plans have limited use per month. If you have a limited use internet service plan, and you exceed your monthly usage, you will be responsible for any indirect costs or additional charges by your service provider.

17. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Daryl Wile at daryl.wile@ubc.ca or the research team at parkinsons.research@ubc.ca

18. After the study is finished

Once the study is completed and the data are analyzed, you will be sent a report on your overall function and the normative values. The report does not provide any diagnostics and you will be encouraged to consult your neurologist or family physician if any values are out of normative ranges.

19. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by email at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

Please reference the study number (H24-02753) when calling so the Complaint Line staff can better assist you.

Signed Consent Form

Research Records Page

By signing "Yes, I consent to participate in the study" means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I consent to wearing a smartwatch device (Actigraph LEAP) during part of this research study, that will record my heart rate and activity levels, and that I may take it off at any time if it is uncomfortable.
- I understand that my participation in this study is voluntary and I can refuse to participate or to withdraw from this study at any time, and this will not change the quality of care I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I have read the Consent Form and I freely consent to participate in this study.

Consent to participate in (H24-02753):

Snacks PD: "Exercise snacks for people with Parkinson Disease: a pilot randomized controlled trial"

Please tick <u>one</u> statement only:

○ Yes, I consent to participating in the study.

○ No, I do not consent to participating in the study.

Please write your name and email address below:

First name *(legal)*: _____

Last name *(legal)*: _____

Email address: _____

Full signature: _____

Date: _____

End of response

Thank you for taking time to complete the **"Exercise snacks for people with Parkinson Disease: a pilot randomized controlled trial"**

Signed Consent Form

Participants Page

By signing "Yes, I consent to participate in the study" means:

- I have read and understood the information in this consent form.
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- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
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First name *(legal)*: _____

Last name *(legal)*: _____

Email address: _____

Full signature: _____

Date: _____

End of response

Thank you for taking time to complete the **"Exercise snacks for people with Parkinson Disease: a pilot randomized controlled trial"**