

The effect of deep brain stimulation on speaking: An exploratory study

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The present study aims at examining the effects of DBS on speaking. We will test participants performing a verbal fluency task but also producing spontaneous language and performing a language task that is dependent on a brain area targeted by DBS.

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

Summary

ID

NL-OMON48257

Source

ToetsingOnline

Brief title

DBS-Speak

Condition

- Movement disorders (incl parkinsonism)

Synonym

deep brain stimulation, Parkinsons

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen

Source(s) of monetary or material Support: NWO

Intervention

Keyword: deep brain stimulation, language production, Parkinson's

Outcome measures

Primary outcome

Behavioural performance on the language tasks for the different ON-OFF states of stimulation and medication

Secondary outcome

NA

Study description

Background summary

Deep brain stimulation (DBS) of the subthalamic nucleus is indicated for Parkinson's disease (PD) patients who no longer respond (optimally) to medication and it has been shown to effectively alleviate motor symptoms in this population. However, negative effects on cognition, and in particular on verbal fluency, have been reported following DBS. It is unclear, however, how this decline relates to decline in language functioning and everyday communication, jeopardising the quality of the information given to patients in the decision-making process and after the surgical intervention.

Study objective

The present study aims at examining the effects of DBS on speaking. We will test participants performing a verbal fluency task but also producing spontaneous language and performing a language task that is dependent on a brain area targeted by DBS.

Study design

We will compare PD patients in ON and OFF medication and stimulation conditions with healthy matched controls and PD patients not candidate for DBS 6 months after surgery.

Study burden and risks

For the control groups, no risks are present and the burden for participation is low. For the DBS group: Medication and stimulation withdrawal themselves do not pose any risk, if appropriate precautions are taken. However, the withdrawal may cause discomfort to patients. There is a moderate chance of a moderate risk in the OFF conditions (e.g., patients may fall). The novel insights will broaden our understanding of the effects of DBS on speaking and will help improve patient counselling

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

- * Between 45 * 75 years of age
- * Diagnosis of idiopathic Parkinson*s disease
- * Native speaker of Dutch

* Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and to comply with the study requirements

Exclusion criteria

- * Dementia
- * Psychiatric condition
- * Other neurological condition known to influence language and cognition
- * Hearing or visual impairment
- * History of neurodevelopmental language disorders (i.e., dyslexia, specific language impairment).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	29-10-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	08-07-2019
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	28-11-2019
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	NL68706.091.19