Towards a Parkinson-specific gait, balance, and posture rating scale: development and validation testing plan of complementary investigator-rated and patient-reported items.

Published: 14-11-2023
Last updated: 07-04-2024

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

Summary

ID

NL-OMON56182

Source
ToetsingOnline

Brief title
MDS rating scale PIGD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Balance and Gait impairments in Parkinson's Disease, Posture

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Movement Disorders Society

Intervention

Keyword: Parkinson's Disease, Rating Scale

Outcome measures

Primary outcome

The main parameters are psychometric attributes of a novel Parkinson*s Disease specific rating scale, that assesses the constructs gait (including freezing of gait), balance, posture and concerns about falling. Using CTT statistics, the following psychometric properties will be tested: data quality and acceptability, reliability (internal consistency and stability or test-retest reliability), precision and construct and structural validity. Using Rasch analysis, the following psychometric attributes are evaluated: internal construct validity, optimal scoringscheme, uni-dimensionality, item fit, item local independency, and item bias by subgroups of respondents.
The test consistency will be assessed using test-retest reliability coefficients.

Secondary outcome

Not applicable

Study description

Background summary

A high number of people with Parkinson*s disease (PD) develop one or more axial

disorders, such as postural abnormalities, balance, and/or gait disorders. These disorders often result in falls, concerns about falling, and a reduced quality of life. Adequate and timely recognition of these disorders is, therefore, essential to identify patients at risk of falling, but also to evaluate efficacy of symptomatic (non-) pharmacological interventions in daily clinical practice and research settings. In 2016, the Movement Disorder Society (MDS) Task Force on Rating Scales commissioned a critique of existing clinical rating scales and questionnaires used in PD, and concluded that none of the existing scales could adequately and separately assesses the required constructs (i.e., gait - including freezing of gait -, balance, and posture. To overcome this limitation, it was recommended that an ideal future scale should, therefore, include separate sections for gait, balance, and posture, and should specifically address freezing of gait and fear of falling.

Study objective

The aim of this study is to develop and validate this much-needed Parkinson*s Disease-specific rating scale; the so-called *Movement Disorders Society Rating Scale: Postural Instability and Gait Difficulties (PIGD)*. This PIGD rating scale assesses the constructs gait (including freezing of gait), balance, posture, and concerns about falling separately. The scale consists of investigator-rated and patient-reported outcomes.

Study design

This study is a multi-centre validation study. The study comprises of three subsequent parts:
Part 1: item development: A pool of possible items is drafted based on the literature and focus groups with clinical experts and public and patient involvement.
Part 2: scale development: fifteen persons with PD, in addition to fifteen health care providers are asked to participate at the Radboudumc Nijmegen (NL) to pilot the pool of possible items. Participants are asked to participate in a single session to perform the newly developed PIGD rating scale. The assessment will last 60-75 minutes. A preliminary psychometric analysis (item reduction analysis) will be performed to adjust the pool of possible items.
Part 3: scale evaluation: A total of 300 persons with PD will be including among the participating centres (Radboudumc Nijmegen (NL), University of Portland (USA), Brain and Mind Centre Sydney (AUS), University of Waterloo (CAN), Emory University School of Medicine (USA), and Newcastle University (UK)). Of the 300 patients, 75 of them will be included at Radboudumc Nijmegen (NL).
Furthermore, 250 patients are asked to participate once, whereas 50 patients will be asked to participate twice (in order to evaluate test-retest reliability). Of these 50 patients, approximately 12-15 (25%) of them will be included at the Radboudumc Nijmegen (NL). Each assessment will last 60-75

minutes.

Study burden and risks

Benefits: Participants will not directly benefit from participating in this study.
Burden: The assessments will last 60-75 minutes.
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 concept PIGD Rating Scale 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, a subject with PD must meet all of the following criteria:
• Men/women of age > 18 years with idiopathic Parkinson*s Disease, as diagnosed by a movement disorders specialist.
• Written informed consent.

In order to be eligible to participate in this study, a health care provider/researcher must meet all of the following criteria:
• Men/women of age > 18 years
• Experience with people with PD

Exclusion criteria

A potential subject with PD who meets any of the following criteria will be excluded from participation in this study:
• Neurological or orthopedic comorbidities that impact balance and/or gait capacity.
• Severe cognitive impairment hampering the ability to follow instructions.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2023
Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO Date:	14-11-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2023
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	NL85250.091.23