

# Ambulosono - A music walking program for patients with Parkinsons Disease (PD)

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| <b>Submission date</b><br>12/12/2013   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/04/2014 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/05/2014       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Ambulosono is a home-based walking program. Its primary objective is to prevent the most common Parkinsonian gait alterations such as low speed, short steps, turning difficulties and to prevent events like shuffle, arm-leg incoordination, falls, etc. Ambulosono trains patients to walk with larger and consistent steps and do so repetitively on a daily basis. Such overtraining not only can increase the physical vigor but it can also enhance voluntary and automatic motor control and transform monotonous strolling into a pleasurable brisk walking exercise. The aim of this study is to assess how well this program works.

### Who can participate?

Individuals with confirmed diagnosis of Parkinsons Disease and able to walk 5-10 minutes unassisted.

### What does the study involve?

This study is about the usage of a contingent music program for gait rehabilitation of individuals with Parkinsons disease.

### What are the possible benefits and risks of participating?

Benefits include reduced risk of falls, functional independence and improvement in quality of life. We also hope that the caregiver and relatives can also indirectly benefit from this Ambulosono approach. The inconveniences are minimal (some patient visits for regular reassessments). There are no risks involved.

### Where is the study run from?

University of Calgary (Canada).

### When is the study starting and how long is it expected to run for?

April 2013 to September 2016.

### Who is funding the study?

Canadian Institutes of Health Research, Alberta Innovates and Health Solutions and University of Calgary (Canada)

Who is the main contact?

Prof. Bin Hu

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

REB13-0009

## Study information

### Scientific Title

A sensorimotor contingency-based musical walking program to promote healthy living and functional recovery for people living with Parkinsons Disease

### Study objectives

Ambulosono is a home-based walking program. Its primary objective is to prevent and modify Parkinsonian gait disorders through early behavioral training and intervention. Gait disorders are unintended changes in walking steps or speed that can be initially manifested as slowness or shuffling steps (bradykinesia), arm-leg incoordination (arrhythmia), hesitation or freezing and etc. With reduced balance, patients can develop fear of falling, injurious falls, loss of functional independency and physical deconditioning. These together accelerate PD progression.

Ambulosono trains patients to walk with larger and consistent steps and do so repetitively on a daily basis. Such overtraining not only can increase the physical vigor of lower limb movements but enhance voluntary and automatic motor control while rendering monotonous strolling into a pleasurable habit of brisk walking exercise.

Gait rehabilitation via Ambulosono is achieved at multiple levels. At first level, music with high emotional salience and likableness are selected and utilized to induce a high level of physiological arousal and as a means to activate locomotor networks and heighten sensorimotor perception, awareness and self-efficacy. At second level, the music play is made contingent upon the amplitudes of walking steps. When walking with steps larger than a pre-defined amplitude music will continue to play. On the other hand, shorter steps will lead to a sudden music

stoppage. Hence, music contingency can help transform walking into a procedural task that is continuously reinforced by two behavioral conditioning paradigms: positive reinforcement of longer steps to invoke active seeking and negative reinforcement of shorter ones by active avoidance. As a result, unintended smaller walking steps, e.g. shuffling, can be prevented before it becomes an undesirable habit. Finally, the third level of Ambulosono training targets the transfer of sensorimotor skills and procedural memory acquired during music walking. Transfer training involves associating music walking with a different condition or specific context that can cause gait abnormalities. Such associative training can help construct new motor sequence through the generalization of motor memory and responses that share similar goals and procedures. An example is the utilization of a common reinforcement paradigm to concurrently increase the amplitudes of arm and leg movements during walking or stepping. Specific protocols of transfer training and memory consolidation will be developed through this study.

Our hypothesis is that a contingent music intervention is able to improve balance, kinematic gait parameters (speed, step length, cadence) and prevent/ameliorate its disturbances (shuffle, freezing, hesitation) in Parkinsons disease.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Conjoint Health Research Ethics Board of the Faculties of Medicine, Nursing and Kinesiology of the University of Calgary, September 2013

### **Study design**

Open label non-placebo controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Quality of life

### **Health condition(s) or problem(s) studied**

Parkinson's Disease/exercise

### **Interventions**

Music walking plus medication tracking and de-freezing training.

Our study uses an iPod touch with an application called GaitReminder that you wear strapped to your leg while walking for exercise. It plays music, provided that you walk with a step size above a pre-set threshold, set specifically for you. However, when your steps become too small, and fall below this threshold value, the music will shut off. This is to act as a reminder to increase your step size. Then, when you do walk with larger steps, you are rewarded with music play.

First On-site Testing Session (Phase I): Ambulosono assessment protocols (AAP), demographic questionnaires and Ambulosono orientation will be scheduled to take place over one day in the Balance Research lab and the First Choice Training Center indoor track (6 min walking test).

Home Baseline Walking (Phase II): After the initial lab visit and Ambulosono orientation, participants will be asked to undergo a one month non-contingent walking program while wearing the GR device. The purpose of this task is to gather baseline data on stride length in a more natural environment.

Second On-Site Appointment (Phase III): Prior to the second appointment, the PI or his/her delegate will prepare a brief summary chart of the AAP results and home baseline walking data that indicates the dominant gait abnormalities of the subject and the suggested training plan. Common diagnoses include bradykinesia, arm freezing, shuffling, fear of falling, freezing, incoordination, or high-risk faller.

Contingent Music Walking Protocol (Phase IV): The objectives of contingent music walking (CMW) training phase are two-fold: 1) to improve specific gait abnormalities identified during baseline testing, and 2) to make large step walking an enjoyable exercise habit and preventative measure, especially for those patients who have a sedentary lifestyle. The new walking habits can be objectively assessed based on walking frequency, speed, time, distance and self-reported improvement in physical and mental quality of life.

Third On-Site Appointment (Phase V): The third on-site appointment will follow the same protocol as the second on-site appointment (AAP, balance assessment, gait tests and questionnaires will be repeated). At this stage of the intervention, our cohort will be split (randomized) into groups A and B. Group A will participate in the transfer training protocol (TTP), while group B will participate in the retention test protocol.

Transfer Training Protocol (Phase VI-A): Participants will be given a second iPod for arm training. The second iPod will be arm-mounted, and set to play white noise that can be stopped by performing a large arm swing; thus, the patient will have to take large arm swings AND large steps in order to hear only music.

Retention Test Protocol (Phase VI-B): Patients will be asked to complete activities of daily living as they normally would for 1 month. No research intervention will occur over this time.

Fourth On-Site Appointment (Phase VII-A): The fourth and final on-site appointment will assess the efficacy of the transfer training protocol on members of Group A. Post-TTP reach-to-grasp kinematics will be collected at this time.

Fourth On-Site Appointment (Phase VII-B): This final on-site appointment will be used to assess the Group B patients retention of the skills learned during the Ambulosono intervention. AAP, balance and gait testing will be completed as during the second and third on-site appointments.

The total study period is expected to last 6 months. At the end of the study, patients will be provided with a final report detailing the assessment and training results as well as the improvements obtained. Patients who have not yet done so will be asked to return the GR device and headphones to the program. However, arrangements may be made should the participant wish to purchase the device to continue the training program on their own.

## **Intervention Type**

Other

## **Phase**

Not Applicable

**Primary outcome(s)**

Patients will be able to undertake brisk walking on a regular basis at a level recommended in National Institutes of Health (NIH) guidelines. Balance and gait will be assessed at each of the four appointments.

**Key secondary outcome(s)**

Improvements in:

1. Freezing of gait (freezing of gait questionnaire [FOG-Q])
2. Drug complications
3. Falls (fall efficacy scale international [FES-I])
4. Standard clinical scores for PD (unified Parkinson disease rating scale [UPDRS] and Hoehn & Yahr [HY])

Measured at the 2nd, 3rd and 4th appointments.

**Completion date**

01/09/2016

**Eligibility****Key inclusion criteria**

1. Confirmed diagnosis of Parkinson's Disease
2. Can walk 5-10 minutes unassisted
3. Have a venue to walk (outdoor or indoor)
4. Disease stage earlier than Hoehn and Yahr Stage IV (HY-IV)
5. Have a safe place to walk
6. Walk a minimum of 3 x week
7. Age range: 50 - 90
8. Gender: male and female

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Reliance on wheelchair or walker for ambulation
2. Presence of any serious medical condition including hearing impairment and dementia
3. History of another neurologic deficit
4. Musculoskeletal impairment or disease injuries that prevent walking

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

01/09/2016

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

3330 Hospital Drive

Calgary

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## **Sponsor information**

**Organisation**

University of Calgary (Canada)

**ROR**

<https://ror.org/03yjb2x39>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Alberta Innovates - Health Solutions (Canada)

**Alternative Name(s)**

AIHS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Canada

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a>              |                               | 06/10/2018   |            | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |