Exploring the functional connectivity of the subthalamic nucleus and the ventral striatum during cognitive and affective processing

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

Summary

ID

NL-OMON57036

Source
ToetsingOnline

Brief title
Understanding brain connectivity in Obsessive-Compulsive Disorder

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive-Compulsive Disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Connectivity, DBS, fMRI, OCD

Outcome measures

Primary outcome

The primary outcomes for this study are the functional connectivity profiles of the STN and the VS from each group during the cognitive and affective tasks, measured with BOLD-fMRI.

Secondary outcome

The secondary outcomes for this study are the answers on the Y-BOCS, MADRS, STAI and POMS questionnaires. Other secondary outcomes are the performance on the (computer) tasks (Trail Making and Emotional-Stroop) and MRI tasks, described by the reaction time and accuracy rating scores.

Study description

Background summary

Obsessive-compulsive disorder (OCD) is a severe disorder, affecting around 1% to 3% of the general population. It is characterized by repeated and heterogenious obsessions and/or compulsions. Cognitive behavior therapy (CBT) and drug treatment are first-line treatment options. Unfortunately, up to 10% to 20% of the patients do not respond to these interventions and become candidates for deep brain stimulation (DBS). In OCD, DBS usually targets the cortico-basal ganglia-thalamocortical system with key areas being the subthalamic nucleus (STN) and ventral striatum (VS; i.e., the nucleus accumbens, ventral capsule, and partially the BNST). Despite the comparable efficacy of these structures, studies indicate only a 30% to 40% symptom improvement. This is a lower rate compared to DBS in movement disorders. However, OCD is a heterogeneous disease. Further, prior research revealed functional differentiated brain networks and ascribes a more cognitive and affective processing role for the STN and VS, respectively. We, thus,

hypothesize that DBS response in OCD is associated with distinct functional connectivity profiles of the VS and the STN, respectively. Studying functional connectivity in OCD patients without DBS provides a baseline understanding of neural networks associated with the disorder. This baseline serves as a reference point for evaluating the effects of DBS on functional connectivity and elucidating its therapeutic mechanisms.

Study objective

The central objective is to explore the functional connectivity profiles of both STN and VS circuits during cognitive and affective tasks and compare these between OCD patients and healthy controls (HC). Secondary objectives are to assess associations between symptom severity and cognitive and affective functioning in OCD.

Study design

The research design will be a matched case-control study, including healthy controls and OCD patients. All participants will take part in an inclusion meeting (pre-session) to examine participation eligibility. If eligible, they will undergo a 3T scanning session assessing structural and functional connectivity of the STN and VS. During the functional scan, all participants will be scanned at rest and while performing a cognitive, an affective and a combined cognitive-affective task.

Intervention

The present research will incorporate existing OCD DBS patients and OCD DBS candidates. For both groups, DBS has been/will be implanted as part of their treatment plan, not for the purpose of the present research. DBS effects will be investigated during ON and OFF stimulation (existing OCD DBS patients) and pre- and post-surgery (OCD DBS candidates).

Study burden and risks

Participants may experience little discomfort during the (f)MRI scan. Such discomfort may include dizziness, nausea, and claustrophobia. All participants will fill out questionnaires to assess for MRI-safety, neuropsychological functioning, symptom severity, anxiety and mood, which in total should not take up more than one hour of their time. All participants will then be scanned (anatomical and functional scan) for approximately 2 hours. The total duration of participation will be no longer than 3 hours.

Although no immediate or direct benefit arise when taking part in the current study for either healthy volunteers or OCD patients, their involvement could assist in establishing fundamental insight into action mechanisms of OCD.

Ultimately, it will provide a basis for tailored DBS-targets based on the complaints of individual patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria for HC:
- The subject provides written informed consent attesting to their understanding of the study's objectives and the procedures involved, as well as their willingness to participate.
- The volunteer is healthy, i.e. absence of all exclusion criteria
- Age between 18-65 years old

Inclusion criteria for OCD patients:
- Clinical diagnosis of OCD

- The subject provides written informed consent attesting to their understanding of the study's objectives and the procedures involved, as well as their willingness to participate.
- Absence of all exclusion criteria for OCD patients
- Age between 18-65 years old

Exclusion criteria

Exclusion criteria for HC:
- Current psychiatric/neurological diagnosis
- History of psychiatric treatment
- Current use of psychoactive medication
- Standard contra-indications for magnetic resonance imaging
- Current substance abuse (e.g. (excessive) use of drugs or alcohol)

Exclusion criteria for OCD patients:
- Current substance abuse (e.g. excessive use of drugs or alcohol)
- Standard contra-indications for magnetic resonance imaging

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:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	01-10-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL86150.068.24