PEARL-PD: Personalized gait rehabilitation in Parkinson's disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON48450

Source
ToetsingOnline

Brief title
PEARL-PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Gait impairment in Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: VENI subsidie

Intervention

Keyword: Gait impairment, Parkinson□s disease, Personalized treatment, Rehabilitation

Outcome measures

Primary outcome

The main parameter of Study I is the correlation of patient characteristics to the effectiveness of each compensation strategy. The effectiveness of compensation strategies is expressed as percent change in gait variability while applying the strategy, compared to baseline gait variability. The main parameter of Study II is the difference in cortical activity, as measured by ambulatory EEG, during the application of selected compensation strategies compared to during baseline gait.

Secondary outcome

Study I

- As a secondary outcome parameter we will look at spatiotemporal gait parameters, as collected by the Vicon motion analysis system
- We will also assess the percentage of time spent frozen (as in: freezing of gait) during the gait task.
- Finally we will include a Likert scale to assess the patient's level of confidence concerning the newly-acquired compensation strategy, and his/her intention to use the strategy in daily life.

Study II

Spatiotemporal gait parameters, as collected by the Vicon motion analysis

system

Study description

Background summary

Gait deficits are common and disabling in Parkinson*s disease (PD). Patients use many different and typically self-developed strategies to compensate for their gait impairments, such as rhythmically bouncing a ball while walking, or counting while walking. However, specific compensation strategies can improve gait in certain patients, but have no effect or even exacerbate gait impairments in others. It is currently unknown which patient characteristics or circumstances can predict the individual efficacy of the various compensation strategies. Moreover, the underlying working mechanisms of these compensation strategies are poorly understood. This lack of fundamental knowledge hampers the development of much-needed personalized rehabilitation strategies, resulting into a frustrating and time-consuming therapeutic struggle, which is based on trial-and-error.

Study objective

This project aims to provide a deeper understanding of compensation strategies for gait impairments in PD. Specifically, the key objectives are: (1) To correlate the effectiveness of each type of compensation strategy to individual patient characteristics (Study I); and (2) To unravel the mechanisms of action of various compensation strategies, using ambulatory electro-encephalography (EEG) (Study II). These insights will pave the way towards a more personalized rehabilitation approach for gait impairment in PD. It will also provide us with more information on the cortical areas involved in gait control.

Study design

This project entails two separate studies, one for each primary objective:
- Study I: Using a within-patients design, the relationship between patient characteristics and the efficacy of compensation strategies will be evaluated.
- Study II: Using a within-patient design, the underlying mechanism of three different compensation strategies will be assessed by using ambulatory EEG.

Study burden and risks

Benefit: We expect all patients to potentially benefit from the compensation strategies that are taught in Study I, which may result in improved gait control.

Burden: For both studies patients will be (partially) assessed OFF-dopaminergic medication, which is expected to cause an increase in Parkinsonian symptoms, and an increase in discomfort during the measurement day(s). However, this is a customary procedure which does not entail any risks. Patients may continue their dopaminergic medication directly after the measurements.

Risks: Patients with PD and gait impairments are generally exposed to an increased risk of falls compared to age-matched controls. Based on previous literature on compensation strategy or *cueing* training, we do not expect participation in this study to aggravate the risk of falls. Additionally, during Study II, patients will be wearing a safety harness on the treadmill. Therefore we do not expect potential issues of concern within this project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men and women of age > 18 years with idiopathic Parkinson*s disease;
- Presence of disabling gait impairment, which they wish to be improved;
- Written informed consent.

Exclusion criteria

- Presence of major stroke in history or a psychiatric disease not related to PD;
- Presence of severe co-morbidity limiting ambulation (eg. orthopaedic problems);
- Inability to walk unaided (with the exception of a customary cane);
- Inability to walk for >3 minutes consecutively;
- Severe visual impairments, hampering perception of visual cues;
- Severe auditory impairments, hampering perception of auditory cues;
- Severe cognitive impairments, hampering the ability to give personal informed consent or to comply to the study protocol.

Additional exclusion criteria for Study II:
- Presence of deep brain stimulation;
- Presence of epilepsy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL70656.091.19