Improving cognitive functioning in Parkinson*s disease with transcranial Direct Current Stimulation (PD-tDCS)

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Determine the efficacy of atDCS as compared to ctDCS and sham stimulation in the improvement of executive functioning in PD-MCI.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42486

Source
ToetsingOnline

Brief title
PD-tDCS

Condition

- Other condition
- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease-related mild cognitive impairment (PD-MCI)

Health condition

cognitieve stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Parkinson Vereniging

Intervention

Keyword: cognitive functioning, Parkinson□s disease, transcranial Direct Current Stimulation

Outcome measures

Primary outcome

Efficacy of atDCS in the improvement of executive functioning in PD-MCI.

Secondary outcome

Network connectivity as a predictor and monitor of treatment response

Instrumental activities of daily living

Motor symptoms

Pain perception

Health-related quality of life

Mood

Study description

Background summary

Rationale: Parkinson*s disease (PD) has traditionally been considered a pure motor system disorder, but it is now widely recognized to be a complex disorder with diverse clinical features that also include non-motor manifestations like neuropsychiatric disorders, cognitive dysfunction (mainly executive dysfunction), dementia, and changes in pain perception.
As much as 26 to 34 percent of PD patients without dementia have been found to meet criteria for Mild Cognitive Impairment that profoundly affects patient*s every-daily-life functioning and quality of life. Considering the increase in the incidence of PD-related mild cognitive impairment (PD-MCI) traditional face-to-face cognitive rehabilitation strategies may not be cost-effective strategies to maintain or enhance the integrity of cognitive functions in PD

patients. In this context, transcranial Direct Current Stimulation (tDCS) may be a viable alternative. Anodal tDCS (or atDCS) causes membrane depolarization, while cathodal tDCS (or ctDCS) hyperpolarizes the neural membrane. atDCS reduces the threshold required for neuronal firing, and can hereby improve cognitive functioning and neural efficiency.

Study objective

Determine the efficacy of atDCS as compared to ctDCS and sham stimulation in the improvement of executive functioning in PD-MCI.

Study design

Double-blind RCT with three arms (atDCS, ctDCS, or placebo)

Intervention

Bipolar tDCS will be administered using two saline-soaked surface sponge electrodes (area 7 x 5 cm2) and delivered by a battery-driven, constant-current stimulator.
For atDCS, the anode will be placed above F3 (according to international 10-20 system of electrode placement) corresponding to the left dorsolateral prefrontal cortex, and the cathode will be positioned above the contralateral supraorbital region, at least 5 cm from the anode. DC stimulation will be delivered for 20 minutes at 2 mA intensity (15 s ramp in and 15 s ramp out). The montage will be reversed for cathodal tDCS. Sham stimulation will be conducted with 5 s of tDCS applied at the onset to induce initial tingling sensation consistent with real tDCS, after which the DC stimulator will be deramped for 5 s.
At baseline (T0), patients will undergo cognitive assessment, detailed testing of executive functioning and MEG recording will be performed, prior to stimulation with atDCS, ctDCS, or sham. After stimulation, another assessment of executive functioning and an MEG will be performed, in order to study the immediate effects of stimulation (T1). On days 2, 3, and 4, stimulation (atDCS, ctDCS, or sham) will be administered at the patient*s home, or at the hospital if preferred by the patient. On day 5 (T2), patients will receive stimulation followed by detailed assessment of executive functioning and MEG to study the cumulative effects of the five consecutive stimulations on executive functioning and network connectivity. Finally, to investigate whether tDCS has longer-lasting effects, extensive cognitive assessment and assessment of executive functioning will also be performed at 35 days follow-up (T3).

Study burden and risks

Measurement sessions, including preparation will take approximately 3 hours for the first session on day 1 and 5, 20 minutes for day 2, 3, and 4 and 1,5 hour

for day 35. Informants fill in a questionnaire on day 1 and 35, which takes 2x30 minutes.
Transcranial Direct Current Stimulation is a non-invasive and safe technique. A slight risk that has been reported is mood changes, therefore potential subjects/patients with a diagnosed bipolar disorder82 or subjects/patients who score more than 7 points on a depression questionnaire (HADS) are excluded from this study, see exclusion criteria. Although never reported in clinical studies, another theoretically low grade risk associated with tDCS may be seizures. Therefore potential subjects/patients with a history of epileptic seizures are excluded from this study, see exclusion criteria. Some non-harmful discomforts that have been reported are: tingling, fatigue, headache and nausea.

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

1) Clinical diagnosis of PD according to the UK PD Brain Bank criteria60
2) PD-related mild cognitive impairment (PD-MCI)
3) If applicable, stable maintenance of their medication, including dopaminergic treatment, for at least 30 days prior to enrollment and throughout the study.;For the collection on data on instrumental activities of daily living
4) Presence of an informal informant
5) Ability of the informant to complete the questionnaire.

Exclusion criteria

1) Insufficient mastery of the Dutch language
2) Inability to understand test instructions in Dutch language
3) Any contra indications to tDCS like metallic implants (pacemaker etc.)
4) History of seizures
5) Substance abuse
6) Dementia
7) Major head trauma
8) Bipolar or psychiatric disorder
9) Signs of depression (Hospital Anxiety and Depression Scale, sub score D >7)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	01-09-2015
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	transcranial Direct Current Stimulation (tDCS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-11-2015
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	NL52779.029.15