ISRCTN18430630 https://doi.org/10.1186/ISRCTN18430630

# Deep brain stimulation for severe obsessive compulsive disorder

| Submission date | Recruitment status |
| --- | --- |
| 22/04/2015 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 22/04/2015 | Completed |
| **Last Edited** | **Condition category** |
| 31/03/2020 | Mental and Behavioural Disorders |

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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**Contact details**
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## Additional identifiers

**Protocol serial number**
13158

## Study information

**Scientific Title**
Deep brain stimulation for severe obsessive compulsive disorder: efficacy and mechanisms of ventral striatum and subthalamic nucleus targets

**Study objectives**

The overarching aim is to compare the effects of VC/VS and STN DBS in the same patients. This study will test the hypothesis, grounded in cognitive neuroscience, that DBS at both sites is better than either site alone for treating the symptom dimensions of OCD. Specifically, this study will employ novel cognitive paradigms and neurophysiological measures of cortical synaptic function to test the hypothesis that VS/VC and STN DBS have different mechanisms of action and that alleviation of OCD symptoms is mediated by improvement in mood/anxiety with VS/VC DBS and by directly interrupting obsessions and compulsions with STN DBS. This study will additionally determine whether adjunctive CBT enhances the response to DBS by providing the cognitive and behavioural skills to optimise symptom management and daily function.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
ref: 12/LO/1087

### Study design
Randomised; Interventional; Design type: Treatment

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Personality disorder; Disease: Personality disorders

### Interventions
1. Cognitive Behavioural Therapy: CBT for OCD including Graded Exposure and Self Imposed Response Prevention
2. Deep Brain Stimulation: A neurosurgical procedure involving the implantation of a medical device in brain
Study Entry : Single Randomisation only

### Intervention Type
Mixed

### Primary outcome(s)
YBOCS improvement greater than or equal to 35%; Timepoint(s): 15 months

### Key secondary outcome(s))
N/A

### Completion date
31/08/2015

## Eligibility

## Key inclusion criteria
The inclusion criteria have been designed to be consistent with previous OCD DBS studies and to ensure that patients have not responded in a useful and sustained manner to either modifications of medication or any form of CBT
1. Patients must have undergone intensive treatment and have demonstrable treatment resistance as defined by:
1.1. At least two SRIs for a minimum of 12 weeks at optimal British National Formulary (BNF) doses
1.2.Augmentation of SRI treatment with antipsychotic drugs administered at maximally tolerated doses or by extending the SSRI dose beyond BNF limits
1.3. Two trials of CBT of at least 10 hours
1.4. Failed inpatient treatment
2. Patients must also satisfy the following criteria:
2.1. Age > 20 years
2.2. Confirmation of a primary diagnosis of obsessive compulsive disorder (ICD10 F42.0—F42.9)
2.3. Duration of illness of at least 10 years
2.4. At least 2 years of unremitting symptoms despite intensive psychopharmacological and psychological treatment or failure to sustain, over a 3 month period, a response to inpatient psychological treatment by at least 33% with accompanying optimised pharmacological therapy
2.5. A minimum score of 32 on Yale Brown Obsessive Compulsive Scale (YBOCS 22) thus constituting profound illness and a maximum score of 50 on the DSM IV General Assessment of Function Scale (GAF)
2.6. Ability to provide sustained informed consent

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Sex
All

## Total final enrolment
6

## Key exclusion criteria
1. Current diagnoses of substance misuse (ICD10 F10—F19), organic brain syndrome (ICD10 F00—F09), adult personality disorder (ICD10 F60—F69), pervasive developmental disorder (ICD10 F84); schizophrenia (ICD10 F20-F29) and bipolar disorder (ICD 10 F30-31)
2. Contraindications to neurosurgery
3. Pregnancy

## Date of first enrolment
22/01/2013

## Date of final enrolment
31/08/2015

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**UCL Institute of Neurology**
Queen Square
London
United Kingdom
WC1N 3BG

# Sponsor information

**Organisation**
University College London

**ROR**
https://ror.org/02jx3x895

# Funder(s)

**Funder type**
Government

**Funder Name**
Medical Research Council (Grant Codes: MR/J012009/1)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2019 | 31/03/2020 | Yes | No |