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Feasibility and acceptability of transcranial stimulation in obsessive-compulsive symptoms

Submission date
08/07/2019

Recruitment status
No longer recruiting

Registration date
22/07/2019

Overall study status
Completed

Last Edited
30/01/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder is a major mental disorder. About 40% of patients are not helped by available treatments. New approaches are needed. One promising treatment is transcranial direct current stimulation (tDCS). tDCS uses an electrode placed for a short time on the scalp to pass a small, almost imperceptible electric current into brain areas connected to OCD. This may help people with OCD think and behave differently and could help existing treatments work better. tDCS is relatively new and experimental in OCD though it has been used with some success in depression. This small-sized study is a pilot (feasibility study) preparing for a larger trial. The aim is to answer basic questions, including if tDCS lessens OCD symptoms, the nature and severity of any side effects and if doctors and patients are willing to use it. The researchers also investigate which specific brain areas should be targeted and how long positive effects last. This information would help the design and conduct of larger clinical trials.

Who can participate?
Treatment-seeking adults with OCD are recruited from mental health units, GP referrals and improved access to psychological therapies services.

What does the study involve?
The study takes place in community mental health facilities. Twenty-five patients with OCD receive three courses of four twice-daily 20-minute sessions of tDCS (either active or sham stimulation) delivered to two separate brain targets. The courses are allocated in a random order. Each 2-day course of tDCS is spaced 4 weeks apart to avoid ‘carry over’ effects, and see how long the effects last. Patients are asked about the experience and have their symptoms and any side effects assessed using questionnaires. The assessor will not know which patients have received which course of treatment to reduce bias. Patients are asked if they found the treatment acceptable.

What are the possible benefits and risks of participating?
Those taking part in the study will have the chance to receive transcranial direct current stimulation (tDCS) which may turn out to be a helpful new treatment for OCD. However, the short course of stimulation received is not expected to provide real lasting clinical benefit. Participants will also have the opportunity to receive extra detailed assessments conducted by a

member of the research team. The information gained from this study will help the researchers to decide whether or not to set up a larger study which in turn should provide information for improving the treatment of OCD. It is important to stress that the tDCS equipment used is designed to be used by patients with depression at their home without supervision. The researchers will be using it in a controlled laboratory environment under constant supervision. It is not anticipated that there will be any severe side effects from taking part in this study.

Where is the study run from?
Southampton University (UK)

When is the study starting and how long is it expected to run for?
December 2018 to July 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Megan Smith
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2. Prof. Naomi Fineberg
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS: 41100

Study information

Scientific Title
Feasibility and acceptability of transcranial stimulation in obsessive-compulsive symptoms

Acronym
FEATSOCS

Study objectives
Obsessive-compulsive disorder is a major mental disorder. About 40% of patients are not helped by available treatments. New approaches are needed. One promising treatment is transcranial direct current stimulation (tDCS). tDCS uses an electrode placed for a short time on the scalp to pass a small, almost imperceptible electric current into brain areas connected to OCD. This may help people with OCD think and behave differently and could help existing treatments work better. tDCS is relatively new and experimental in OCD though it has been used with some success in depression. This small-sized study is a pilot (feasibility study) preparing for a larger trial. The aim is to answer basic questions, including if tDCS lessens OCD symptoms, the nature and severity of any side effects and if doctors and patients are willing to use it. The researchers also investigate which specific brain areas should be targeted and how long positive effects last. This information would help the design and conduct of larger clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/03/2019, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0) 2071048102), ref: 19/EE/0046

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder

Interventions
In this study, treatment-seeking adults with OCD are recruited from mental health units, GP referrals and improved access to psychological therapies services. Twenty-five patients with OCD will receive three courses of four twice-daily 20-minute sessions of tDCS (either active or sham stimulation) delivered to 2 separate brain targets. The courses are allocated in a randomised order. Each 2-day course of tDCS is spaced 4 weeks apart to avoid 'carry over' effects, and see how long the effects last. Patients will be asked about the experience and have their symptoms and any side effects assessed using questionnaires. The assessor will not know which patients have received which course of treatment to reduce bias. The researchers will ask patients if they found the treatment acceptable. Recruitment is expected to take 12 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Acceptability, tolerability and safety of the intervention is determined using treatment logs recorded during and following study visits. Specifically:
1.1. Sessions completed and missed (acceptability, tolerability)
1.2. Recording of issues raised by patients at any point during the study. Adverse events reported at any point, specifically recorded at study visits (safety)
2. Feasibility of recruitment is determined using logs of referral into the services, by recording the numbers of potential patients, as well as why patients were excluded at each point, and the number of patients consented.
3. Adherence to tDCS and the study protocol assessed by recording sessions, and the proportion of study outcomes completed is determined using notes on issues raised by patients and researchers that are recorded during the study.
4. Willingness evaluated by recording the numbers of key staff approached, those declining study participation and the reasons given.
5. tDCS in a clinical setting assessed by recording any issues relating to setting up the sessions, delivery of the stimulation, and issues raised by the participants during or in the hours after the stimulation sessions. Difficulties with the application of the treatment protocols and equipment failures are noted

Key secondary outcome(s))
Current secondary outcome measures as of 24/07/2019:
1. Optimal stimulation target (OFC, SMA) effect on OCD symptoms is measured using Y-BOCS and Y-BOCS challenge (as appropriate)scores utilising all available data (from 1 hour after the first stimulation to 14 days after the last stimulation).
2. Likely magnitude of the effect of the intervention on OCD symptoms is measured using the Y-BOCS 24 hours after the final stimulation.
3. Duration of effect of stimulation is measured separately for the OFC and SMA targets using paired tests usingY-BOCS and Y-BOCS Challenge at all time points following the first stimulation.
4. Usefulness and limitations of specific neurocognitive tests is measured using the CANTAB (stop signal reaction time test, intra-extradimensional set shift), Prisoner's Dilemma test (cooperation test), andFabulous Fruit game (habit learning test) at baseline and 3 hours.

Previous secondary outcome measures:
1. Optimal stimulation target (OFC, SMA) effect on OCD symptoms is measured using Y-BOCS and Y-BOCS challenge (as appropriate) scores utilising all available data (from 1 hour after the first stimulation to 14 days after the last stimulation)
2. Likely magnitude of the effect of the intervention on OCD symptoms is measured using the Y-BOCS 24 hours after the final stimulation
3. Duration of effect of stimulation is measured separately for the OFC and SMA targets using paired tests using Y-BOCS and Y-BOCS Challenge at all timepoints following the first stimulation
4. Usefulness and limitations of specific neurocognitive tests are measured using the CANTAB (stop signal reaction time test, intra-extradimensional set shift), Prisoner's Dilemma test (cooperation test), and Fabulous Fruit game (habit learning test) at baseline and 3 hours

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Community-based service-users, aged 18-65 years
2. DSM-5 defined obsessive-compulsive disorder determined by a research psychiatrist using the structured interview for DSM-5
3. Duration of symptoms > 1 year (from medical history)
4. Baseline score >= 20 on the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)
5. Ongoing medication (SSRI, tricyclic antidepressant, antipsychotic, benzodiazepine) is allowed as long as the dose is kept stable for a sustained period before (> = 6 weeks) randomisation and remains so throughout the study. CBT is not allowed during or within 6 weeks of the start of the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
20

Key exclusion criteria

1. History of psychotic disorder (schizophrenia, psychotic symptoms, bipolar disorder), Tourette syndrome (tic disorders not amounting to Tourette syndrome will not be exclusionary), organic mental disorder, psychosurgery, personality disorder of borderline or histrionic type
2. Alcohol/substance-abuse disorders within the past 12 months
3. Any other DSM-5 disorder that is considered the primary focus of treatment
4. Severe depression, defined by a Montgomery-Åsberg Depression Rating Scale (MÅDRS) score > 30 at baseline
5. Actively planning suicide (scoring 5 or 6 on item 10 of MADRS) or judged by the clinician to be at significant risk of self-harm
6. Received CBT involving ERP from an accredited (British Association of Behavioural and Cognitive Psychotherapies (BABCP) approved or equivalent) therapist (e.g. IAPTs stage 2) in the last 6 weeks
7. Highly CBT resistant (inadequate clinical response, equivalent to < 25% improvement) > = 3 previous adequate (> 12 weeks) trials of CBT involving ERP from an accredited (BABCP-approved or equivalent) therapist
8. Highly medication resistant (inadequate clinical response, equivalent to < 25% improvement) > = 3 previous adequate (> 12 weeks) trials of any SSRI or clomipramine taken at optimal doses with adequate adherence
9. Needing regular psychotropic drugs other than permitted medication
10. Currently involved in a treatment research study
11. Acute or unstable physical illness
12. Skull defects, or skin lesions on scalp (cuts, abrasions, rash) at proposed electrode sites
13. History of surgical procedure with implanted body materials or devices (e.g. metal, pacemakers)
14. Epilepsy or other clinically defined neurological disorder or insult
15. Inadequate understanding of English to give informed consent or such that the outcome measurement is impossible
16. Women of child-bearing age not using reliable contraception (e.g. oral contraception pill, intra-uterine contraceptive device or condom)
17. Pregnant or breastfeeding women

Date of first enrolment
15/07/2019

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Rosanne House
HPFT

Welwyn Garden City
United Kingdom
AL8 6HG

Study participating centre
Southampton University Department of Psychiatry
College Keep
4-12 Terminus Terrace
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SO14 3DT

Sponsor information

Organisation
Hertfordshire Partnership University NHS Foundation Trust

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20005

Results and Publications

Individual participant data (IPD) sharing plan
The data will be made available in a generic format (e.g. tab-delimited) and will be available on completion of reporting of the main trial outcomes. Requests for data access should be directed to the CI (Prof Naomi Fineberg) or the Sponsor (University of Hertfordshire, email: uhclinicaltrialsupportnetwork@herts.ac.uk) who will review the data request to evaluate the extent to which the request is appropriate to the needs of the clinical and patient community and meets appropriate ethical standards.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/01/2023	30/01/2023	Yes	No
Protocol article		06/12/2021	08/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes