

Tackling freezing of gait in Parkinson's disease

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We aim to experimentally evoke FOG in patients walking on a motorised treadmill, using either expected or unexpected obstacles, or changes in visual feedback of gait

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

Summary

ID

NL-OMON30278

Source

ToetsingOnline

Brief title

Tackling freezing of gait

Condition

- Movement disorders (incl parkinsonism)

Synonym

Parkinson's disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Prinses Beatrix Fonds

Intervention

Keyword: falls, Freezing, gait, Parkinson's disease

Outcome measures

Primary outcome

Visual assessment of videotaped gait performance on the treadmill will be used as gold clinical standard; primary outcome is occurrence of freezing of gait.

Secondary outcome

We propose an elaborate and sophisticated battery of outcome measures to optimise detection of subtle FOG manifestations. Measures in both experiments will include kinematics of individual body segments, reactive forces under the feet and telemetric (wireless) surface electromyography of eight muscles.

Study description

Background summary

Freezing of gait (FOG) is a common cause of falls in Parkinson's disease (PD). Optimal treatment requires timely and reliable recognition of FOG episodes, and calls for a better understanding of the underlying pathophysiology. Unfortunately, it proves difficult to reliably elicit FOG in clinical practice. Here, we aim to *tackle* this problem by exploring two new ways to elicit FOG in an experimental setting.

The first hypothesis is that a necessity to negotiate suddenly appearing obstacles while walking on a motorised treadmill frequently elicits FOG. This hypothesis is based on serendipitous observations made during a pilot study where we noted that PD patients commonly froze when they had to avoid a suddenly appearing obstacle on the floor. Gait in PD is dependent on visual feedback, and improves with visual cueing; and FOG commonly occurs when patients attempt to cross a narrow doorway.

Study objective

We aim to experimentally evoke FOG in patients walking on a motorised treadmill, using either expected or unexpected obstacles, or changes in visual feedback of gait

Study design

While walking on a motorised treadmill, FOG is measured in the following conditions; undisturbed gait, gait with expected obstacles, gait with unexpected obstacles, looking sideways, placing stripes on the treadmill and virtual reality unexpected obstacles.

In the first experiment we will compare the degree of FOG during normal gait and gait with expected and unexpected obstacles. We predict that unexpected obstacles will induce FOG, while expected obstacles will decrease FOG.

In the second experiment we aim to evoke FOG in patients walking on a motorised treadmill by changing visual feedback.

These experiments will be executed on two different days to be able to measure patients on and off medication.

Study burden and risks

Subjects will be wearing a parachute harness attached to the ceiling to prevent actual falls, without interfering with natural gait. Each condition lasts 10 minutes, and the total experiment lasts 2* hours, including preparation and resting periods. This will be repeated in a second experiment on a different day. Hence the experiment will be performed on two different days, once on and once off medication.

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

Parkinson's disease

Ability to walk without help for 10 minutes on a treadmill

Exclusion criteria

atypical hypokinetic rigid syndrome

cognitive impairment (Mini Mental State Examination (MMSE) score <24)

other cause of gait disorder (neurological, muscles, bones, visual, balance)

major psychiatric disease

major comorbidity

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): 03-01-2007

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Application type:

First submission

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	NL15383.091.06