Official Title: Amped-PD: Amplifying Physical Activity Through a Novel Digital Music Therapeutic in Parkinson Disease

NCT#: NCT05421624

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Study Protocol

Study Design:

The study is a parallel community-based 2-arm randomized controlled trial (RCT) in which the study evaluations will take place at the Center of Neurorehabilitation (CNR) at Sargent College, Boston University. We will enroll 44 community-dwelling adults ages 40-80 yrs with idiopathic PD of mild to moderate disease severity, who are independent community ambulators. We will exclude those with atypical PD, have significant freezing of gait, have history of falls in the past 3 months, have a comfortable walking speed <0.4 m/s, and significant cognitive or hearing impairments. Eligible participants will be randomly allocated to either

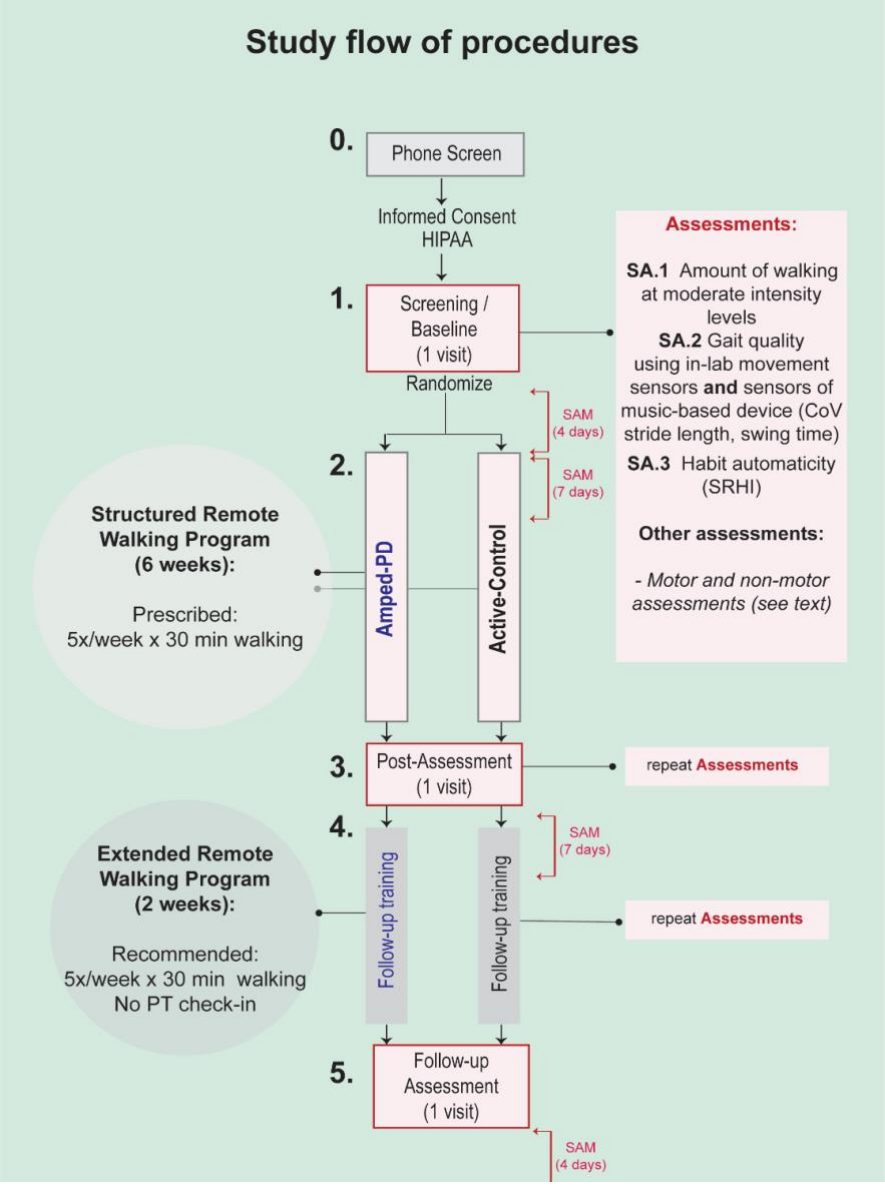

Figure 1 Study flow. Abbreviations: CoV: Coefficient of Variation; SAM: Step Activity Monitor; SRHI: Self-Report of Habit Index

Amped-PD (experimental arm) or Active Control (control arm). Assessments will include a standard set of motor and non- motor assessments and will be administered at Baseline, Post-Assessment (after 6 weeks of training), and Follow-up (after 2 additional weeks of unstructured training). Figure 1 summarizes the study flow for the protocol.

Study Procedures

Primary Screen (approximately 10 minutes):

A primary screen will be conducted over the phone 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 Appendix I: Primary Screen), potential participants will be asked their age (exclude if < 40 years of age), if they are currently participating in physical therapy (exclude if yes), if they are currently performing walking exercise of at least 30 min for > 3x/week (exclude if yes), and if a medical doctor diagnosed them with Parkinson disease (exclude if no). Potential participants will be asked about their ability to walk independently without physical assistance or an assistive device (exclude if no), their history of falls of > 1 fall over the past 3 months, or a singular fall over the past 3 months that is PD-related, with a fall defined as an unexpected event that caused a person to unintentionally land on a lower surface (e.g. floor, ground), regardless of presence or absence of resultant injury (exclude if yes), and whether they experience freezing episodes during daily walking (exclude if moderately or significantly disturbing – see operational definition under exclusion criteria). Lastly, a brief medical history based on self-reports from the participant will be reviewed to determine the following:

- Those with known cardiac problems that interfere with the ability to safely exercise (e.g., congestive heart failure, uncontrolled cardiac arrhythmias, chest pain) will be excluded.
- Those with known orthopedic conditions in the lower extremities or spine that may limit walking distance (e.g., severe arthritis, spinal stenosis, significant pain) will be excluded.
- Those with other medical conditions that would preclude successful participation, as determined by a physical therapist on the research team, will be excluded. The physical therapist will make this determination based on participant self-report and a PTs informed questioning which is part of a licensed PTs training.

It is possible to have self-reports of cardiac, orthopedic, or other medical conditions that may need further clarification and clinical assessment due to limited information from the participant or unclear description. The physical therapist will decide whether an in-person screening will be appropriate. Additionally, communication with the participant's physician may take place to understand their health status. A HIPAA authorization from the participant will be obtained prior to any communication with the participant's health provider.

If the participant is deemed eligible based on primary screen, the participant will be

asked about scheduling an informed consent. The participant will be given the option to receive this virtually or in-person. Virtual consenting may be administered right after the primary phone screen if the participant wishes, or may be scheduled at a different time. In-person consenting will be held on the same day of the first in-clinic visit prior to any study procedure. The researcher will coordinate scheduling with the participant.

Data on the screening form will be entered into REDCap to allow investigators to monitor the number of persons screened and pass/failure rate. Potential participants who are deemed eligible based on the preliminary phone screen will be scheduled for an in-person screening and baseline assessment visit at Boston University.

1. <u>First Evaluation Visit: In-Person Screening & Baseline Assessment Visit (approximately 2-3 hours)</u>:

The in-person screening and baseline assessment visit will take place at the Center for Neurorehabilitation at Boston University. All participants will have completed and provided their informed consent prior to Screening and Baseline Assessment (see Appendix II: Informed Consent; see section K). After consenting, participants will be asked to sign a HIPAA Authorization to Disclose Protected Health Information for Research Purposes (see Appendix III: HIPAA Authorization). This will allow our team to communicate directly with the participant's healthcare provider during the study if needed.

***1.a In-Person Screening**:* An in-person Screening will be administered to determine if participants meet all study inclusion/exclusion criteria. The elements included in the screening process are part of routine physical therapy evaluation. A physical exam will be conducted to assess cognitive status, Parkinson's symptoms and walking capacity.

1. A diagnosis of Parkinson disease will be confirmed per participant report.
2. The Mini-Mental State Exam (MMSE) will be administered to screen for significant cognitive impairment (exclude MMSE score < 24) (see Appendix VI: Screening Tools). The MMSE is a brief screening tool that examines cognitive impairment. Participants are tested on 11 items that cover multiple cognitive domains. The score ranges from 0-30, with higher scores indicating less cognitive impairment.
3. Disease severity will be assessed by a licensed physical therapist using the Modified
4. Hoehn & Yahr Scale (only H&Y 1-3 will be included) (see Appendix VI: Screening Tools). The Modified H&Y Scale includes additional criteria to rate Parkinson disease symptoms on a scale from 1 to 5. Higher scores indicate increased disease progression.
5. Walking capacity assessments instrumented with wearable sensors:
    - The following tests on walking will be instrumented with in-lab movement sensors (XSENS, Enschede, the Netherlands), which will be worn on both mid-shank (2) and mid-thigh (2) areas, and on mid-

line low-back area (1), and the sensors of the music-based device (MedRhythms, Portland, ME), which will be secured on to the outer sides of the shoes (2). The other components of the music-based device such as its audio-cue mechanism and headphones will not be used during this screening procedure.

- The 10-meter walk test (10MWT) will be administered by a licensed physical therapist (comfortable walking speed <0.4 m/s excluded based on the average of 3 trials at comfortable walking speed) (see Appendix VI: Screening Tools). The 10MWT is an assessment of gait speed over a short distance (2 meters ramp up, 6 meters walking, 2 meters ramp down). The aforementioned distances will be pre-measured for accuracy and only the middle 6 meters will be timed. Participants will be asked to walk at a comfortable pace for 2 trials and a fast pace for 2 trials. The physical therapist conducting the test will be guarding the participant as necessary to optimize safety.
- The six-minute walk test (6MWT) (see Appendix VI: Screening Tools) will be administered by a physical therapist. The 6MWT, a measure of long- distance walking capacity, assesses how far a person can walk over a 6- minute period. The test will be performed along a pre-measured (30-meter), level, obstacle-free hallway. Participants will be instructed to walk as far as possible in 6-minutes. The physical therapist conducting the test will be guarding the participant as necessary to optimize safety. Physiological measurements (e.g., heart rate, blood pressure) and perceived ratings of walking intensity (using Borg's Rating of Perceived Exertion) will be taken prior to initiation of the walking test to determine whether the participant is safe to participate in the walking program. The participant will be excluded based on the following: resting heart rate >100 beats/min; resting systolic BP >160 mmHg, resting diastolic BP >100 mmHg. The same physiological measurements will be taken upon completion of the walking test to assess hemodynamic response to exercise.

  - Walking duration from both 10MWT and 6MWT will be used to generally gauge the participant's walking tolerance. Exclude if the physical therapist determines that the participant is unable to walk independently for at least 10 minutes.
  - While wearable sensors are used during the 10MWT and 6MWT, sensor data will not be used for determination of participant eligibility. Instead, sensor data will be used as part of Baseline Assessment and is integrated in this screening procedure in the clinical screening to reduce the repetition of testing of the same test (10MWT, 6MWT) during the Baseline Assessment, once the participant determined to be eligible to proceed.

6. Based on clinical expertise and judgement, the physical therapist conducting the in- person screening will determine if a participant requires additional guarding and/or assistance during walking activities (i.e., occasional hand contact to maintain balance or dynamic stability and/or an assistive device). If guarding is needed at any point during the evaluation,

the participant will be excluded.

1.b Baseline Assessment: Participants who are deemed eligible through the in-person screen will continue on to complete the remainder of the baseline assessment measures, including:

- Demographic questionnaire consisting of age, gender, education level, living situation, employment, ethnicity, race, and PD-specific questions. This form will be completed interview-style by the physical therapist.
- Medication form pertaining to PD and non-PD medications (see Appendix VII: Outcome Measures). Participants will be asked during the phone screen to bring their medication list to this first evaluation visit. The physical therapist will transcribe the medications onto the designated form. Medication lists that contain identifiable information will be given back to the participant and not be kept by the research team.
- Motor & Functional Measures:

i. Dynamic balance will be measured using the Mini Balance Evaluation Systems Test (Mini BESTest). This test comprises of 14 items that span anticipatory postural adjustments, reactive postural control, sensory orientation, and dynamic gait.

ii. Motor symptoms will be assessed using the Movement Disorder Society Unified Parkinson Disease Rating Scale (MDS-UPDRS)-III (see Appendix VII: Outcome Measures). The MDS UPDRS is the most widely used clinical rating scale fork Parkinson disease. Part III is a motor examination (33 scores summed from 18 questions) conducted by the rater. Total scores can range from 0 to 141, with higher scores indicating worse disease severity.

iii. Quantification of movement will be performed using in-lab movement sensors (XSENS, Enschede, the Netherlands) and sensors of the music-based device (MedRhythms, Portland, ME) (see Appendix VII: Schematic of Wearable Sensors). These sensors will be used to measure gait quality during performance of the 10MWT and 6MWT as performed in the in-person screening, and to measure posture as examined in posture-related items within the UPDRS III and Mini BESTest. Sample metrics include but are not limited to gait velocity, stride length, cadence, and limb velocities, and postural sway measures based on velocity, magnitude, smoothness. As a clarification, the instrumented 10MWT and 6MWT as performed during the initial screen provide the data needed for this Baseline Assessment, therefore these tests will not be repeated.

iv. Functional Mobility will be measured via the Five Times Sit to Stand (5xSTS). The 5xSTS objectively assesses the time it takes to complete 5 sit-to-stands and is a method to observe movement strategies or compensations. The test will be performed in a standard chair with participants instructed to stand up and sit down 5 times as quickly as possible. The physical therapist conducting the test will be guarding the participant as necessary to optimize safety; however, if guarding is needed for the 5xSTS, participants will not be allowed to continue with the

intervention.

- Self-report/ Interview Measures:
  i. Section I and II of the Movement Disorder Society Unified Parkinson Disease Rating Scale (MDS-UPDRS) will be utilized to assess non-motor and motor signs. Section IA includes 6 items related to non-motor experiences such as cognition, mood, and motivation which are assessed by the examiner. Section IB consists of 7 items related to non-motor aspects of experiences of daily living such as sleep and fatigue which are filled out by the participant (with or without the help of a caregiver), but independent of the examiner. Section II is a self-administered questionnaire consisting of 13 items related to motor aspects of experiences of daily living.
  ii. The Self-Report Habit Index (SRHI) will be administered to measure exercise-habit strength and automaticity. This self-report index comprises of 12 statements with constructs spanning behavior repetition, automaticity, and identity, with responses made on 11-point Likert scales (0 = strongly disagree; 10 = strongly agree) (see Appendix VII: Outcome Measures).
  iii. Self-Efficacy of Walking – Duration (SEW-D) is a 10-item self-report that will be administered to determine participants' beliefs of their physical capabilities to successfully complete incremental 5-minute intervals (5 to 40 minutes) of walking at a moderately fast pace, with responses made on 11-point Likert scale (0% = not at all confident; 100% = highly confident).
  iv. Geriatric Depression Scale (GDS) is a brief, self-report involving yes/no questions instrument on psychological aspects and social consequences of depression in the elderly. The short form of GDS of 15-items will be used in this study.
  v. Health-related quality of life will be measured by the Parkinson's Disease Questionnaire – 39 (PDQ-39)(see Appendix VII: Outcome Measures). The PDQ-39 is a self-report questionnaire that assesses quality of life over the past month across 8 different dimensions. Items are scored based on a 5-point ordinal system with lower scores reflecting better quality of life.
- Walking Activity:
  - Step Activity Monitor: Walking activity will be measured using the StepWatch 4 Activity Monitor (SAM; Orthocare Innovations, Mountlake Terrace, Washington). The SAM is a self-contained, maintenance-free device that combines acceleration, position and timing information to count complete gait cycles (strides) of the user. It is the size of a pager, weighs 38g (roughly the weight of two AA batteries for comparison) and will be attached with self- adhesive straps above the lateral malleolus (where the shin meets the foot) of the participants' less impaired lower extremity. Data from the SAM, which includes measurement of daily step counts and step intensities, will allow us to examine changes in physical activity in response to the intervention. The validity and reliability of the SAM for capturing stride counts has been demonstrated in persons with various neurological disorders including PD (Shepard 1999, Coleman

1999, Macko 2002, Salarian 2004, Gaines 2005, Manns 2009, Speelman 2011).

- General wear instructions and considerations: Participants will be instructed to wear the SAM for 4-11consecutive days depending on the assessment timepoint. The SAM will be worn continuously during all waking hours, expect when bathing, showering, or swimming. The physical therapist will fill out the SAM researcher form to appropriately document the SAM calibration process for each participant. Participants will be given instructions on how to don/doff the device and will be provided with a form to record times the SAM is removed over wear period. The SAM requires no maintenance by the user besides remembering to keep it on. The physical therapist will provide strategies to help the participant remember to put the SAM back on if they do take it off at any time (e.g., if the SAM is taken off at night, place it on a nightstand next to the bed so it is seen in the morning).
- Specific wear schedule for Baseline Assessment: For the Baseline Assessment, the SAM will be worn for 4 consecutive days prior to initiating the intervention (and will continue to wear it for another 7 days during training – please see next section 2. Intervention). Participants will be contacted via phone within 24-48 hours following the evaluation session to ensure that they are comfortable with the device and to address any questions or concerns. Furthermore, participants will be notified that they may contact study staff during work hours at any point during the wear period if they experience any technical issues with the SAM or have any questions.
- Operation and data download: Using the manufacturer's software, the SAM will be calibrated by a physical therapist to each participant's gait pattern based on height, typical walking speed, and leg motion. Collected data will be downloaded to a tablet computer, with which manufacturer's software will convert stride counts to step counts and calculate daily step count values. No identifiable information is collected by the SAM.

1.cRandomization : At the completion of procedures for Baseline Assessment, the participant will be randomized to receive either the experimental or control arm of the intervention. The experimental arm, called Amped-PD, is a 6-week community-based structured walking program that uses a music-adaptive RAS followed by 2 weeks of unstructured walking protocol (continue as desired) for a total of 8 weeks. The control arm, called Active-Control is a similarly structured 6-week community-based walking program that does not use RAS, followed by 2 weeks of unstructured walking protocol (continue as desired) for a total of 8 weeks of training. Block randomization with balanced allocation between the two groups will be implemented. A randomization list will be generated prior to enrollment of participants. The researcher will gain knowledge of treatment assignment only after procedures in In- person Screen and Baseline Assessments have been completed.

1.d **Device Training Amped-PD Intervention:**

Training Procedures / Instruction to Participants:

Music-Based Device Training (Only for Amped-PD)

Participants who are randomized to receive Amped-PD intervention will undergo training on how to use how to use the music-based device and independently conduct the remote walking program. The music-based device (MedRhythms, Portland, ME) is specifically designed for gait training in people with neuromotor impairments. Participants will be trained to independently use the device. A simple setup which takes < 2 min involves initiating the smartphone application, wearing the headphones, and attaching a movement sensor to the outer side of each shoe below the ankle. The smartphone is kept in the user's pocket throughout the session. The music-based device obtains real-time walking information through the shoe sensors that communicate wirelessly with the smartphone application software. The music-based device delivers music cues that are adjusted according to the user's walking pace as detected by the shoe sensors. These music cues serve as the substrate for rhythmic auditory stimulation during walking.

Training with the music-based device will be administered after completing the In-person screening and Baseline Assessment procedures. To ensure that the participant is able to hear the music, the physical therapist will have the participant put on the headphones while music is played. The physical therapist will instruct participants to listen to the music at a safe volume so they can still hear sounds in their environment. The participant will then practice donning/doffing, adjusting the volume, setting up, and using the device (i.e., walk for 5 minutes) to demonstrate comprehension and independent use. A team member will provide the participant with the necessary equipment (i.e., smartphone, shoe sensors, headphones, study diary). The physical therapist will be able to determine safe and independent walking ability during the 5 minutes of walking with the device. Five minutes is enough time for the participant to experience an increase in music tempo and for the physical therapist to determine if guarding is needed during these transitions. At the end of this training period, if the physical therapist determines that the participant will need continued assistance from another person to walk and perform transitions (i.e. turns, step initiation) while using the music-based device, the participant will be withdrawn from the study. Otherwise, the physical therapist will proceed and discuss the space and location in which the participant plans to conduct the walking program, and review space adequacy and safety considerations. A safe environment will be considered to be the following: *indoor spaces* – level surfaces, obstacle-free, no slippery surfaces, no unsecure area rugs; *outdoor* spaces – avoid auto or bike traffic, obstructive tree roots, divots in the asphalt and concrete. These environments could include, but are not limited to: home, apartment building hallway, neighborhood sidewalks, local track or park, office environments, and community/ recreation centers. Ideally the space is at least 50 feet in length that meet the above indoor and outdoor space criteria. This will decrease

the amount of pivot turns thereby optimizing the amount of continuous walking. The purpose of the music-based device is to help participants entrain to a musical beat to improve the quality of their walking. Leveraging the benefits of RAS such as increased stride length, cadence, and speed enable walking at faster speeds and higher intensities, thus making it advantageous to perform greater amounts of walking at moderate intensities – an important health objective set forth by guidelines by public health and clinical practice sectors. The device monitors a participant's cadence using the sensor placed on the shoe. The musical tempo is matched to the baseline walking cadence of the participant. As the quality of a participant's walking improves and the participant accurately "entrains" to the tempo of the music, the tempo will adapt and increase cadence by 5%. For example, if the participant starts off walking 100 steps/minute, once considered entrained, the tempo will increase to 105 steps/minute. This increase is very small and will most likely not be noticed by the participant. If the participant is unable to increase their cadence to match this tempo, the tempo is reduced back to baseline. The algorithm used to set the tempo is dynamic and adjusts to the cadence of the participant. If a participant feels that they cannot keep up with the faster cadence, they can continue walking at their comfortable pace. Participants will also be instructed to stop the intervention if they feel uncomfortable or anxious at any time.

Following this training, it is expected that participants will be able to independently setup (including donning/doffing the device), perform and conclude a walking session independently. Participants will have access to Instructions for Use (IFU) that will detail all procedures required for proper operation of the system. However, participants will be encouraged to contact the research team if they have any additional questions, issues or concerns. Participants will be excluded from the study if unable to demonstrate how to use the device independently as determined by the physical therapist. Please note, participants will be provided with a pre-established username and password. No personally identifiable information will be recorded or stored in the device application.

2. Intervention:

Amped-PD: Remote Walking Program Description

(prescribed walking program of 15 hours total over six weeks + concurrent use of SAM device 4 days during early training)

Overview: The remote walking program is a self-directed, structured walking program held in home/community settings using the music-based device. Participants will be instructed to complete five home/community-based walking sessions per week (one session/ day, 30 minutes in duration) for six weeks. Participants may choose to perform these 5 training sessions on any days of the week according to their needs.

Description of Walking Program: Using the music-based device, participants will conduct the walking sessions at their self-selected pace in

a home/community environment that limits the amount of stops and/or pivot turns in order to optimize continuous walking. For the purposes of this study, home/community environment is considered any environment outside a professional healthcare facility. This includes but is not limited to the home, apartment building, independent living retirement homes, outdoor environments (tracks, parks, sidewalks), office environments and community/ recreation centers.

Duration of Walking Session: Each individual walking session will be completed within a 30- minute timespan (i.e., should not be split up throughout the day). Participants are allowed to rest as needed during the 30-minute training period. The time clock will continue to run down continuously once the 30 minutes are started (i.e., if a participant rests for 5 minutes, this will equate to 25 minutes of walking). Participants will be instructed to terminate any walking session in the event of technical or medical issues to allow for adequate resolution.

Walking program diary: Participants will be asked to record in a study diary their schedule (dates and times) of walking, location, record of any falls they experience and any comments/issues they experience while using the device (see Appendix VII: Outcome Measures).

Safety Considerations: Participants will be informed of the potential risk of falls that can occur as part of the walking program in the community. Determination of a safe environment (as described in the *Music-Based Device Training* section above) will be discussed with the participant to mitigate external risk factors that could lead to a fall. Participants will be instructed to reach out to their healthcare provider if experiencing dizziness, chest pain, or other serious symptoms and will be asked to notify the study team following the episode. If participants experience a fall while using the device, they are advised to seek medical attention (if needed) and record the incident in their study diary. In addition, participants will be asked to contact the research team following the event to determine whether it is safe for them to continue. The physical therapist will examine the context of the fall. It is possible to discontinue the training program due to but not limited to the following reasons: (1) participant self-report of injuries that prevent them from participating fully and safely in the program; (2) participant self-reports on change in function and mobility after a fall; (3) concerns related to the execution of the walking program or proper use of the device, its components, and functionality; (4) considerations related to a change in participant's walking function.

The program may be continued based on discretion of the physical therapist if the fall is determined to be ancillary, unrelated to the training program or the device, resulted in negligible or insignificant injuries post-fall, and no change in safety determination. Participants will be contacted by a member of the study team weekly to see if they have any questions or concerns with the walking program. However, participants will be encouraged to reach out to the research team at any point if they do not feel comfortable using the device.

Physical therapy check-in call: During the baseline evaluation visit, the research team will ask the participant which time each week is preferred to have a check-in call. This phone call will last approximately 5-10 minutes to check on participant engagement in the walking program, and to provide guidance regarding any questions/concerns and/or any medical/ technical issues. If participants are unable to carry out the walking program 5- days per week, a study staff member will discuss the barriers to implementation (by phone) and suggest ways to optimize adherence to the program (e.g., setting a schedule). A study staff member will also inquire about adverse events during the weekly phone call and ensure that the participant is comfortable with the walking program.

Step Activity Monitoring: After completing 4 days of wear prior to starting training, the participant will continue to wear the SAM for an additional 7 days upon intervention initiation (total of 11 days continuous wear). During training, both the SAM and the shoe sensors of the music-based device can be worn simultaneously on the same side of the body without interfering with a participant's walking and/or increasing the risk for trips/falls. Participants will return the SAM to study personnel via a pre-labeled, addressed envelope to mail following 11 days of continuous monitoring period. The researchers will download the data and will store in a secure server.

Interruptions in training: In the event of unavoidable interruptions in training, booster sessions may be implemented to promote treatment fidelity. For training interruptions that last up to 2 weeks, the participant will continue the program and receive booster sessions at 100% of the time missed. For training interruptions of greater than 2 weeks, the training will be restarted after a reasonable washout interval, as determined by the Principal Investigator (a licensed physical therapist). If training interruption resulted in permanent change in eligibility, the participant will be withdrawn from the study.

Active-Control Intervention: Remote Walking Program Description

(Prescribed walking program of 15 hours total over six weeks + concurrent use of SAM device 4 days during early training)

Overview: The Active-Control Intervention is similarly structured as Amped-PD Intervention, with the only exception of not using RAS/ music-based device. Participants will be instructed to complete five home/community-based walking sessions per week (one session/ day, 30 minutes in duration) for six weeks.

Description of Walking Sessions: Without using the music-based device, participants will conduct the walking sessions at their self-selected pace in a home/community environment. All other considerations as outlined above apply to this intervention.

Duration of Walking Session: Each individual walking session will be completed within a 30- minute timespan (i.e., should not be split up throughout the day. Participants will be asked to use their own wristwatch,

timer, or cellphone to monitor the time/ duration of walking session. Participants are allowed to rest as needed during the 30-minute training period.

Walking program diary: Participants will be asked to record in a study diary their schedule (dates and times) of walking, location, record of any falls they experience and any comments/issues they experience while performing the walking program.

Safety Considerations: Same as above as outlined in Amped-PD.

Physical therapy check-in call: Same as above as outlined in Amped-PD.

Step Activity Monitoring: Same as above as outlined in Amped-PD.

Interruptions in training: In the event of unavoidable interruptions in training, booster sessions may be implemented to promote treatment fidelity. For training interruptions that last up to 2 weeks, the participant will continue the program and receive booster sessions at 100% of the time missed. For training interruptions of greater than 2 weeks, the training will be restarted after a reasonable washout interval, as determined by the Principal Investigator (a licensed physical therapist). If training interruption resulted in permanent change in eligibility, the participant will be withdrawn from the study.

3. **Second Evaluation Visit: Post-Assessment Visit (approximately 2-3 hours):**

The post-intervention assessment visit will be scheduled within approximately 7 days of completion of the structured walking program and take place at the Center for Neurorehabilitation at Boston University. This visit will entail the same battery of assessments performed at Baseline Assessment including: 10MWT, 6MWT, Borg's RPE, Mini BESTest, MDS-UPDRS I/II/III, 5xSTS, PDQ-39, SRHI, GDS. Quantification of movement will be performed using wearable sensors to measure balance and walking as examined in the aforementioned battery of assessments.

Further, a usability questionnaire will be administered for those who completed Amped-PD. For both Amped-PD and Active-Control groups, participants will be asked to bring in their study diary for study personnel to review and to make a copy for their data file. This study diary will be returned to the participant for continued use if needed during the Follow-up Period. For the Amped-PD group, they will have continued access to the music-based device during the Follow-up Period. The SAM monitor will be given to the participant to wear for 7 days during Follow-Up Training. Participants who withdraw or are withdrawn prior to completing their last walking session may be asked to complete closing visit activities, if feasible.

4. **Follow-Up Walking Program (2 weeks):** Extended Remote Walking Program Description for both groups (recommended continuation of routine walking + concurrent use of SAM device 4 days during follow-up training)

Overview: Participants in both Amped-PD and Active-Control groups will be recommended to carry out the walking program independently for another 2 weeks,

with walking duration and amount similar to that of the 6-week Remote Walking program (i.e. 30 min/ session x 5x/week). This recommendation to continue the walking program is similar to the common practice of a home exercise program that is recommended after discharge from an episode of physical therapy care. The main difference in this Follow-up Training relative to the prior Remote Walking Program is that this Follow-up Training is completely self-managed by the participants, where participants will naturally make choices on how they will continue and adhere with the recommended balance and walking as examined in the aforementioned battery of assessments. For both Amped-PD and Active-Control groups, participants will be asked to bring in their study diary for study personnel to review and to make a copy for their data file. For participants in the Amped-PD, they will return the music-based device to the research team.

Step Activity Monitoring: The participant will wear the SAM for 4 days after this final assessment visit. Once completed, the participant will return the SAM to study personnel via a pre-labeled addressed mailing envelope which will be provided to them during the final assessment. The researchers will download the data and will store in a secure server.