UNITE-PD: Unraveling the Neural Mechanisms underlying Compensation Strategies for Gait Impairments in Parkinson*s Disease: a Transnational, Multimodal Approach

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

Summary

ID

NL-OMON51823

Source
ToetsingOnline

Brief title
UNITE-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: ZonMW;via het JPDN programma

Intervention

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

Outcome measures

Primary outcome

The main parameter is the degree of cortical activation during walking, as measured by ambulatory high-density EEG.

Secondary outcome

Secondary parameters involve spatiotemporal parameters, including gait speed and stride length. The use of the application by responders will be recorded (expressed in frequency and duration). Responders additionally report the efficacy of cueing in daily life, which is expressed as the self-reported number of times using the strategy and the perceived efficacy using a five-point Likert scale during follow-up.

Study description

Background summary

Gait impairments are common in Parkinson*s disease (PD) and significantly impact mobility, independence and quality of life. The application of compensation strategies - such as external or internal cueing - is an essential and evidence-based element of gait rehabilitation in PD. Cueing can be highly effective in improving mobility, but not every patient benefits equally from the same cueing strategy. A one-size-fits-all approach to gait rehabilitation therefore does not suffice. At present, the underlying working mechanisms of cueing strategies are poorly understood, and it is unknown how the efficacy of different modes of cueing changes longitudinally. Improving the understanding

of the key mechanisms underlying compensation at the neurological systems level will help to refine cueing strategies and their timely delivery for a hallmark impairment in PD.

Study objective

This study aims to achieve 4 goals: (1) to identify the brain network involved in mediating the effects of cueing as an important compensation strategy; (2) to identify differences in brain connectivity patterns elicited by internal versus external cueing, so as to identify shared and dissimilar neural circuitries; (3) to compare brain connectivity patterns between patients who benefit from cues versus those who do not, to identify the key effective components of the compensatory networks in the brain; and (4) to identify the temporal network changes elicited by long-term use of cueing in order to ascertain how adaptation to cueing manifests in the brain.

Study design

This study is a case-control study with a six month follow-up period.

Intervention

At baseline, the efficacy of both external and internal cueing strategies will be determined. Responders will be instructed to apply the effective cueing strategies in daily life as much as possible when needed during the follow-up period of six months. Furthermore, they will use an application that runs on a smartphone that presents a rhythmic auditory stimulus, and records actual use during gait.

Study burden and risks

Benefit: We expect responders to potentially benefit from either the external or internal cueing strategies, which may result in improved gait control and reduced fall risk.

Burden: Subjects are invited to complete at least one baseline visit to our laboratory, lasting approximately four hours. If a subject is a responder or non-responder to cueing, she/he will revisit the laboratory shortly after the baseline visit and after approximately six months, both lasting approximately four hours.

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. Therefore, we do

not expect potential issues of concern within this study.

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;
- Written informed consent.

Exclusion criteria

- Usage of compensation strategies for the past six months;

- Presence of deep brain stimulation (DBS);
- Presence of severe co-morbidity limiting ambulation (e.g. stroke, orthopaedic problems);
- Inability to walk unaided (with the exception of a customary cane);
- Inability to walk for >3 minutes consecutively;
- Severe auditory impairments, hampering perception of auditory cues;
- Severe cognitive impairments, hampering the ability to comply to the study protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2023
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-12-2023
Application type:	Amendment
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	NL82251.091.22