An international multimodal protocol for the evaluation of freezing or gait in persons with Parkinson*s disease

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To determine whether the ClinRO and PRO are valid and reliable measures for use in intervention trials, specifically:1. Evaluate the reliability and validity of the proposed ClinRO protocol to assess freezing of gait in individuals living with...

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

Summary

ID

NL-OMON56869

Source
ToetsingOnline

Brief title
FOG-COA

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson' disease

Research involving
Human

Sponsors and support

Primary sponsor: Tel Aviv Sourasky Medical Center
Source(s) of monetary or material Support: Michael J. Fox Foundation

Intervention

Keyword: Freezing of Gait, Parkinson, Rating Scale, Validation

Outcome measures

Primary outcome

The primary parameters are the ClinRO and PRO. The primary endpoints will be

criterion validity and intra-rater reliability of the ClinRO.

Secondary outcome

• Inter-rater reliability of ClinRO & PRO

• Test-retest reliability of ClinRO & PRO

• Construct validity of ClinRO & PRO

• Responsiveness to dopaminergic medication of the ClinRO

Study description

Background summary

Freezing of gait (FOG) affects most people with Parkinson*s disease (PD). Accurate assessment and measurement of FOG severity and its impact on daily life are critical to evaluate and develop new effective treatments. However, currently, there is no clinician-reported outcome (ClinRO) measure that can be reliably used as an endpoint to detect meaningful improvement, severely limiting clinical trials of FOG. As an outcome of an international working group, a new standardised assessment and outcomes were developed (ClinRO). Before using this assessment in clinical practice and research, it is important to provide appropriate evidence on its measurement properties. Previous attempts at quantifying FOG using self-report questionnaires failed to accurately reflect symptom severity and generated high test-retest measurement errors. These approaches also do not fully capture the patient*s perspectives on the impact of FOG on their quality of life. A new patient-reported outcome (PRO) is needed to address these limitations and ensure that the changes detected are consequential and meaningful to patients.

Study objective

To determine whether the ClinRO and PRO are valid and reliable measures for use in intervention trials, specifically:
1. Evaluate the reliability and validity of the proposed ClinRO protocol to assess freezing of gait in individuals living with Parkinson's disease;
2. Assess the test-retest reliability of the ClinRO to determine whether it is stable over time and valid;
3. Assess the test-retest reliability of a newly developed PRO to determine whether it is stable over time and valid;
4. Determine the Minimal Detectable Change (MDC) value for the ClinRO and PRO to enable reliable quantification of change over time;
5. Assess the convergent validity of the ClinRO and PRO by demonstrating a correlation between similar outcomes.

Study design

This study is a (cross-sectional) validation study of a novel Parkinson*s Disease-specific rating scale for Freezing of Gait. The study is part of an international task force (Project leader: Prof. Jeffrey M. Hausdorff, Tel Aviv Sourasky Medical Center, Tel Aviv, Israël).

Study burden and risks

Burden: The assessments will last 3 hours.
Risks: People with PD are generally exposed to an increased risk of falls compared to age-matched controls. As this study is a validation study and no intervention is introduced, we do not expect additional risks within this study. The individual items of the ClinRO are inspired by clinical balance and gait tasks that are part of routine assessment.

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

In order to be eligible to participate in this study, all subject must meet all of the following criteria:
1. Voluntary written informed consent of the participant or their legally authorized repre-sentative has been obtained prior to any screening procedures;
2. At least 18 years of age at the time of signing the Informed Consent Form (ICF);
3. Able to read and write in the first language of their respective country;
4. Able to consent and comply with any study specific procedure.
Participants with Parkinson*s disease must also meet all of the following criteria:
1. Diagnosis of idiopathic Parkinson*s disease (PD) made by a neurologist according to the Movement Disorders Society guidelines;
2. Able to walk independently for a distance of 10 meters, without walking aid;
3. Absence of a Deep Brain Stimulator;
4. Stable PD treatment in the 4 weeks prior to participation that is not expected to change in the course of the study.
5. For patients with FOG: a score of >= 1 on the New Freezing Of Gait Questionnaire (NFOG-Q).

Participants without Parkinson*s disease (caregiver/observer) must meet all of the following criteria:
1. Be a family member or close friend of the participant with Parkinson*s disease;
2. Have had a minimal interaction of 3 times/week in the past month with the participant with Parkinson*s disease.

Exclusion criteria

1. Occurrence of any of the following within 3 months prior to informed consent: myocardial infarction, hospitalization for unstable angina, stroke, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy device (CRTD), active treatment for cancer or other malignant disease, uncon-trolled congestive heart disease (NYHA class >3), acute psychosis or major psychiatric disorders or continued substance abuse, other neurological (than PD) or orthopaedic im-pairment that significantly impacts on gait.
2. Unwilling to temporarily delay the morning anti-Parkinsonian medication

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	03-07-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-10-2024

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	NL86875.091.24