Treating Stooped Posture in Parkinson's Disease: a pilot study

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

Summary

ID

NL-OMON34784

Source
ToetsingOnline

Brief title
StoPa

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,bedrijf: 2M engineering ltd. levert de hardware

Intervention

Keyword: ambulatory device, feedback, parkinson's disease, stooped posture

Outcome measures

Primary outcome

primary outcome:

1. trunk position characteristic of mean time of "good posture" and "stooped posture" evaluated from the trunk angle data obtained during the baseline (week 1) and the intervention (week 2)

2. VAS score of patient satisfaction, feasibility and user friendliness of the Park Assist

Secondary outcome

1. trunk position characteristics and activity level: percentage of corrections after feedback signal (week 2)

2. Unified Parkinson's Disease Rating Scale (UPDRS) motor section

3. 10 meter walk test

4. functional reach test

5. Timed get up and Go test

6. Occiput to wall distance

7. C7 to wall distance

8. Berg Balance Scale

9. PDQ 39

Study description

Background summary

One of the motor symptoms of Parkinson*s Disease (PD) is a characteristic stooped posture of the trunk with drooped shoulders(1) .
While the cause is essentially unknown, this postural deficit has been linked to postural instability and rigidity, two other key symptoms of the disease(2;3).
Stooped posture is less susceptible to drug therapy and can impair the patients* ability to walk and perform other daily activities, which has a major impact on quality of life. On the other hand, the stooped posture lowers the centre of gravity and may improve patients ability to control postural control while standing and walking. Currently, there is the general assumption that physical therapy should focus on improving postural strategies during daily activities(4 5). In addition, rhythmic as well single sensory cues can be used to facilitate gait and balance performance in PD (6-8).
One of the disadvantages of existing therapy programs is that they are mostly applied and evaluated in an outpatient clinical setting, while the impact of having a stooped posture (as are other motor symptoms) in patients* home environment is unknown. Moreover, assessment in a clinically test setting may underestimate the severity of having a stooped posture, in particular knowing that patients are able to restore their trunk posture when conscious attention is asked.
One way of coping with these disadvantages in patients own home setting is to monitor and correct posture using an ambulatory device that provides online feedback using a sensory cue when the trunk angle exceeds a threshold value. However, the efficacy, practical utility and user-friendliness of such a method remains to be determined.

Study objective

The objective of this study is testing the efficacy, practical utility and user-friendliness of a trunk angle sensor and feedback device (Parkinson Assist, 2M Engineering Ltd) in the home setting of patients with Parkinson's disease with a stooped posture.
Ultimately, the aim is to use the device in a regular therapeutic setting.

Study design

The Parkinson Assist will be tested in a repeated measurement single subject design. (Pilot study)

Intervention

All participants will wear the Parkinson Assist (ambulatory trunk angle sensor and feedback device) in the home environment for two times one week, with minimally a one week interval.
The first week consists of baseline measurements, the sensor or the Park Assist is active and records actual trunk angle continuously in a memory chip, the feedback signal is not active.
The second week, one week later, the patient will in addition receive online feedback of their stooped posture by the Park Assist device (a single cue in the form of a vibration) whenever the angle exceeds a predetermined threshold. This threshold will be determined at the beginning of the baseline session. Patients will be instructed on the use of the device prior to wearing it.

Study burden and risks

Burden associated with participation may be the fact that the Parkinson Assist device is attached to the body for two seperate weeks. It is a small light weight device comparable with a mobile phone and it is carried underneath the clotes in a pouch at the sternum, which is with a strap around the thorax connected to the body.

If the time that the patient is active walking and standing is more than usual during the use of the device, the time that he is exposed to the risk of falling is also extended and might lead to a higher number of falls, although in comparable exercise interventions with Parkinson's disease patients, there were no changes in number of falls when Parkinson patients were more active during the intervention period.

The benefit for the patients may be that they experience a better control and possibility to correct their stooped posture and are able to walk better and take part in daily activities.

The partner of the Parkinson patient may feel less burden because the device is giving feedback about the stooped posture and he or she does not have to correct the patient anymore.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. patients with Parkinson's Disease with Hoehn and Yahr stage 1-3,
2. stooped posture as a major motor symptom (score 2 or higher on item 28 "posture" of the UPDRS (Unified Parkinson's Disease Rating Scale)
3. patients are able to correct their posture when attention is asked
4. sufficient cognitive function (MMSE > 24)
5. Parkinson's medication is stable during the study period

Exclusion criteria

absence of (other) neurological, cardiovascular or orthopaedic problems that can impair participation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-11-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ParkinsonAssist
Registration:	No

Ethics review

Approved WMO

Date:	20-10-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31556.029.10