Biofeedback Rehabilitation in Parkinson's Disease (GAMEPAD_PD)

ClinicalTrials.gov Identifier: NCT02713971

Study Description

Brief Summary:

Background: In this study, a new biofeedback system for balance and gait rehabilitation (Gamepad) was developed. The system, based on wearable inertial sensors, provides users with real-time visual and acoustic feedback about their movement during functional tasks. Gamepad was applied on subjects with Parkinson's disease (PD) in a pilot randomized controlled trial to investigate its feasibility and efficacy versus conventional physiotherapy. The investigators hypothesized that Gamepad system can be easily applied in clinical settings and that biofeedback training with Gamepad provides larger improvements of balance and gait in PD subjects, respect to conventional physiotherapy.

Methods: Forty-two PD patients underwent a 20-session training for balance and gait (45 minutes per session, 3 sessions per week). Participants were randomized into Gamepad Group (biofeedback rehabilitation with Gamepad system), and Control Group (conventional physiotherapy). Clinical and instrumental assessments were performed by a blind examiner pre-, post-intervention and at 1-month follow-up.

Condition or disease	Intervention/treatment	Phase
Parkinson Disease	Device: Gamepad systemOther: Conventional physiotherapy	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	42 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Wearable Sensor-based Biofeedback Training for Balance and Gait in Parkinson's Disease: a Pilot Randomized Controlled Trial.
Study Start Date :	January 2013
Actual Primary Completion Date :	April 2015
Actual Study Completion Date :	April 2015

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Parkinson disease

MedlinePlus related topics: Parkinson's Disease Rehabilitation

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Gamepad Biofeedback rehabilitation with Gamepad system.	Device: Gamepad system Patients executed a set of tailored exercises including the control of weight-shift and body posture during static (e.g. upright sitting and standing), quasi-dynamic (e.g. sit-to-stand and gait initiation) and dynamic tasks (e.g. getting on a step, straight-line walking, walking with turns and over obstacles). Participants executed the tasks using Gamepad system which provided patients with visual and auditory feedback about their performances and assigned a score at the end of each exercise. The physiotherapist progressively adjusted training complexity by changing the reference values, including more difficult taks, changing the perceptive context, and/or including a dual-task.
Active Comparator: Control Conventional physiotherapy.	Other: Conventional physiotherapy A set of tailored exercises was defined by the clinical staff following current guidelines for physiotherapy in Parkinson's disease. In particular, stretching, joint mobilization, and balance and gait exercises were provided to participants, without any instrumentation producing biofeedback or external cues.

Outcome Measures

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Primary Outcome Measures :

1. Post-treatment score of Berg Balance Scale [Time Frame: 7 weeks]

   Score of Berg Balance Scale assessed at the specified time frame, adjusted for baseline score through ANCOVA procedure.

   Berg Balance Scale rates balance from 0 (cannot perform) to 4 (normal performance) on 14 items exploring the ability to sit, stand, lean, turn and maintain the upright position on one leg. Maximum score (i.e. 56 points) indicates unimpaired balance.

2. Post-treatment score of 10-meter Walk Test [Time Frame: 7 weeks]

   Score of 10-meter Walk Test assessed at the specified time frame, adjusted for baseline score through ANCOVA procedure.

   10-meter Walk Test measures, with a stopwatch, the time (T) taken by the subject to walk between two lines at the distance of 10 meters. Walking speed is thus computed as 10/T (m/s). Both comfortable and fast gait speed can be measured. In the present study only comfortable gait speed was assessed.

Secondary Outcome Measures :

1. Follow-up score of Berg Balance Scale [Time Frame: 11 weeks]

   Score of Berga Balance Scale assessed at the specified time frame, adjusted for baseline score through ANCOVA procedure.

2. Follow-up score of 10-meter Walk Test [Time Frame: 11 weeks]

   Score of 10-meter Walk Test assessed at the specified time frame, adjusted for baseline score through ANCOVA procedure.

3. Scores of Unified Parkinson's Disease Rating Scale - Motor examination (UPDRS-III) [Time Frame: 7 weeks and 11 weeks]

Score of UPDRS-III assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

4. Scores of Timed Up and Go test [Time Frame: 7 weeks and 11 weeks]

   Score of Timed Up and Go test assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

   Timed Up and Go test is a mobility test evaluating the time taken by the subject to rise from a chair, walk 3 meters, turn around, walk back to the chair and sit down.

5. Scores of Activities-specific Balance Confidence scale (ABC) [Time Frame: 7 weeks and 11 weeks]

   Score of ABC assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

   Activities-specific Balance Confidence scale is a questionnaire through which the subject rates his/her perceived level of confidence while performing 16 daily living activities. Scores range from 0% (not confident) to 100 % (completely confident).

6. Scores of Freezing Of Gait Questionnaire (FOGQ) [Time Frame: 7 weeks and 11 weeks]

   Score of FOGQ assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

   Freezing Of Gait Questionnaire evaluates freezing severity with a 6-item interview. Each item is rated on a 5-point ordinal scale from 0 (absence of freezing) to 4 (severe freezing).

7. Scores of Parkinson's Disease Questionnaire-39 (PDQ-39([Time Frame: 7 weeks and 11 weeks]

   Score of PDQ-39 assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

   Parkinson's Disease Questionnaire-39 is a 39-item, self-report questionnaire, which assesses Parkinson's disease-specific health related quality of life over the last month. Scores are from 0 to 100, with 100 representing maximum level of problems.

8. Tele-healthcare Satisfaction Questionnaire - Wearable Technology (TSQ-WT) [Time Frame: 7 weeks]

   TSQ-WT consists in six areas (Benefit, Usability, Self-concept, Privacy and loss of control, Quality of life, and Wearing comfort) that evaluate the satisfaction of the subject with the wearable part of a system. Each area includes 5 statements rated by the user on a 5-pint Likert scale between 0 (strongly disagree with the statement) and 4 (strongly agree with the statement). In the present study, only Benefit, Usability and Wearing Comfort areas were administered. TSQ-WT was administered to the Gamepad Group only.

9. Amplitude of body sway in antero-posterior (Sway AP) and medio-lateral (Sway ML) directions [Time Frame: 7 weeks and 11 weeks]

   Sway AP and ML assessed at the specified time frames, adjusted for baseline score through ANCOVA procedure.

   Subjects were tested for 30 seconds during upright standing on a stabilometric force platform in four sensory conditions: eyes open, eyes closed, eyes open with foam pads under feet, and eyes closed with foam pads under feet. Center of Pressure (CoP) sway in AP and ML directions was computed as the standard deviation of the time-course of AP and ML CoP displacements recorded by the platform.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Hoehn-Yahr stage 2 to 4.
- Ability to stand up more than 10 s and inability to stand on one foot more than 10 s.
- Ability to walk for at least 6 m even with an assistive device.
- Stable drug usage.

Exclusion Criteria:

- Mini-Mental State Examination < 24.
- Implanted deep brain stimulator.

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02713971***

Locations

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More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Bowman T, Gervasoni E, Parelli R, Jonsdottir J, Ferrarin M, Cattaneo D, Carpinella I. Predictors of mobility domain of health-related quality of life after rehabilitation in Parkinson's disease: a pilot study. Arch Physiother. 2018 Dec 27;8:10. doi: 10.1186/s40945-018-0051-2. eCollection 2018.
Carpinella I, Cattaneo D, Bonora G, Bowman T, Martina L, Montesano A, Ferrarin M. Wearable Sensor-Based Biofeedback Training for Balance and Gait in Parkinson Disease: A Pilot Randomized Controlled Trial. Arch Phys Med Rehabil. 2017 Apr;98(4):622-630.e3. doi: 10.1016/j.apmr.2016.11.003. Epub 2016 Dec 10.

Responsible Party:	Fondazione Don Carlo Gnocchi Onlus
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