Long term (neuro)psychological outcome of deep brain stimulation for obsessive-compulsive disorder

Published: 10-08-2021
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Primary Objective: Does DBS result in cognitive changes in patients with OCD on the long term? Secondary Objective(s): Does DBS result in personality changes in patients with OCD on the long term?Are certain cognitive profiles associated with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON51067

Source
ToetsingOnline

Brief title
Psychological outcome of DBS for OCD

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive behaviour

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive side effects, deep brain stimulation, obsessive-compulsive disorder, personality features

Outcome measures

Primary outcome

Outcomes on a (neuro)psychological test battery

Secondary outcome

Personality variables measured with the Young Schema Questionnaire.

Study description

Background summary

Around 60% of people that are diagnosed with a treatment resistant Obsessive-compulsive improve after treatment with DBS.
A recent survey amongst patients in the Amsterdam UMC has shown that at least 50% of patients have subjective complaints of cognitive decline following DBS. Furthermore, before the surgery, many patients are concerned about personality changes. Literature on cognitive functioning and personality following DBS is scarce. The aim of the current study is to follow-up on the cognitive functioning and personality changes of OCD patients who were treated with DBS.

Study objective

Primary Objective:
Does DBS result in cognitive changes in patients with OCD on the long term?

Secondary Objective(s):
Does DBS result in personality changes in patients with OCD on the long term?
Are certain cognitive profiles associated with clinical outcome of patients?
Are certain personality traits or schemas associated with the outcome of DBS or cognitive functioning on the long term?

Study design

The study is a cross-sectional observational study, combined with a retrospective chart study. All patients have been treated with DBS for OCD. For the current study, a (neuro)psychological test battery will be administered

once in a single session to establish current (neuro)psychological functioning. This session will last a maximum of 2 hours and will take place in the Amsterdam UMC, location AMC. Results of these (neuro)psychological tests will then be compared with the results of the tests that were administered before DBS -during the standard intake- to establish whether there is cognitive decline.

Study burden and risks

There are no risks associated with participating in this study. The burden is restricted to a one time visit to the Amsterdam UMC to ondergo a neuropsychological test battery for about 120 minutes. There are no direct benefits for the participating subjects.

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

- Patients are treated with vALIC DBS for OCD for at least one year.
- Written informed consent must be obtained before participation.

Exclusion criteria

- Current substance abuse (excluding nicotine abuse)
- Diagnosed comorbid conditions that can influence cognitive functioning or personality, such as dementia, Parkinson*s disease, or haemorrhage.
- Insufficient knowledge of the Dutch language to understand the test 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):	14-12-2021
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	04-02-2022
Application type:	Amendment
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	NL75894.018.21