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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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

Secondary outcome measures
N/A

Overall study start date
22/01/2013

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 6; UK Sample Size: 6

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
England

United Kingdom

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

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
United Kingdom
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Sponsor type
University/education

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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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