The effect of forward arm extension on gait initiation in patients with Parkinson*s disease

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To assess whether forward extension of both arms improves gait initiation in patients with PD, measured by faster coverage of the initial two meters of walking. Secondary objectives are to determine whether this change in performance can be measured...

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

Summary

ID

NL-OMON44386

Source
ToetsingOnline

Brief title
Arm extension and gait in PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arm extension, gait, Parkinson's disease

Outcome measures

Primary outcome

gait velocity over the initial two meters and full six meters of walking after starting as determined using (i) a stopwatch and distance markers or (ii) IMU signals, comparing gait initiation with and without forward arm extension.

Secondary outcome

left and right step length as derived from IMU signals, compared between gait initiation with and without arm extension. Correlation between the primary and secondary outcome parameters and the MDS-UPDRS (Part III) motor score and item gait (3.10), in particular. Correlation between the primary study parameters and subjective assessment of changes in gait performance.

Study description

Background summary

Walking of patients suffering from Parkinson*s disease (PD) is characterized by small steps, loss of arm swing and starting problems. Impaired function of the Supplementary Motor Area (SMA), which is an important output target of striato-thalamic projections, is argued to play a causal role in this disturbance of both motor initiation and organization of multi-limb movements. By applying forward arm extension as a cue for gait initiation, we hypothesize that starting to walk will improve due to (i) facilitating SMA activity to fuel the cyclic motor program of gait and (ii) a forward shift of the patient*s axial center of gravity, stimulating the natural response of a forward foot placement.

Study objective

To assess whether forward extension of both arms improves gait initiation in

patients with PD, measured by faster coverage of the initial two meters of walking. Secondary objectives are to determine whether this change in performance can be measured accurately using only a stopwatch and distance markers and to what extent the use of inertial measurement units (IMUs) adds essential information. Moreover, the relationship between these parameters and the patient*s subjective assessment of gait initiation will additionally be assessed.

Study design

Observational study

During the tasks gait initiation performance will be measured using IMUs (integrating accelerometers, gyroscopes and magnetometers in a matchbox-like container) on both shanks and both thighs and a stopwatch and distance markers. The IMUs can be used to determine bilateral step size and gait velocity objectively and accurately. Gait will be assessed over a distance of six meters with timing passage of the initial two meters distance and the full six meters. For future clinical application, we will additionally investigate whether measurement of gait velocity using only a stopwatch and distance markers is sufficiently accurate, as well. After measurement preparation and task instruction, the participant has to perform the following tasks:
1. 6 meter walk test (repeated 3 times, initiated at a verbal signal of the examiner) without arm extension
2. 6 meter walk test (repeated 3 times, initiated at a verbal signal of the examiner) with simultaneous arm extension at gait initiation

The six gait trials will be executed semi-randomly; the first trial will always be gait initiation without arm extension. After executing all trials patients will be asked about their subjective assessment of their performance using a questionnaire.

Other parameters of interest (Hoehn & Yahr stage, MDS-UPDRS part III score, side of symptom dominance) will be collected from the patient*s file.
The study will consist of a pilot study and a cross-sectional study in which gait initiation performance with and without arm extension will be compared in PD patients.

Intervention

Forward arm extension at gait initiation

Study burden and risks

There are no risks or benefits, and the burden is limited to the time invested

in the test (approximately 30 minutes, with breaks if necessary).

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

Healthy individuals:
- Perceived healthy
- Age >= 18 years
- Written informed consent
PD Patients:
- able to walk (Hoehn & Yahr scale: Stage 2-3)
- trouble initiating gait (as reported in the medical file)
- PD diagnosis according to the UK Parkinson*s Disease Society Brain Bank criteria (A.J. Hughes, 1992)

- Age < 80 (to limit the presence of general age-related deficits)
- Written informed consent

Exclusion criteria

All participants
- (other) neurological or motor disorder (for patients: other than PD)
- Use of medication influencing movement (for patients: other than for PD)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2017
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL62280.042.17