# Balance control asymmetries and stepping responses in Parkinson\*s disease patients

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To investigate whether balance control is asymmetrical in PD patients. In addition, we want to investigate the relationship between asymmetrical balance control and stepping responses, fall history and freezing of gait.

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

# Summary

### ID

NL-OMON34205

**Source** ToetsingOnline

**Brief title** Balance control asymmetries in PD

## Condition

• Movement disorders (incl parkinsonism)

**Synonym** Parkinson's disease, shaking palsy

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Universiteit Twente **Source(s) of monetary or material Support:** Smartmix Braingain

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### Intervention

Keyword: asymmetries, falls, freezing, posture

### **Outcome measures**

#### **Primary outcome**

Balance control asymmetry index (ASI), quantifying balance control asymmetry.

#### Secondary outcome

stepping responses as quantified by mean step length and step speed.

# **Study description**

#### **Background summary**

Parkinson\*s disease (PD) is an asymmetric disease; symptoms usually start on one side of the body and this side remains the most impaired. Clinically, asymmetry of symptoms is most evident for appendicular impairments (e.g., upper and lower limb rigidity, bradykinesia and tremor). For axial impairments (i.e., stooped posture, shuffling gait, postural imbalance and freezing), asymmetry is less obvious. To date, asymmetries in balance control in PD patients have seldom been studied, but preliminary evidence suggests that balance control is asymmetrically affected at least in some PD patients (Rocchi et al., 2002; van der Kooij et al., 2007)). We would like to investigate asymmetries in balance control in a larger group of patients and subsequently determine the clinical relevance of this symptom (i.e., relationship with actual falls).

#### **Study objective**

To investigate whether balance control is asymmetrical in PD patients. In addition, we want to investigate the relationship between asymmetrical balance control and stepping responses, fall history and freezing of gait.

#### Study design

Intervention, cross-sectional, non-invasive.

Methods: Biomechanical responses will be recorded using motion capture (VICON) and a dual forceplate (AMTI) during quiet stance, small mechanical perturbations and large platform translations. Patients will be tested during their subjective on phase, using their regular medication regimen. Clinical tests will be performed to determine disease severity and severity of axial

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symptoms. In addition, participants will be asked to fill in questionnaires regarding their balance during daily life.

#### Intervention

Delay of moning dose of antiparkinsonian medication. Subsequently, the balance of the patients will be challenged by applying external mechanical perturbations.

#### Study burden and risks

Participants are asked to come to the VR-laboratory at the University of Twente once. During a three hour experiment (including preparations and clinical assessment), biomechanical responses will be measured. The burden and the risk for the participants are very low. During the experiment participants will be secured by a safety harness preventing falls. Benefit for participants: none. Benefit for patients with Parkinson\*s disease in general: novel insight into PIGD pathology, potentially improving treatments such as physiotherapy and Deep Brain Stimulation (DBS).

# 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**

Idiopathic PD, according to the UK Brain Bank criteria (patients) Hoehn and Yahr stage 1-4 (patients) Freezing of gait (FOG+ patients), Ability to stand independently for approximately three consecutive minutes Written informed consent

### **Exclusion criteria**

Severe cognitive impairment (MMSE score < 24) Other causes for balance disorders (neurological, musculoskeletal, visual or vestibular) Major psychiatric disorders Severe co-morbidity (e.g. cancer) dependent on walking aids severe dyskinesia uncorrected visual disturbance

# Study design

# Design

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

## Recruitment

NL

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Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2010
Enrollment:	40
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	28-10-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

# **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** CCMO **ID** NL32765.044.10