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PROTOCOL

Official Title: Walking and mHealth to Increase Participation in Parkinson Disease

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PROTOCOL AND CONTACT INFORMATION

Protocol Number (To be assigned by IRB Office):	4854E
Protocol Title:	Walking and mHealth to Increase Participation in Parkinson Disease (WHIP-PD)
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STUDY SUMMARY

Objectives/Aims

Parkinson disease (PD) is one of the most disabling chronic health conditions affecting older adults globally. Of particular concern is walking decline, which is considered a red flag signaling emerging disability. The primary factors that limit engagement in walking in PD are psychological (e.g., low self-confidence) rather than physical (e.g., movement impairments) in nature. We will evaluate an approach targeted at enhancing walking activity by addressing not just movement but also psychological factors. Our "connected behavioral approach" links physical therapists to persons with PD using a mobile health (mHealth) platform that incorporates strategies to increase self-confidence and provides goal-oriented, dynamic walking routines and exercises to enhance walking over the course of one year. We will compare this approach to a control intervention which provides equivalent components and dosing of walking and exercises to enhance walking delivered by physical therapists but without using mHealth.

Specific Aims and Hypotheses:
Primary Aims: Determine if our "Connected Behavioral Approach" is more effective than an active control in increasing real-world walking activity in persons with PD. **Hypothesis 1:** Participants in the mHealth arm will accumulate **(1a)** more daily steps (Step Activity Monitor worn in the free-living environment) and **(1b)** more moderate intensity steps (# of minutes of >100 steps) at 1 year compared to an active control condition.

Secondary Aims: Determine if our "Connected Behavioral Approach" is more effective than an active control condition in improving walking capacity in persons with PD. **Hypothesis 2:**

Participants in the mHealth arm will have greater walking capacity (6-min walk test, 10-meter walk test) at 1 year compared to the control arm.

Eligibility Criteria

Inclusion Criteria: Based on our experience conducting exercise trials in PD, the following criteria have been established to ensure participants can safely engage in a home/community walking and exercise program.

During COVID19, all potential and currently enrolled participants will be screened for High Risk of severe illness from COVID19 and will be eligible based on the university guidelines at the time of screening.

Inclusion Criteria:

1. diagnosis of idiopathic, typical Parkinson disease according to the UK Brain Bank Criteria;
2. Hoehn & Yahr stages 1-3 (mild to moderate disease severity);
3. stable on all PD medications for at least 2 weeks prior to study entry;
4. willing and able to provide informed consent.

Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria):

Exclusion Criteria:

1. < 18 years of age;
2. Pregnant;
3. diagnosis of atypical Parkinsonism;
4. Hoehn & Yahr stages 4-5;
5. engaged in a walking program for greater than 90 minutes per week for at least 1 month;
6. engaged in an exercise regime of moderate intensity for greater than 90 minutes per week for at least 1 month;
7. a score of $\geq$ 2 on item 7 of the new freezing of gait questionnaire (moderately or significantly disturbing freezing episodes during daily walking);
8. significant cognitive impairment
9. unstable medical or concomitant illnesses or psychiatric conditions, which in the opinion of the investigators would preclude successful participation;
10. cardiac problems that interfere with ability to safely exercise (i.e., uncontrolled congestive heart failure, complex cardiac arrhythmias, chest pain or pressure, resting tachycardia (>120 beats/min); uncontrolled BP (resting systolic BP >180 mmHg or diastolic BP >100 mmHg));
11. orthopedic problems in the lower extremities or spine that may limit walking distance (i.e., severe arthritis, spinal stenosis or pain);
12. unable to walk for 10 continuous minutes independently;
13. live in an institution or medical facility (i.e., not in the community)

If participants are deemed ineligible based on the inclusion/exclusion criteria, they will be informed that they do not meet the necessary criteria to participate in this study. Participants will not be informed which categories were not met (i.e., cognitive impairment). Participants will simply be informed that they did not meet the collective criteria.

RECRUITMENT

At BU, recruitment will occur primarily through the PD and Movement Disorders Center at the School of Medicine/Boston Medical Center and The Center for Neurorehabilitation (CNR) serving more than 2000 people with PD. At WU, recruitment will occur through the Movement Disorders Center at WU School of Medicine, which follows more than 2,500 individuals with PD. At WU, recruitment will also occur through Volunteers for Health, EPIC, and MyChart. Recruitment will occur in the following ways: 1) potential participants from patient registries at each institution are contacted by study personnel; 2) Clinical staff and members of the research team within the Parkinson's Disease & Movement Disorders Center (PDMDC) at BUMC will access medical records of PDMDC patients to identify eligible patients. Eligibility will need to be confirmed by referencing a participants PHI (see waiver of consent & waiver of HIPAA authorization as applied to review of medical records only) to verify a diagnosis of Parkinson's and ensure there are no contraindications to participation. If potentially eligible, members of the research team will provide information about the study to these individuals; 3) Clinical staff and members of the research team within Washington University will run reports and look at medical history to find patients diagnosed with Parkinson disease within the Epic system. Study staff will either call these potential participants, or send a "recruitment request" directly through the MyChart interface; 4) potential participants are informed of the study by their neurologist or physical therapist during a regular clinical visit and if they express an interest, the neurologist or physical therapist provides their contact information to study coordinator who initiates contact; 5) IRB-approved flyers are distributed to PD support groups throughout MA and MO; 6) IRB-approved flyers are distributed to physicians and physical therapists in the community; 7) IRB-approved recruitment materials are included in the American Parkinson Disease Information and Referral Center newsletter in MA and MO sent out regularly (via US mail or e-mail) to the Parkinson's community (5000 - 9500 contacts per site); 8) Study information will be posted on Clinical Trails.gov and Fox Trial Finder, online services; 9) IRB-approved recruitment materials are posted on the CNR website; 10) IRB-approved recruitment materials are posted on the APDA's Facebook page and other relevant social media sites; 11) IRB-approved recruitment materials are sent via: email, Facebook posts, and Twitter posts through Volunteers for Health .

CONSENT AND ASSENT

At the first in-person study session, the trained study staff will begin the face-to-face interview by explaining the study in detail and reviewing the informed consent document with each potential study participant. If consent is done remotely, via phone or videoconference, consent forms will be provided ahead of time for review. When consented remotely, participants will either sign the hard copy received through mail or secure email, a secure link in OneDrive (approved for restriced use data at Boston University) and send back electronically or in hard copy. They may sign also an secure electronic version of the consent form through RedCAP. As part of the consent, participants will be informed of use and risk of non-secure email communication and will have the choice to opt-out of secure email (as allowed by study site/institution guidelines). The potential subject will be informed that participation in the study is entirely voluntary and will have no effect on any present or future medical or rehabilitation care. The potential participant will be encouraged to ask questions about the study to ensure complete understanding of all study elements. Potential subjects will be provided with as much time as they request to review the informed consent and to ask questions. All questions will be answered thoroughly by the trained study personnel. Only when the study subject has provided full written informed consent will trained study personnel proceed to the in-person screening and subsequent study procedures.

For the qualitative portion of the study, participants who have completed trial participation will be contacted by phone to explain the purpose of this portion of the study. Participants who are due to complete their final 12-month assessment will be provided the information about the qualitative portion of study by the blinded assessor at the end of their assessment. If interested in participating, a suitable time will be organized with the participant to be interviewed over Zoom or by telephone. Participants will provide verbal consent at the start of the Zoom/telephone session before proceeding with the semi-structured interview.

STUDY PROCEDURES

Study Design:

This project is a 2-site randomized controlled study which will take place at the Center for Neurorehabilitation (CNR); Sargent College, Boston University and in the Program in Physical Therapy, Washington University in St. Louis. This is a two-arm, single-blinded, 1-year randomized controlled trial. Persons with mild to moderate PD are randomly assigned to one of two treatment arms, the mobile health exercise condition (mHealth) or active control exercise condition (control). The same procedures will occur at each of the sites as described below.

Methods of Data Collection:

Restructuring Assessment Visits with COVID19: Remote, In Person Off-Campus and In-person on Campus/Research Site Procedures

In order to optimize safety of our current and new participants and also adhere to state and university guidelines directing research operations during COVID19, research staff will do as much as possible remotely (over the phone or videoconference). For any study procedures that are not able to be done remotely (e.g. motor and cognitive testing), off campus visits at the

participants home or an alternate space in their neighborhood or community may be conducted. Alternatively, research site visits may be conducted at BU as guidelines permit. Ramping up and ramping down of in-person visits in response COVID19 will follow CRC IRB guidelines for termination and resumption of in-person research activities. Please see Campus Research Plan for details of in-person visits.

COVID19 Symptom and High Risk Screening procedures, PPE guidelines and social distancing protocols for all in-person visits are outlined in the COVID 19 Research Plan. Washington University, St. Louis will follow their own institutions research re-opening plan and will supply Boston University with copies of approvals.

Remote Screening Process:
A phone screen will be conducted to make a preliminary determination if potential participants meet the initial inclusion / exclusion criteria prior to scheduling a more in-depth, in-person screening assessment. During the phone screen (see attached phone screen script), potential participants will be asked their age (exclude in < 18 years of age), whether they are pregnant (exclude if pregnant), if they live in the community (exclude if institutionalized), and if a medical doctor diagnosed them with Parkinson disease (exclude if no). In addition, screening will include questions about walking habits (exclude if walk > 90 minutes per week during the past month), exercise regimens (exclude if participate in moderate intensity exercises >90 minutes per week during the past month), mobility status such as ability to walk for 10 minutes continuously and independently (exclude if no) as well as walking difficulties including freezing of gait. Item #7 of the New Freezing of Gait Questionnaire (NFOG-Q) will be administered over the phone (see phone screen question # 8) to determine impact of freezing of gait (exclude if freezing moderately or significantly disturbs during daily walking). Potential participant's email and home address information will be recorded on the phone screen form.
Lastly, a brief medical history will be reviewed to determine the following:

- Those with unstable medical or concomitant illnesses or psychiatric conditions, which in the opinion of the investigators would preclude successful participation, will be excluded.
- Those with a history of cardiac problems that interfere with ability to safely exercise (i.e., uncontrolled congestive heart failure, complex cardiac arrhythmias, chest pain) will be excluded.
- Those with orthopedic conditions in the lower extremities or spine that may limit walking distance (i.e., severe arthritis, spinal stenosis, significant pain) will be excluded.

A COVID19 High Risk Screen will be done based on CDC's risk factors and those who fall into one of the categories of "high risk" or "might be at high risk" will be eligible to participate in in-person care based on state and university guidelines and the Boston University Research Office's approval for in person research activities. Those that are not eligible at one time point may be eligible later as COVID 19 restrictions change.

The data on the screening forms will be coded and retained in REDCap to allow investigators to monitor the number of persons screened and pass/failure rate.

During normal research operations (non COVID19), participants who meet inclusion/exclusion criteria as part of the phone screen will be scheduled for an in-person visit. During COVID19, research staff will continue with screening and consent process over the phone or through a

secure teleconference platform. Research staff will also make sure participants' Parkinson's medications are stable (had not had any changes or additions) for two weeks prior to their first in-person visit. Screened-in participants will be mailed, secure emailed, or handed a letter with information to help them prepare for their subsequent baseline assessment visit. This letter will also contain contact information for study personnel if questions arise.

In-Person Screening Process:
After consenting, potential participants will be screened in-person to determine if they meet all study inclusion / exclusion criteria. The elements included in the screening process are part of a routine Physical Therapy Evaluation.

Assessment Procedures:
Those subjects who meet inclusion criteria will participate in a baseline assessment session (approximately 3 hours in duration if fully done in person, approximately 45 mins - 1 hour if portions done remotely), followed by random allocation to one of two exercise conditions (each lasting 12 months in duration). Participants will be informed of their group assignment at the time of the baseline assessment or 1-2 business days after the assessment via phone. Participants will receive information about their group assignment and preparation for their initial visit by mail, secure email or in person. Both exercise conditions include up to 8 physical therapy intervention sessions (approximately 1 hour in duration), at 3 and 6 months, and end with participation in a final assessment session (approximately 3 hours in duration if done fully in person, approximately 1 hour if portions done remotely) occurring post intervention at 12 months.

Primary Outcome Measure:
Physical Activity: Physical activity will be measured during a one-week period following each of the 4 assessment sessions using the StepWatch™ Activity Monitor (SAM). Subjects will wear the unobtrusive StepWatch 4 Activity Monitor (SAM, Modus Health, Edmonds, WA,), 24 hours per day for 7 days, except when bathing, showering, or swimming. The SAM is approximately the size of a pager, weighs 38g, and is attached using Velcro closures immediately proximal to the lateral malleolus of either leg. Study personnel will log pertinent setup information (start time, height, weight etc) on the SAM Setup form. The SAM is a small, waterproof, highly durable, self-contained device that is worn on the ankle and records the number of strides taken every minute. The SAM uses a combination of acceleration, position, and timing to detect steps taken with the leg of attachment. It is designed for long-term use during daily activities performed in an individual's customary environment over hours or days without maintenance by the user. Data are recorded as a temporal series of counts, with each data point represents the number of steps per one-minute interval. Step counts will be summed across days. In the rare event that the SAM device is returned after the 7 day wearing period and the data is unusable or the device has been damaged, the participant may be asked to wear an alternate SAM device for another 7 consecutive days.

The SAM will continuously monitor the number of steps taken over 7-days between the assessment period (after consent), but before the initiation of the intervention. The primary

comparison will be to a 7-day period following the 12-month intervention period. The SAM does not provide feedback to the subjects regarding number of steps taken in order to reduce influence on behavior. The SAM has good validity and reliability in older adults and people with PD (Resnick, 2001). Step detection accuracy exceeds 98% both for unimpaired gait and for movement styles that have traditionally been difficult to monitor accurately such as Parkinsonian shuffling, hemiparetic gait, and dyskinetic gait (Cavanaugh, 2007; Speelman, 2011). The SAM is considered to be a more accurate method of assessing adherence to a walking program than alternative strategies such as exercise calendars, which can experience inaccurate recording (Gaines, 2005). The SAM can be setup remotely and mailed to the participant for use for 7 days at home. Devices will be returned to study staff through pre-paid boxes provided to participants and include pickup at their home.

At each assessment visit (whether in person or remote), subjects will be set up with the SAM and provided a handout with instructions about wearing the device and logging "non-wearing" time. After each assessment, subjects will be provided with a pre-paid box to return the device to study staff.

Secondary Outcome Measures: It is indicated next to each assessment, whether it can be done remotely, in person (research site or home) or both.

Motor Assessments

- Six-Minute Walk Test (6MWT) (In-person only)
- Ten-Meter Walk Test (10MWT) (In-person only)

Six-Minute Walk Test (6MWT): This is a measure of the distance a participant walks in a six-minute time period. The six-minute walk test is a safe, simple, and useful measure of walking ability in patients with Parkinson's disease. The test will be carried out on level, obstacle-free enclosed corridors. Each participant will be instructed to cover as much ground as possible on foot in six minutes. A tester will accompany the participant, acting as a timekeeper and guarding the participant as needed. This test takes about 10 minutes to administer. Greater distances indicate increased ability for community ambulation.

Ten-Meter Walk Test (10MWT): This is a measure of gait speed. The test includes an initial two meter acceleration phase, followed by six meters of ambulation, and finished with a two meter deceleration phase. Each of the distances mentioned will be marked for accuracy, and only the middle six meters will be timed. Each participant will be instructed to walk at a comfortable walking pace (2 trials). A tester will accompany the participant, acting as a timekeeper and guarding the participant as needed. This test takes about 5 minutes to administer.

Methods - Description of the Intervention:

Intervention: mHealth Condition

Overview: Participants in the mHealth intervention will attend up to 8, approximately 1 hour, visits (in-person at a research site, at a participant home or remote via videoconference) with a trained physical therapist in the clinic at BU or WU. The first 6 visits will be spread out over the

first 3 months of the 12-month intervention period to optimize uptake of the walking program and walking enhancing exercises. Remote interaction using the mHealth platform will also occur during this 3-month period. During months 4-6 of the intervention period, interaction between the PT and each participant will occur remotely through the mhealth application – with 2 in-person "booster" sessions provided at 3 and 6 months to review goals, address barriers to exercise and strategies for relapse prevention. During the final 6 months (months 7-12), no planned interactions (in-person or remote) will occur between the PT and participants; however, participants will continue to use the mHealth application to support continued successful engagement in the exercise program. Participants will be able to contact the PT through the app during months 7-12 if needed; however, planned interactions will not be scheduled. In the event that a participant in this group has difficulty with use of their device or app or requires training on a study provided device if theirs is no longer available (and this is not easily resolved remotely and there are no available clinical study visits), up to 2 additional non-clinical visits with study personnel may occur outside of the scheduled 8 visits. During the study period, if a medical issue arises that may impact a subjects' ability to continue to carry out their exercise program safely, additional visits will be added to assess and modify the program as needed by the licensed physical therapist.

During the first physical therapy session, a trained physical therapist (PT) gives each participant in the mHealth condition a tablet containing the mobile health application ("Wellpepper"). Alternatively, participants can choose to use their own tablet or smartphone and the PT or research assistant will instruct the participant on how to download the Wellpepper app on their device. The mobile health application allows the PT to prescribe an exercise program that includes video demonstrations and audio instructions that participants can access through the "app" from the convenience of their homes / community.

Walking and Exercises to Enhance Walking: The program consists of walking and exercises to enhance walking. The PT sessions during the first 3 months allows the therapist to provide the necessary instruction to ensure participants are properly implementing the exercise program and feel comfortable using the "app." The **walking program** consists of two parts: 1) dedicated bouts of daily walking and 2) gradually increasing amount of walking during daily routines. The dedicated walking bouts consist of continuous walking in the community or on the treadmill for 30 minutes. If necessary, participants will start with a minimum of 10 and gradually increase to 30 consecutive minutes of walking over days or weeks. A bout of walking is designated as an "exercise" in the application. Locations for safely walking in the community or on a treadmill and options for increasing walking in daily routines will be discussed. The **walking enhancing program** consists of progressive resistance and stretching exercises based on a set of exercises (developed and published by study investigators) used successfully in our pilot study: American Parkinson Disease Be Active & Beyond Booklet). These exercises are part of standard physical therapy care and are routinely prescribed and therefore not considered experimental. No specialized equipment is needed to implement any of these exercises, reducing barriers to implementing them in the home. The standardized set of exercises are video recorded during the first 3 months (initial 6 in-person PT visits) and prescribed over the course of the year. The videos and exercise prescription information (sets, reps and auditory instructions) are added to the subject's Wellpepper account. However, only walking and approximately 5-7 walking enhancing exercises are accessed by participants from home at any one time. Participants are

instructed to complete the walking, progressive resistance and stretching exercises 5 times per week.

Cognitive-Behavioral Elements of the Intervention: Cognitive-behavioral elements will be integrated into the walking and exercise program emphasizing participant engagement in managing their health condition through increasing self-efficacy. The in-person physical therapy sessions include motivational interviewing to identify readiness for change, education to reinforce benefits of exercise and to introduce connection between thoughts, mood, and behavior (e.g., exercise adherence), identification of unhelpful thoughts that serve as barriers to physical activity and introduction to thought challenging (e.g., weighing evidence for and against thoughts, constructing new, balanced thoughts). In the 2 booster sessions provided at 3 -month and 6-months, these concepts will be reviewed to help optimize ongoing adherence to exercise. Overcoming barriers to physical activity will be discussed along with strategies to prevent relapse (i.e., inactivity). These sessions may be video recorded to allow designated research staff to review content to ensure treatment fidelity across therapists.

Components of Mobile Health Intervention:

- Goal Setting / Action Planning: The PT works collaboratively with each participant to set specific, incremental, attainable walking and exercise goals which are entered into the mHealth application. This contains a detailed action plan of what (which exercises, duration of walking), how (appropriate technique) when (time of day, days per week) and where (community, mall) each participant will engage in exercise.
- Tailored Exercise Videos: The PT prescribes walking and walking enhancing exercises (from a select set). Each exercise is video recorded while the participant performs the exercise with verbal instructions on proper technique. This individualized approach ensures a "just right level" of challenge.
- Adaptations to Exercise Program: Exercise programs need to be modified for many reasons, such as pain, being too difficult or not challenging enough. The PT is able to remotely add or replace exercises to meet the needs of each individual participant.
- Automated reminders and rewards: Reminders prompt individuals to walk and exercise. The system tracks successful completion, provides rewards (i.e. fireworks display) when goals are attained.
- Monitoring adherence and performance: This mHealth platform provides a "dashboard" where the PT can view adherence and progress of participants, monitor exercise performance and adapt the walking and exercise program over time.
- Progress towards goals: Participants receive visual feedback through the app in the form of graphic displays showing progress toward individualized goals, encouraging self-monitoring and feelings of mastery. Rewards are earned for reaching pre-determined benchmarks, increasing self-efficacy.
- Connected to PT: Participants can stay connected to the PT via the text chat feature to seek assistance with overcoming barriers, getting back on track, asking questions and seeking advice. Increased connectivity to the PT provides participants with personal support they need to effectively interpret physiologic and affective states, and to develop the behavioral competencies and greater self-efficacy.

For each exercise that participants complete, they report on the difficulty level and number of sets and reps completed. These results are available to the intervention physical therapist to allow remote monitoring of participant progress and progression of the exercise program. To optimize outcome of individuals, exercises are tailored based on the needs and preferences of each participant. The application also provides secure communication (HIPAA compliant) between participants and the PT using a "text chat" feature. Participants use the chat feature to stay connected to the PT – to ask clarifying questions about the exercise program, to report any barriers or problems that may have arisen, seek advice or confirmation of success. The PT monitors progress, adapts the exercise program and responds to inquiries through the application over the course of the year. If the participant has not logged into the app for 7 consecutive days, this will trigger a phone call from the PT who will inquire about lapse in engagement. If the lapse is due to the onset of a new medical condition or to a change in status related to PD, the PT will adapt the exercise program as appropriate. If the lapse is due to cognitive-behavioral barriers, the PT will address these barriers to facilitate re-engagement.

Control/Exercise Condition: Participants in the control group have up to 8 visits (in person at a research site, at participant home or remote via teleconference) with the intervention PT over 12 months. Six visits will occur in the first 3 months with follow-up visits at 3 and 6 months – equivalent to the dose provided to the mHealth condition. Participants are instructed by the PT to engage in walking and perform the same progressive resistance and stretching exercises (tailored to their needs and provided in written format) at the same frequency (5x/week) as subjects in the mHealth condition. Participants in the control condition will also be instructed to gradually progress their exercise program and to increase the amount of walking over a 1-year period. No cognitive-behavioral approaches or mHealth technology will be provided. Subjects will also be provided with a phone number to reach the treating PT should they have any further questions or concerns about their exercise program. As in the mhealth group, if a medical issue arises during the study period that may impact subjects ability to continue to carry out their exercise program safely, additional visits will be added to assess and modify the program as needed by the licensed physical therapist. To monitor exercise adherence, subjects in the control group will be given exercise journals to indicate those days in which they completed the exercises and walking program. Subjects will be instructed to bring journals in with them on assessment visits. As in the mHealth group, on the rare occasion that the participant is in the first 6 months of the study and is not able to attend intervention sessions in person, there will be an option for videoconferencing either using their own device or one issued to them.

Qualitative portion of the study:
Participants who have completed the study (from both the intervention and control groups) will be invited to participate in the qualitative portion of the study. The aims are to identify, from the perspective of people with PD, what factors facilitated or hindered their ability to maintain or increase regular physical activity, community access and social participation. Participants who have completed their 12-month assessment will be contacted by telephone to explain the aims and requirements; participants who are due to complete their 12-month assessment between 1 September 1 2023 and December 31 2023 will be provided information about the qualitative portion of the study at the end of their 12-month assessment session by the blinded assessor. For participants who wish to participate in this portion of the study, a time to interview them will be organized. They will then participate in a 45-60 minute semi-structured interview by telephone or online (via Zoom) with a trained member of the research team.

Indicative prompts for the semi-structured interviews are listed below. Prompts 1-4 relate to physical activity, prompts 5-8 to community access and prompts 9-12 to social participation.
1) Please describe what activities you do to try and stay active. How often and for how long do you do these over the course of a week?
2) What helps you to remain active? Prompts about family support, therapist support, intrinsic motivation, environment/access
3) Is there anything that makes it difficult for you to remain active? Prompts about family/healthcare provider attitudes, costs (monetary, time, logistics), motor/non-motor symptoms, activity limitations, comorbidities/acute illness, environment/seasons
4) Was there anything that you learned from taking part in this research study that helped or hindered you to remain active?
5) How often do you get out of the house and into the community?
6) What motivates you to get out of the house?
7) Is there anything that helps you get out of the house and into the community? Prompts about logistics (driving / community transport options, time), environment
8) Is there anything that hinders your ability to get out of the house as often as you would like? Prompts about motor/non-motor symptoms, activity limitations, comorbidities, logistics, environment, weather/seasons
9) How engaged are you with life? Are you doing all that you would like to do?
10) What helps you continue to do the things you enjoy doing?
11) Is there anything that hinders your ability to continue doing the things you enjoy doing?
12) Was there anything that you learned from taking part in this research study that changed your views or ability to get out of the house, and/or do the things you enjoy?

Audio recordings from the interviews will be retained for verbatim transcription and field notes will be taken by the interviewer, with reflexivity (Kitto, 2008) practiced throughout. The interviewer will debrief with other members of the research team between interviews to review interview prompts and saturation of themes. Data collection will cease once thematic saturation is reached, anticipated to be within 8-15 participants (Hennink & Kaiser 2022). Thematic analysis (Braun & Clarke 2006) will be used to identify facilitators and barriers of physical activity participation, community access and social participation. Data will be analysed using NVivo software (QSR International, Denver CO).