Tactile cueing as a means to oppose gait impairments deriving from Parkinson*s disease

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Primary Objective: To establish whether it is feasible to oppose slowness caused by gait impairments deriving from Parkinson*s disease effectively by using a tactile-based cueing device. Secondary Objective(s): To establish if the device influences...

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

Summary

ID

NL-OMON45512

Source
ToetsingOnline

Brief title
Tactile cueing

Condition

- Movement disorders (incl parkinsonism)

Synonym
Festinating gait, walking impairment

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Eventueel gemaakte kosten worden gemaakt door de uitvoerend onderzoeker. Er wordt niet verwacht dat er verdere kosten

gemaakt zullen worden.

Intervention

Keyword: Cueing, Gait impairments, Parkinson, Tactile

Outcome measures

Primary outcome

The main parameter is the time it takes for the patient to complete the prescribed walking test. The results of the repeated tests will be compared to see if improvements can be ascribed to situations (e.g. walking with/without device).

Secondary outcome

There are two secondary study parameters, namely the number of freezing episodes the subject experiences, and secondly the number of steps (step length) the subjects exhibits during testing. Value will be allotted to these secondary parameters by comparing the repeated tests in which the situation was altered (e.g. walking with/without device).

Additional study parameters will consist of:

o Age

o Sex

o Score on Hoehn and Yahr scale

o Medication state (ON/OFF)

o Outcome of the freezing of gait questionnaire

These study parameters will be assessed during the anamnesis.

Study description

Background summary

Parkinson's disease (PD) is the second most widespread progressive neurological ailment. PD imposes a heavy burden on quality of life (QOL). Motor symptoms that contribute most to a decline in QOL are medication related impediments and gait impairments. Additionally, gait deficiencies are widely associated with loss of independence and an increased chance of falls. Therefore, the improvement of these features can bring about enormous enhancement in quality of life for Parkinson*s patients, and may postpone patient dependency on continuous care or heavy medication.

Cueing is a relatively novel technique to improve gait in PD patients, and is based on the phenomenon kinesia paradoxa (KP). Kinesia paradoxa is an abrupt and temporary loss of akinesia or other walking inhibitions, both continuous and episodic. Even though PD is a progressive disorder, its patients are susceptible to this phenomenon. Patients with severe walking impairments can exhibit sudden increases in mobility when stimulated suitably.
Research has shown that external sensory cues can help the patient retain a regular gait

Study objective

Primary Objective:

To establish whether it is feasible to oppose slowness caused by gait impairments deriving from Parkinson*s disease effectively by using a tactile-based cueing device.

Secondary Objective(s):

To establish if the device influences other Parkinson related gait symptoms, including number of freezing episodes and step length.

To establish whether patient*s characteristics influence the effectiveness of the device.

To establish the patient*s experience when using the device.

Study design

The study is in a single-centre intervention study in which the proof of

principle method will be leading. This study will recruit patients suffering from gait deficiencies caused by Parkinson*s disease.
All patients will be asked to perform three short, minimally taxing tests.
First off, a short anamnesis will be performed in order to form a comprehensive image of the disease progression and the extent of walking disabilities. This anamnesis will consider patient privacy by omitting personal references.

Then the standardized timed up and go (TUG) test will be performed. This test will be executed thrice.
a) Once to establish the patients regular gait performance.
b) Then once to determine whether the inactive device influences regular gait performance.
c) Lastly to ascertain if the device has an impact on gait deficiencies.

Lastly the patient will be asked to perform the 10-meter walk test. This test is divided into two phases.
During the first phase
a) Once to establish the patients regular gait performance.
b) Then once to ascertain if the device has an impact on gait deficiencies.
c) Lastly to determine whether the inactive device influences regular gait.
Secondly, the trajectory will be traversed thrice again to establish the effect of the device when deliberate concentration in targeted and minimalized by adding a manual component. The subject is asked to balance a cup filled with water while walking the allotted distance. This extension to the test is performed to ensure possible gait fluctuations are not solely attributable to the patients focussed attention to the walking tests.
a) One to establish the patients regular gait.
b) Then once to determine whether the inactive device influences regular gait.
c) Lastly to ascertain if the device has in impact ton gait deficiencies.

In the both walking tests, value will be allotted not only based on interval measurements, but also on number of freezing episodes and step count. Video footage of the test will be acquired and number of steps will and number of freezing episodes will be evaluated by two researchers separately. The cycle sequence will be changed throughout to avoid operant conditioning.

Intervention

The intended intervention is described as follows:
A prompt will be offered by providing an alternating vibration underneath either foot of the subject by using the prototype. The frequency of the rhythm will be adjusted to the desired walking cadence of the patient, therefore adjusting the walking pattern.

Study burden and risks

Study population, exclusion criteria and additional safety measured are all adjusted to minimize the overall risk associated with this study.
Furthermore, the risks associated with the non-invasive tactile cueing device are minimal. The incidence of side effects due to either the product or the testing method are negligible and almost exclusively mild.
The medical device used during testing is designed in such a way as to ensure accompanying risks are negligible. For example, the inclusion of a fast way to deactivate the device and the addition of a plug connection to ensure the patient does not get caught on the wire.
Moreover, the intended testing methods are selected on their minimally burdensome character and the fact that safety measures can be implemented. For example, the patient is allowed to use habitual walking support devices and the researcher will walk along the patient in order to catch the subject in the unlikely case of a fall.
Lastly, the intended effect associated with the device is improbable to cause any walking difficulties or other complications, for it gently stimulates the patient to move, but does not force any actions.
The remaining risks are minimal and therefore acceptable to the subjects who will willfully consent to participation in this study.

This study has the potential to drastically improve quality of life and independence of patients and may lower the risks of falls and associating (crippling) injuries. Therefore, the risk and burden for the participating capacitated adults are in proportion with the potential value of the study.

Contacts

Public
Universiteit Twente

Koningsplein 1
Enschede 7512 KZ
NL
Scientific
Universiteit Twente

Koningsplein 1
Enschede 7512 KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The patient exhibits gait impairments caused by Parkinson*s disease
- Patients' age is over 18 years
- Able to visit the neurology clinic at MST Enschede

Exclusion criteria

- Unable to provide written informed consent
- Exhibits gait impairments as a result of any other factor than Parkinson*s disease
- Significant cognitive deterioration that causes the patient to be unable to understand the research purpose and accompanying instructions

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	10

Type:	Actual

Medical products/devices used

Generic name:	Tactile cueing device
Registration:	No

Ethics review

Approved WMO Date:	17-05-2017
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	ID
CCMO	NL60670.044.17