

Deep brain stimulation for severe obsessive compulsive disorder

Submission date
22/04/2015

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/04/2015

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
31/03/2020

Condition category
Mental and Behavioural Disorders

☐ 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

WC1E 6BT

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