ISRCTN06023392 https://doi.org/10.1186/ISRCTN06023392

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

Submission date
12/12/2013

Recruitment status
No longer recruiting

Registration date
30/04/2014

Overall study status
Completed

Last Edited
19/05/2014

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 wvents 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
hub@ucalgary.ca

Study website
https://foxtrialfinder.michaeljfox.org/trial/3603/

Contact information

Type(s)
Scientific

Contact name
Prof Bin Hu

Contact details
3330 Hospital Drive
Calgary
Canada
T2N 4N1
+1 403 210 8640
hub@ucalgary.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/04/2013

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

Age group
Senior

Sex
Both

Target number of participants
400

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
Canada
T2N 4N1

Sponsor information

Organisation
University of Calgary (Canada)

Sponsor details
c/o Prof Bin Hu
3330 Hospital Drive
HRIC Rm:1ac60
Calgary
Canada

T2N 4N1
+1 403 210 8640
hub@ucalgary.ca

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?

Abstract results	06/10/2018	No	No