Efficacy of the Cue-shoe on freezing of gait and activity level: A pilot study

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This study tests the ability of the Cue-shoe, a new cueing device, to provide patients with FoG with successful cueing.

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

Summary

ID

NL-OMON40903

Source
ToetsingOnline

Brief title
Cue-shoe for freezing

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinsonism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Marie Curie European project

Intervention

Keyword: Cueing, Freezing of gait

Outcome measures

Primary outcome

The statistical design will focus on the comparison between the two periods of Phase 2 (with and without visual cueing) on activity level.

Secondary outcome

• During Phase 1, the immediate effect of the Cue-shoe on gait parameters and FoG will be investigated by comparing the trials with and without cueing.

• Application of a previously validated algorithm to detect FoG episodes and comparison of the two periods of Phase 2 (with and without visual cueing) on these data will give an idea of the functional efficacy of the Cue-shoe on FoG in the home environment.

• The presence of a learning effect will be investigated by comparing the activity level and FoG during Phase 3 with those same measures during Phase 2.

• For each of the home-based measurement, evolution of the activity level over days will be examined with the help of the patients' diaries.

• Subjective impression of the patients on the Cue-shoe will be compared between each time point.

• The Frontal Assessment Battery score will be used as a covariate in all performed analyses.

Study description

Background summary

Freezing of gait (FoG) is defined as a brief, episodic absence or marked reduction of forward progression of the feet despite the intention to walk

(Nutt et al., 2011). This symptom is one of the most debilitating of Parkinson's disease and related diagnoses as it increases the risk of falls, related injuries and fear of falling, impeding patients' autonomy and quality of life (Rahman et al., 2008, Grimbergen et al., 2013). While the therapeutic treatment of FoG remains a challenge, its characteristic to highly depend on attentional, motivational, emotional and arousal processes opens the way for rehabilitation strategies to provide the patients with tricks to help them prevent and overcome their freezing episodes. External cueing is one of those strategies (Nieuwboer, 2008). Lines placed at regular intervals on the floor, stair tiles or the sound of a metronome are some illustrations of external cueing and strikingly show how only one single step often separates freezing from freedom.

Study objective

This study tests the ability of the Cue-shoe, a new cueing device, to provide patients with FoG with successful cueing.

Study design

This study will be divided into three phases, each of those phase answering a specific question regarding the Cue-shoe:

* Phase 1: Lab measurement: Is there an immediate effect of the Cue-shoe?
To answer this question, a lab-measurement will be conducted both Off and On medication, preferably on two consecutive mornings.
* Phase 2: Home-based measurements: Is the Cue-shoe functionally efficient?
To answer this question, patients will be measured at home over two one week periods, with and without visual cueing (both periods using the Cue-shoe but with visual cueing being disabled during the period without visual cueing).
* Phase 3: Home-based measurement: Is there a learning effect from cueing training using the Cue-shoe?
To answer this question, patients will be measured at home over one week period, after withdrawal of the Cue-shoe

The following dependant variables will be collected:

Phase 1: Lab-measurement
- MDS-UPDRS Part III (motor part)
- Frequency and duration of FoG episodes occurring during a walking protocol (using the DynaPort and Axivity devices)
- A composite score on specific items of the Gait and Balance Scale (Thomas et al., 2004)
- Patients subjective impression of the Cue-shoe on a 7 points Likert scale
- Gait parameters (velocity, step length, cadence, duration of single and double support phases)

- Score on the Frontal Assessment Battery (Dubois et al., 2000)
- Score on the Parkinson's Disease Questionnaire 39 (PDQ39)
- Score on the NFOGQ (Nieuwboer et al., 2009)
- Patients interest (yes - no - maybe) in acquiring the Cue-shoe

Phases 2 and 3: Home-based measurement
- Activity level (using the DynaPort and Axivity devices)
- Frequency and duration of FoG episodes occurring (using a previously validated algorithm, (Delval et al., 2010))
- Score on the NFOGQ (Nieuwboer et al., 2009)
- Score on the Parkinson's Disease Questionnaire 39 (PDQ39)
- Patients subjective impression of the Cue-shoe on a 7 points Likert scale
- Subjective impression about effect on FoG episodes and falls using a structured diary
- Patients interest (yes - no - maybe) in acquiring the cue-shoe

Intervention

Use of the Cue-shoe to improve freezing of gait.

Study burden and risks

Patients with FoG are subjects to falls. During the lab-measurement, a person will be permanently walking next to the patients to avoid falls. We do not expect the Cue-shoe to aggravate the risk of falls. In the unlikely case that the lab-measurement reveals worsening of gait and FoG in some patients, those patients will not be included in Phases 2 and 3. This study is therefore not dangerous and poses no risk to the patients. Note however that some discomfort is expected from resurgence of the parkinsonian symptoms following withdrawal of antiparkinsonian medication in Phase 1.

We expect patients to physically benefit from the week with visual cueing. Expected decrease of FoG episodes should increase their quality of life. Likewise, they might show a learning effect from training with the Cue-shoe during Phase 2, leading to extension of the benefit during Phase 3 or even further.

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

• Men/women of age > 18 years.
• Written informed consent.
• Presence of freezing of gait (defined as a score of 1 on question 1 "Have you experienced FoG in the past month" from the New Freezing of Gait Questionnaire)
• Disabling freezing of gait (defined as a score of 3 "Very often, more than one time a day" on question 2 "How often do you experience FoG" from the New Freezing of Gait Questionnaire)

Exclusion criteria

• stroke in history or a psychiatric
disease
• Any visual impairment or physical inability to perform the assessment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Cueing device
Registration:	No

Ethics review

Approved WMO

Date:	27-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	03-12-2014
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	NL48032.091.14