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

NCT#: NCT05421624

Date: August 20, 2024

Informed Consent

INFORMED CONSENT

Study Summary

The purpose of this study is to evaluate if a community-based walking program that uses music cues during walking is more effective than a similarly structured community-based walking program that does not use music cues in improving physical activity, quality of walking, and exercise habits in people with Parkinson disease. Participants who take part in this research study will be in this research study for approximately 10 weeks. During this time, subjects will make 3 study visits to the Center for Neurorehabilitation at Boston University. In between these three study visits, the participants will carry out a structured walking program in their home/community 5 days/week for 6 weeks with or without a music-based device, depending on their treatment group assignment. Additionally, participants will be asked to continue and extend their engagement with the walking program for another a 2-week follow-up training period. Participants will also complete an evaluation of walking ability, functional mobility, quality of life, and self-reports on exercise habits before training and after weeks 6 and 8 of training. The risks of taking part in this research study include: muscle soreness, fatigue, and injury from falls.

Introduction

This form describes the research study and provides you with important information to help you decide if you want to participate. It provides information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant.

You should read this form carefully and make sure that you understand the information and your role as a research participant. If you have questions about anything on this form, you should ask a member of the research team to clarify before you agree to participate. A member of our research team will go over this form with you either in-person or virtually, based on your preference. If in-person, we will administer the informed consent procedure with you on the same day as your first in-clinic visit and just prior to any study procedure. If virtually, we will administer the informed consent procedure with you days before your first in-clinic visit, depending on your preferred schedule. If you decide to participate in this research study, you will be asked to sign either a paper form or provide your electronic signature through a secure web application through REDCap (applies to both in-person and virtual consenting), depending on your preference. You will receive a copy of the signed informed consent for your own record that is either a paper or electronic copy, depending on your preference.

Dr. Franchino Porciuncula and Dr. Terry Ellis are in charge of this study. Dr. Porciuncula is the principal investigator and can be reached at fporciun@bu.edu or (617)-353-7571. Dr. Porciuncula and his team will be referred to as “researchers” on this form

Purpose

The purpose of this study is to evaluate if a community-based walking program that uses music cues during walking is more effective than a similarly structured community-based walking program that does not use music cues in improving physical activity, quality of walking, and exercise habits in people with Parkinson disease.

What Happens in this Research Study

You will be one of about 70 subjects with Parkinson disease asked to participate in this study. The study evaluations will take place at Boston University. The walking program that either uses music cues or without music cues, based on your group assignment, will take place at your home or in your community.

If you agree to participate in this study, you will be asked to participate up to 30 structured walking sessions over 1 month in your home/community environment, followed by a 2-week follow-up period to have you continue and engage in the walking program. There are 3 in-person evaluation visits that will be held at the Center for Neurorehabilitation, Sargent College, Boston University. The first evaluation visit will occur before you participate in the walking program, followed by another evaluation visit right after you complete the walking program (after 6 weeks), and a final evaluation visit at the completion of the program (after 8 weeks). The researchers will be available via phone if you have any questions about the walking program or experience any medical issues that impact your ability to continue in the study. In total, the study will last about 10 weeks.

Who is Funding the Study?

This study is supported by the Boston Roybal Center for Active Lifestyle Interventions, funded by the National Institute on Aging. The study involves the use of a device created by MedRhythms, Inc ("MedRhythms"). De-identified data collected from this study will be shared with MedRhythms and may be used by MedRhythms to improve their product. In addition, one of the researchers in this study, Dr. Lou Awad, might benefit financially from this study. Dr. Awad serves as a paid clinical advisor for MedRhythms. Additionally, Dr. Awad has an investment in MedRhythms (such as stock). The amount of money the investment is worth might be affected by the results of this study. This means a researcher involved with this study could gain or lose money depending on the results of this study.

Study procedure overview

This study comprises of the following procedures as shown in Figure 1: 0) phone screen to determine your preliminary eligibility, 1) screening/ baseline assessment, 2) six-week structured remote walking program (either with music cues or without music cues), 3) post-assessment, 4) two-week extended follow-up training (either with music cues or without music cues), and 5) final follow-up assessment.

In this study, you will be asked to use different devices related to measurement of movement, as well as in the delivery of the intervention depending on your group assignment. Screening procedures for eligibility will not use information from these devices. Instead, these devices will be used to measure effects of training, and to deliver the training itself: :

1) Wearable sensors to measure movement and walking activity:
   a) Step Activity Monitor (SAM, Orthocare, Edmonds, WA): measures walking activity. The SAM is approximately the size of a pager.
   b) In-lab movement sensors (XSENS, Enschede, Netherlands): measures walking quality during walking assessments in the clinic. These sensors are approximately the size of a wristwatch.
   c) Sensors of music-based device (MedRhythms, Portland, ME): measures rhythm and quality of your walking. These sensors will be used during in-clinic assessments, and during the walking program with music cues. These are the same type of wristwatch-size sensors that are used for assessing walking quality in the clinic as in 1.b above.
2) Components of the music-based device
   a) Music-based device (MedRhythms, Portland, ME): You will be asked to use this digital music therapeutic if you are assigned to the walking program with music cues. This device includes the following components:
      a. Headphones: Bone conduction headphones will provide sound transmission while still allowing you to hear the outside environment.
      b. Smartphone: A dedicated smartphone with pre-installed software application.
      c. Sensors of the music-based device: measures rhythm and quality of your walking. Information from these sensors are communicated to the smart phone to deliver tailored music tempos based on how you are walking. These sensors are the same as 1.c above,

1. First Evaluation Visit: In-Person Screening and Baseline Assessment (approximately 2-3 hours)

You are now participating in the first evaluation session of the research study. After you have read and signed this consent form, we will ask you to fill out a form that will allow us to communicate with your healthcare provider if needed to ensure your safe participation in the study. During this first visit, you will first undergo an in-person screening to determine your eligibility, which will then be followed by a Baseline Assessment, as follows:

a) <u>In-person screening:</u> The in-person screening comprises of tests and questions to make sure that you meet the criteria necessary to participate safely in this study. This will be done through screening tests which will include:
   - Questions about your medical history, memory, and Parkinson's symptoms
   - Physical assessments of your functional motor skills
   - Heart rate and blood pressure and ask you to perform two walking tests to ensure that you will be able to safely participate in the walking program.
   - Walking tests that will assess your walking speed over a short distance (for a total of 10-meters, which is about 33 feet) and the other will assess how far you can walk for a span of six minutes. During these walking tests, we will measure your movement while walking using wearable sensors (in-lab movement sensors and sensors of the music- based device). These sensors are lightweight, small (i.e.

about the size of a wristwatch), and unobtrusive (i.e. does not interfere with your movement), and will be secured on to
your shoes, on both legs (outer thigh and outer shank), and around the waist using straps or sensor clips to measure your movement while walking. Other components of the music-based device such as headphones and audio-cue mechanism will not be used during the screening. While these wearable sensors are worn during the screening, the information from these wearable sensors will be used for Baseline Assessment, and will not influence your eligibility to participate in the study.

If you do not meet the eligibility criteria, then you will not be able to participate in the study and the evaluation will be completed.

b) Baseline Assessment: If you meet the eligibility criteria, then we will ask you to do the following:
   - Answer questions about yourself such as your work history, living situation and your Parkinson's symptoms and medications.
   - Perform some balance- and mobility-related tasks. This will include activities requiring rising from a chair, standing still, and walking. One of the researchers will always be nearby to prevent falling, if needed.
   - We will measure your performance during these balance tests using wearable sensors (in-lab movement sensors).
   - Fill out some questionnaires related to your Parkinson's symptoms, quality of life, exercise habits, and perceptions on physical abilities.

Instructions for measuring your walking activity at home

After completing all the evaluation measures, you will be asked to wear a small, lightweight step- activity monitor (called a SAM, about the size of a pager) that measures walking activity while you are at home or in the community. At different timepoints in the study, you will be asked to wear the SAM all day for 4 - 11 consecutive days depending on time of evaluation. We will ask you to wear the SAM continuously during this period except while bathing, showering, or swimming and sleeping. For this initial wearing period, the first 4 days (days 1-4) that you wear the SAM, you will be asked to carry out your usual activities. For the next 7 days (days 5-11) that you wear the SAM, we will ask you to engage in the first week of your walking program. The SAM will assess your walking health throughout the day, including times when you are engaging in the walking program. The researcher will provide you with written instructions with the dates and specific details as to when you will wear the SAM and how to put it back on after you shower. The SAM is worn above the ankle and fastens with a Velcro strap; it has no buttons, switches, or dials; you simply need to remember to wear it. You'll be shown how to put it on and take it off and will be allowed to try it on to make sure it is comfortable during today's visit. We will give you a pre-paid shipping box during your first in-person evaluation, and you will use this to mail the SAM back to the study team at the end of this 11-day period. A member of the research team will call you within 24-48 hours at a time most convenient for you after this evaluation session to make sure you are comfortable with the device and address any questions you may have.

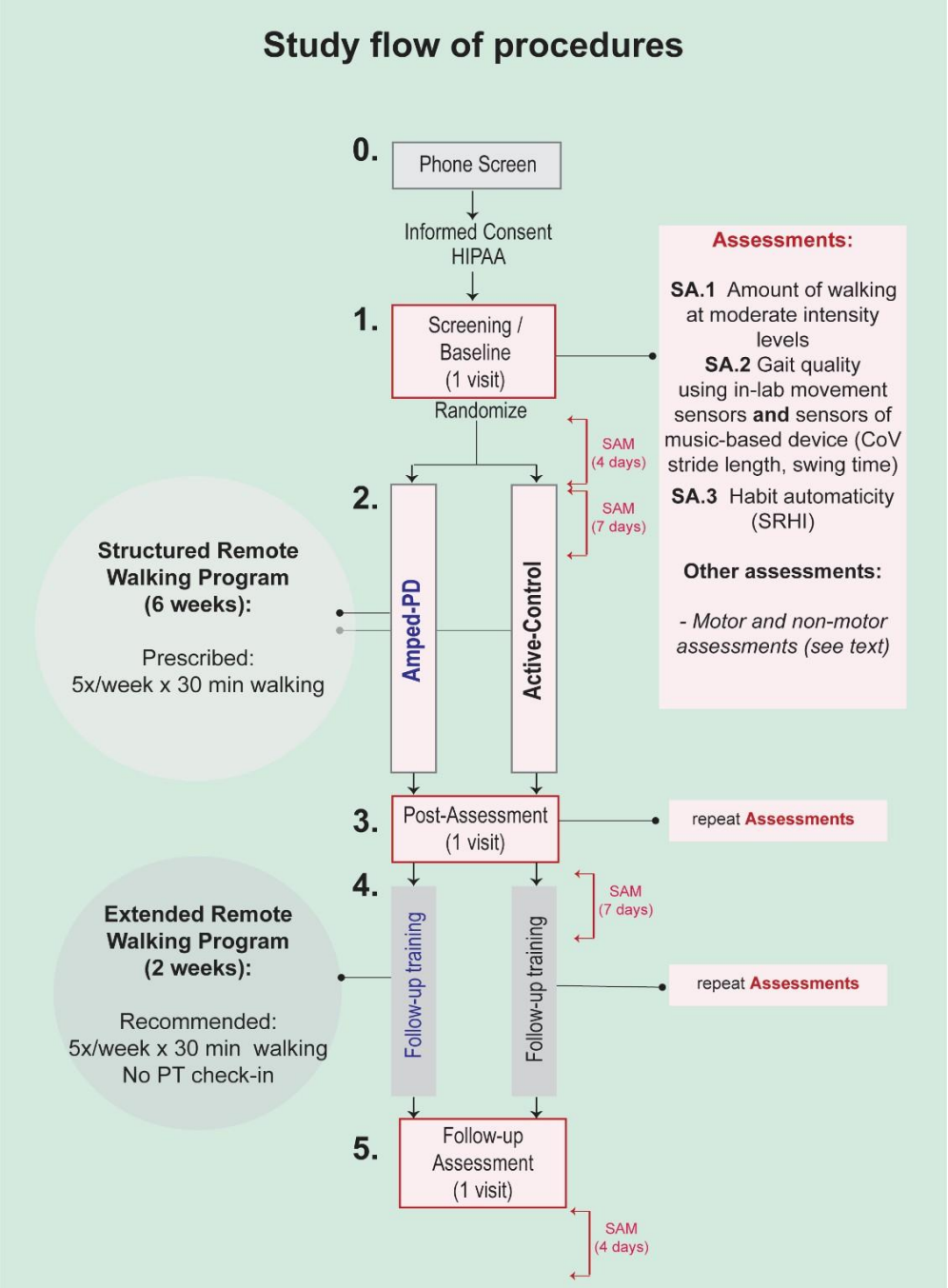

Figure 1 Study flow of procedures. Abbreviation: SAM: Step Activity Monitor (Orthocare)

Assignment to an intervention

After completing all screening and assessment procedures, you will be assigned to a type of intervention of either: (1) a community-based walking program with music cues, or (2) a similarly structured community-based walking program without music cues. The assignment of the walking program is based on random allocation.

The entire evaluation session will take about 2-3 hours. You will be allowed to rest, have a drink and snack during this time if you wish. You will be called by a member of the research team on a weekly basis to ensure that you feel comfortable with the walking program and to discuss any relevant medical and/or technical issues. During the evaluation visit, the research team will ask you at which time each week you would like to have this check-in call.

Instructions for using the music-based device (only for participants assigned to a walking program with music cues):

At the end of the evaluation session, a researcher will review with you how to use the music- based device that you will use during the walking program. You will be provided with the necessary equipment which includes a smartphone that is pre-installed with an application for the walking program, two small (wristwatch-sized) sensors of the music-based device that will be hooked onto the sides of your shoes (directly below your outer ankles), and one set of headphones. The sensors on your shoes collect information about your walking based on your steps. This information is then relayed through the application which will adjust the tempo of the music that will be played through the headphones. The wide music selection, typically contemporary, will include those with a recognizable beat pattern to make it easier for you to match your steps with the music tempo. The music is designed to adapt to your steps and the pace at which you walk. There is potential for the device to increase the pace at which you are walking such that you may walk a little bit faster than usual. At any time if you feel uncomfortable or anxious at the pace the device is prompting you to walk, you can slow down, take a break, and/or stop the session. We will show you how to set up and use the music-based device to make sure you are comfortable with all the steps. During this training, you will have the chance to practice putting on and setting up this device, ensure that you can hear the music through the headphones, and walk to the music while the researcher is present. If questions arise following this session, you will have access to a set of instructions about the device, however, feel free to reach out to the research team with any additional questions.

2. Remote Walking Program (6 weeks including up to 30 sessions of 30 minutes each in your home/community environment; 15 hours total)

If you agree to participate in the study, you will be asked to perform up to 30 structured walking sessions in your home/community environment.

For both walking programs (with or without music cues): Regardless of your intervention group, you will be asked to perform the following structured walking program as described below.:

Overview: The remote walking program is a self-directed walking program held in your home/ community settings. You will be instructed to complete five home/community-based walking sessions per week (approximately 30 minutes in duration) for 6 weeks, or as

tolerated. You may choose to perform these 5 training sessions on any days of the week according to your needs.

Description of Walking Program: You will be asked to perform the walking sessions at your self-selected pace. With repeated practice over days and weeks, it is typical to notice that your walking might get faster. However, it is also common that your walking pace may vary on a day-to-day basis. You will be asked to perform the walking program in home/ community environments that contain clear paths without obstacles such as furniture, area rugs, tree roots and divots, minimizing the need for stops and/or pivot turns in order to maximize continuous walking. You will be asked to avoid walking on slippery surfaces, environments with low light conditions (i.e. poorly-lit hallways; walking at night), during inclement weather if walking outside, and environments that have excessive distractions (e.g. busy street, very busy park). For the purpose of this study, home and community environments include but are 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: You will be asked to complete each walking session within a 30- minute timespan. You are allowed to rest as needed during the 30-minute training period; however, the time clock will continue to run down continuously once the 30 minutes are started. However, if the stop is due to a technical or medical issue, you will be instructed to end the walking session so that you can adequately resolve the issue with the help of study staff if needed. ***Walking program diary:*** You will be asked to record in a study diary your schedule (dates and times) of walking, location, record of any falls they experience and any comments/issues you experience while performing the walking program.

Safety Considerations: You will be informed of the potential risk of falls that can occur as part of the walking program in the community. The researcher will discuss with you what to look for in selecting safe and suitable environments for training that can help mitigate external risks that could lead to a fall. If you experience dizziness, chest pain, or other serious symptoms, you will be advised to reach out to your healthcare provider notify the study team following the episode. If a fall is experienced while engaging in the walking program, you are advised to seek medical attention (if needed), record the incident in your study diary, and contact the research team following the event to determine whether it is safe for you to continue. A member of the study team will contact you weekly to see if they have any questions or concerns with the walking program. If at any point you do not feel comfortable using the device, please reach out to the research team.

Physical therapy check-in call: You will receive a phone call from the research team to check in with you regarding your engagement in the walking program, and to provide guidance regarding any questions/concerns and/or any medical/ technical issues. The call will last approximately 5-10 minutes and will occur within the first week of the walking program. You will work with the researcher/ physical therapist if there is a preferred schedule for these regular weekly check- in calls. If you 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 assist with carrying out the walking program. A study staff member will also inquire about any adverse events during the weekly phone call, or any considerations.

Using SAM to measure walking activity in the home/community: At this time, you will already have completed 4 days of continuous wear of the SAM following your first in-

person evaluation visit. You will be asked to continue wearing the SAM for an additional 7 days upon starting the walking program. Therefore, you will complete 11 days of continuous wear of the SAM. At the conclusion of the 11 days of continuous wear of the SAM device, you will be asked to return the SAM to our lab using a pre-labeled, addressed envelope. The researchers will download the data and will store this in a secure server.

Interruptions in training: In the event of unavoidable interruptions in training, booster sessions may be implemented to promote the overall continuity of your walking program. For training interruptions that last up to 2 weeks, you will be asked to continue for an additional amount of weeks (called booster sessions) at 100% of the time missed. For training interruptions of greater than 2 weeks, you may be asked to restart the training after a reasonable washout interval, as determined by the Principal Investigator (a licensed physical therapist). If training interruption resulted in permanent change in your eligibility, you will be withdrawn from the study.

For walking program with music cues: If you get assigned to perform the walking program with music cues, you will conduct the same walking program as described above with the addition of the use of a music-based device. The following are considerations specific to the walking program with music cues.:

Conducting the walking program with music cues: You will be asked to use the music-based device as you perform the walking sessions at your self-selected pace in a home/community environment. The tempo of the music cues will adapt to your walking. That is, it is possible for the device to offer a slightly faster tempo at which you are walking such that you may walk a little bit faster than usual. Music cues will automatically be adjusted (i.e. faster, slower, no change) according to the pace of your walking. If you are assigned to this condition, the last four days of the SAM activity procedure will overlap with the first four days of the music-based device walking procedure. This means you will be wearing the SAM and the music-based device simultaneously for up to 7 days. The SAM (worn above the ankle) and the music-based device's sensors (clipped to the shoes below the ankle) can be worn at the same time on the same side of the body as they are placed in different locations that will not interfere with your ability to walk and/or lead to an increased risk of trips/falls

Duration of Walking Program: Same as above.

Duration of Walking Session: Same as above.

Walking program diary: Same as above.

Physical therapy check-in call: Same as above.

Safety Considerations: Same as above. If a fall is experienced while using the music-based device, you will be advised to seek medical attention (if needed) and record the incident in your study diary. Additionally, you will be asked to contact the study team following the event to determine whether it is safe for you to continue the walking program using the device.

Using SAM to measure walking activity in the home/community: Same as above. It is worth noting that both the monitor that measures walking at home/ community and the shoe sensors of the music-based device can be worn simultaneously on the same side of the body without interfering with your walking and/or increasing the risk for trips/falls.

Interruptions in training: In the event of unavoidable interruptions in training, booster sessions may be implemented to promote the overall continuity of your walking program. For

training interruptions that last up to 2 weeks, you will be asked to continue for an additional amount of weeks (called booster sessions) at 100% of the time missed. For training interruptions of greater than 2 weeks, you may be asked to restart the training after a reasonable washout interval, as determined by the Principal Investigator (a licensed physical therapist). If training interruption resulted in permanent change in your eligibility, you will be withdrawn from the study.

3. Second Evaluation Visit: Post-training Assessment Session - After the Walking Program is Completed (2-3 hours)

You will be asked to come back to Boston University within 1 week of completing the 6-week walking program or the next earliest date based on scheduling to participate in post-training assessment visit. You will complete the same questionnaires related to your Parkinson's symptoms, quality of life, exercise habits, perceptions of walking abilities, as well as the balance and mobility tests that are instrumented with wearable sensors as you have done them during the first evaluation visit (in-lab movement sensors and sensors of the music-based device). This session will take about 2-3 hours. If you were assigned to the walking program with music cues, we will ask that you bring in the music- based device (if one was supplied to you) as well as your study diary, and complete a questionnaire regarding your experiences on the use of the music-based device. Regardless of your walking program, you will be asked to use the sensors of the music-based device in one of the mobility tests so that we can measure the quality of your walking. We will make a copy of the study diary for our record.

At the end of this session, we will give you back the music-based device and the study diary for continued use for another 2 weeks of follow-up training (see next section). Additionally, we will give you back the SAM that measures walking health for use during the first four days of Follow-up Training (see next section), along with a pre-paid shipping box for you to use to return the SAM after 4 days of wear.

4. Follow-up Walking Program (2 weeks of extended remote walking program in your home/community environment; Recommended training of 30 min/session x 5x/week)

Regardless of your group assignment, you will be recommended to continue performing the walking program independently for an additional 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).

Description of the Follow-up Walking Period: For an additional 2 weeks, you will be encouraged to continue to be engaged in the walking program as you have done so in the previous 6-week walking program (i.e. 30 min/ session x 5x/week). You will be asked to carry out the walking program on your own on an ongoing basis for 2 weeks, however, this time, without the supervision or encouragement of the physical therapist or researcher. This recommendation to continue the walking program is similar to the common practice of independently performing a home exercise program that is recommended to you after being discharged from an episode of physical therapy care.

Duration of Walking Session and Program: You will be recommended to continue engaging in the walking program 30 min/ session, 5x/week for 2 weeks.

Walking program diary: You will be asked to continue using the walking program diary to log your walking sessions (date, time, duration).

Physical therapy check-in call: You will not receive regular phone call check-ins from the physical therapist to guide you with the walking program or to provide encouragement. However, you will be advised to continue to communicate with the physical therapist or researcher if you have any questions regarding the device, safety, medical questions, or other aspects of the study.

Safety Considerations: Same as above.

Using SAM to measure walking activity in the home/community: Upon starting the Follow-Up Walking Program, you will be asked to wear the monitor that measures your walking health for 24 hours per day for the next 7 days except while bathing, showering, or swimming. You will use the pre-paid envelope with our address (i.e. provided to you during the post-training assessment) so that you can mail the monitor back to us after the 7 days.

Interruptions in training: In the event of unavoidable interruptions during your follow-up period, booster sessions may be implemented to promote the continuity of your walking program. For training interruptions that last up to 2 weeks, you will be asked continue the follow-up walking program and receive additional weeks of training (called booster sessions) at 100% of the time missed. For training interruptions of greater than 2 weeks, we will forgo your missed training.

For walking program with music cues: If you are assigned to the walking program with music cues, you will perform the Follow-Up training as described above. The only difference will be that you will also have continued access to the music-based device for continued use.

You will be encouraged to keep doing the walking program with the music-based device as you have performed during the 6-week Remote Walking Program with music cues.

5. Third Evaluation Visit: Follow-Up Assessment Session: After the Walking Program is Completed (2-3 hours)

You will be asked to come back to Boston University within 1 week of completing the 2-week Follow-up Walking Program or the next earliest data based on scheduling to participate in a final evaluation visit. The study staff will work with you to schedule this visit at a time that is convenient for you. You will complete the same questionnaires related to your Parkinson's symptoms, quality of life, exercise habits, perceptions of walking abilities, as well as the balance and mobility tests that are instrumented with wearable sensors as you have done them during the first evaluation visit (in-lab movement sensors and sensors of the music-based device). Also, we will ask about your about your opinions and experience with the walking program. This session will take about 2-3 hours. If you were assigned to the walking program with music cues, we will ask that you bring in the music-based device. Regardless of your walking program, you will be asked to use the sensors of the music-based device in one of the mobility tests so that we can measure the quality of your walking. You will also be asked to bring in your study diary to be returned to the study team.

Lastly, at the end of this third evaluation visit , we will give you back the monitor that measures walking activity. You will be asked to wear the monitor for 24 hours per day for the next 4 days except while bathing, showering, or swimming. We will again give you a pre-paid envelope with our address so that you can mail the monitor back to us after the 4 days of wear.

How much walking will I do?

In summary, you will be asked to participate in 30 total walking sessions over the course of 6 weeks during the Remote Walking Program. This breaks down into 5 sessions per week (for 6 weeks) each lasting up to 30 minutes based on your tolerance. Thereafter, you will be asked to continue the walking program for an additional 2 weeks during the Follow-Up Walking Program. The amount and duration of walking is not specified by the physical therapist. Instead, you will determine the extent of your engagement in a walking program based on what feels best and right for you as you continue with a walking program.

Where should I carry out the walking program?

At the first assessment visit, the researcher will also review with you a safe environment in your home/community that you will be able to conduct the walking program. A safe environment is 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: your home, apartment building hallway, neighborhood sidewalks, local track or park, office environments, and community/recreation centers. Ideally the space should be at least 50 feet in length. You will be asked to record in the study diary (provided to you during your first evaluation visit) your schedule (dates and times) of walking, location, any falls you experience, and comments/issues you experience while using the device. If you experience any technical or medical issues during your walking sessions, stop the session until the issue is resolved. If a medical issue, fall, or other health-related concern (e.g., dizziness, chest pain) occurs during the walking program, we advise you to reach out to your healthcare provider or call 911 if it is an emergency. Please contact the study team following the event prior to resuming the walking program to determine if it is safe for you to continue. In addition, if at any time you feel uncomfortable with the device, you should stop the walking program and reach out to the research team.

Photo/ Video Recording

We would like to take a photo and/ or audio-video of you during this study. This will help us review and understand how you perform in certain motor and walking tests, as well as walking activities. An audio recording will help us document your opinions about the walking program at the completion of the study. If you are videotaped it may be possible to identify you in the video. We will store these videos on a password-protected SharePoint folder. We will label these videos with a code instead of your name. The key to the code connects your name to your video. The researcher will keep the key to the code in a password-protected file on a different computer server. These recordings will be uploaded and stored in a secure BU server. Agreement or refusal to audio/ video will not impact your eligibility to participate in the study. If you agree to this, we may use the video for publications, presentations, training and educational purposes, or promotional purposes.

Do you agree to allow us to photo/ audio-video record you during this study?

_____YES _____NO _____Participant Initials

Do you want your face to be blurred on photo/ video if it is captured?

_____YES _____NO _____Participant Initials

Risks and Discomforts

There are some potential risks and discomforts that you may experience if you decide to participate in this study. The evaluation sessions are 2-3 hours long; however, you can take as many breaks as you need in order for you to feel comfortable. There is a small risk that you could feel some fatigue or muscle pain from performing the mobility tests or experience a fall during the evaluation process. However, this risk is low since the evaluation sessions are not vigorous and will be conducted by a trained researcher. Physical therapists will be on hand during these in lab sessions to provide guarding in the event you lose your balance or begin to fall.

There is the potential for you to have muscle soreness after carrying out the walking program; however, this should resolve within a 1-2 days and will lessen as you get used to the walking.

It is possible to have skin irritation from elastic straps that secure lab sensors and the SAM, as well as the clips-on sensors of the music-based device. Risks related to skin irritation can be minimized by wearing good walking shoes (i.e. not too tight to accommodate clip-on shoe sensors), wearing the SAM over socks and avoiding direct contact to your skin. We will also provide you with printed instructions on proper wear of the SAM. During your in-person visits, a trained research staff will ensure that the sensor straps are secured properly (i.e. snug but not too tight), and will perform regular skin checks.

You could also experience fatigue with walking; however, this will be minimized by only very gradually increasing the speed of walking and allowing rest periods during the 30-minute walk, if needed. Since the walking program is conducted in your home/community environment without the direct supervision of a trained researcher, there is the potential that you could fall and harm your skin, joints, or bones. It is also possible to hit your head during a fall. Additionally, there are possible environmental risks and pedestrian hazards related to traffic, weather, uneven
terrain, and other elements. However, the risk of this will be minimized if you wear good walking shoes and carry out the walking session in a safe environment as discussed between you and the researcher. You could also experience dizziness, shortness of breath, chest pain, or onset of new orthopedic conditions; however, this is unlikely as the intensity of the walking is low to moderate.

Electronic devices used in the study, which includes the smartphone and wearable sensors (SAM, sensors of the music-based device), when operated outside the scope of its recommended use and proper care (i.e. water damage, improper storage in damp environments) may cause the device to malfunction and may cause electric shock. Do not use or attempt to repair the device if damaged. Please contact the research team if you have concerns related to device damage.
You will be instructed on proper handling and care instructions to ensure proper operation. We will also check-in with you regarding proper device-use during the weekly phone calls as necessary.

If you do end up with a medical issue or injury of any kind please call your healthcare provider or 911 if an emergency, in addition to contacting our team. When you call to let us know of the event, we will ask questions to make sure that this walking program is still safe for you. You may stop participating in this study at any time. If you do experience a fall or other medical issue/injury, please call us at this number: (617)-419-0704 at any time If you call outside of business hours (Monday – Friday, 9:00 a.m. – 5:00 p.m.), please leave a voice message with your name and contact information and a member of our research team will return your call during the next business day.

There may be unknown risks/discomforts involved. The study team will update you on any new information that may affect your health, safety, or decision to continue participating in this study.

Potential Benefits

You may experience benefits from participating in this study regardless of the assigned intervention as you will engage in 30 structured walking sessions that may be helpful in developing regular walking routines and improved overall physical activity. The walking program with the music-based device has the potential to result in improved home and community walking ability in persons with Parkinson disease. However, it is possible that you may not receive any benefit from participating.

Alternatives

The alternative is not participating in this research study.

Subject Costs and Payments

There are no direct costs to you if you decide to participate in this study. However, you will be responsible for providing your own transportation to and from the study site. You will receive free parking for all three evaluation sessions. The structured walking program and music-based device will be provided to you at no cost. You will receive Amazon gift cards after completing each evaluation session (Baseline assessment: $25; Post-training assessment: $50; Follow-up assessment: $75; total of $150 for 3 visits).

Confidentiality

Your participation also carries a risk of confidentiality loss. The researchers will take measures to minimize this risk. Only researchers working on this study and other authorized Boston University personnel will have access to the information collected about you. You will be given a unique code (your name won't be used), with a master list matching your unique code with your name on an encrypted and password-protected database that only researchers involved in the study and authorized Boston University personnel will have access to.

The music-based device includes a sensor that you wear on your shoe. This sensor measures walking pace, which is used to set the tempo of the music. The music-based device contains

this data on walking pace. This data is linked to a research staff created ID only (no names or identifying information are linked to the device). The music-device company (MedRhythms) has access to the walking pace data linked only to your ID and will not be able to link the ID number to you.

The SAM device collects certain biometric information, such as your walking pace, speed, and rhythmicity, but does not collect any identifiable data.

There are also times when federal or state law requires the disclosure of your records. All paper copies of information gathered will be kept in a locked cabinet in a locked office.

The following people or groups may review your study records for purposes such as quality control or safety:

- The researchers on this study.
- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- Federal and state agencies that oversee or review research.
- BU Central Offices.

The results of this study may be published or used for teaching purposes. They will also be shared with MedRhythms, Inc. who may use the data to improve their device. We will not put identifiable information on the data that are used for these purposes, so MedRhythms, Inc. will not have access to your identifiable information A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Right to Refuse or Withdraw

Taking part is this study is completely voluntary. You have the right to refuse to take part in this study. If you decide to participate in this study and then change your mind, you can withdraw from the study at any time. If you withdraw from the study, there will be no penalty, loss of benefit, or ability to receive health care here or at any other place.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

The researcher may also take you out of the study without your permission if:

- A change in your medical or functional status occurs that interferes with your safe participation in this study
- You are unable to follow verbal instructions from the researchers and your safety during the study is compromised
- You are unable to complete baseline assessments and unable to demonstrate independence during walking and general mobility tasks.
- The researcher thinks it is in your best interest
- You can’t make the required study visits

- Other administrative reasons

Emergency Care and Compensation for Injury

If you are injured as a result of taking part in this research study, we will assist you in getting medical treatment. However, your insurance company will be responsible for the cost. Boston University does not provide any other form of compensation for injury

Certificate of Confidentiality

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless: there is a law that requires disclosure (such as to report child abuse or communicable diseases, but not for legal proceedings); you have consented to the disclosure, including for your medical treatment; or the research information is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audits or program evaluations requested by the agency that is funding this project or for information that may be required by the Food and Drug Administration (FDA). Any research information that is placed in your medical record would not be covered under this Certificate.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Storing Study Information for Future Use

Identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable private information may be used for future research of Parkinson disease rehabilitation and other neurological conditions including but not limited to stroke, dementia-related disorders, and other neurodegenerative disorders. If the researcher distributes your private information to other researchers or institutions, your private information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your private information if you check “Yes” to the question below.

If you have questions about storing your information or would like to request that your information be removed from storage, please let us know. It is not always possible to remove information from storage or retrieve information from which identifiers have been removed and/or that have already been sent to other investigators.

If you check “No” to the question below, private information collected from you during this study will not be used for future research studies or shared with other researchers for future research, even if the information identifying you are removed from the private information.

Do you agree to let us store your study information for future research related to Parkinson disease rehabilitation?

_____ YES _____ NO _____ INITIALS

Future Contact

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University.

Do you agree to let us contact you in the future?

_____ YES _____ NO _____ INITIALS

Statement of Consent

Signing this form means that you have read (or have had it read to you) and understand the information on this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of the signed consent form.

Please feel free to reach out to us with questions at any time, now or in the future, regarding the research or your participation. The Principal Investigator in the Center for Neurorehabilitation, Sargent College, Boston University will be happy to answer any questions you might have.

Dr. Franchino Porciuncula, EdD, PT, DScPT Principal
Investigator Research Scientist
Center for
Neurorehabilitation
Boston University
(617) 353-7571

You may obtain further information about your rights as a research participant by calling the Institutional Review Board for Human Subject Research for the Boston University Charles River Campus at (617)- 358-6115 or by emailing irb@bu.edu. The IRB Office webpage has

information where you can learn more about being a participant in research, and you can also complete a Participant Feedback Survey.

If any problems arise as a result of your participation in the study, including research-related injuries, please immediately call the Principal Investigator, Franchino Porciuncula, at Boston University at 617- 353-7571.

Participant's name:_____

Participant's signature: _____

Date: _____

I have fully explained to _____the nature of the above-described research study and any risks involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedure or the risks and benefits if any should occur during the course of the study.

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent_____

Date_____