Effect of vibrotactile stimulation on Parkinson*s tremor * an explorative study

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

Summary

ID

NL-OMON51063

Source
ToetsingOnline

Brief title
Vibrotactile stimulation for Parkinson*s tremor

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Tremor

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Parkinson's Foundation

Intervention

Keyword: Parkinson's Disease, Tremor, Vibrotactile stimulation

Outcome measures

Primary outcome

The effect of vibrotactile stimulation at tremor frequency on tremor severity (delta tremor power between stimulation and baseline).

Secondary outcome

The effect of continuous vibrotactile stimulation, stimulation at 1.5 times tremor frequency and sham on tremor severity (delta tremor power between stimulation/sham and baseline).

The effect of continuous vibrotactile stimulation on bradykinesia (average button presses per second in the keyboard finger tapping test during stimulation versus sham).

The effect of vibrotactile stimulation at step frequency on gait, with three outcome measures of Timed up and go performance: Time to complete, number of freezing episodes and duration of freezing episodes.

Study description

Background summary

Parkinson*s disease (PD) is the second most common neurodegenerative disease, of which tremor is a common and highly burdensome symptom. The pathophysiology of tremor involves a cerebral network that consists of basal ganglia and a cerebello-thalamo-cortical motor circuit. Emerging evidence suggest that

somatosensory input from the tremulous limb to the brain may influence this network. Specifically, tremor-related activity was observed in primary and secondary somatosensory cortex and thalamic cells that are involved in tremor are also responsive to somatosensory stimulation. Somatosensory afferents may thus play a role in tremor pathophysiology and could therefore be used as treatment target. Here, we will test this hypothesis by investigating the effect of modulating somatosensory input (with vibrotactile stimulation) on tremor severity.

Study objective

The primary objective is to test whether rhythmic somatosensory input (vibrotactile stimulation at tremor frequency) reduces tremor power of Parkinson*s tremor, as compared to other vibrotactile stimulation settings (continuous stimulation, stimulation at 1.5 times tremor frequency, sham stimulation). As secondary objectives, we will test whether the effect of vibrotactile stimulation on tremor power depends on the context in which tremor occurs (rest, cognitive coactivation, posture) and whether vibrotactile stimulation has an effect on two other common PD symptoms: impaired gait and bradykinesia.

Study design

Cross-sectional exploratory intervention study.

Intervention

The intervention involves subtle mechanical vibrations (vibrotactile stimulation) on the wrist or ankles. This is a non-invasive and painless way to provide somatosensory stimuli, in a continuous (80Hz) or rhythmic fashion (brief bursts of 80 Hz at tremor or step frequency).

Study burden and risks

The load on patients consists of the time spent on this project, and potentially a temporary worsening of symptoms caused by withholding medication. Patients will arrive in a practically defined OFF state, i.e. at least 12 hours after having taken their last dopaminergic medication. At the end of the measurement, they will resume their normal medication regime. All measurements are non-invasive, painless, and without nuclear radiation. Individual participants do not directly benefit from participation. However, we expect that this study will provide mechanistic insights into if and how somatosensory (vibro-tactile) afferents influence the cerebral tremor circuit in Parkinson*s disease, and may provide a solid basis for designing further clinical treatment studies.

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

-18-80 years old
-Have a diagnosis of idiopathic PD made by a movement disorders specialist.
-Medically optimized without planned medication changes for the duration of the study.
-Resting tremor subscore >/<= 2 of the most affected arm on the Movement Disorders Society Unified Parkinson*s Disease Rating Scale (MDS-UPDRS) item 2.10
-Postural tremor subscore >/<= 1 of the most affected arm on the MDS-UPDRS item 3.15

Exclusion criteria

-The presence of additional neurologic diseases that might confound testing or the coexistence of PD and essential tremor together (action tremor that was present prior to the development of parkinsonism).
-Moderate to severe peripheral neuropathy (reduced vibratory sensation)
-Montreal cognitive assessment (MoCA) score < 20 or previously documented dementia
-Unable to walk without walking aid.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2021
Enrollment:	37
Type:	Actual

Medical products/devices used

Generic name:	Vyblife system
Registration:	No

Ethics review

Approved WMO

Date:	11-08-2021
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	NL77202.091.21