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A brain imaging study of the effects of electrical brain stimulation on attention in healthy people

Submission date
07/08/2018

Recruitment status
No longer recruiting

Registration date
08/08/2018

Overall study status
Completed

Last Edited
06/09/2023

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
Transcranial direct current stimulation (tDCS) is a non-invasive method of brain stimulation using weak electrical currents. The practice of using direct current to treat neurological disorders has been around for over a century, but is now used less often due to the development of antidepressant drugs in more recent years. However, the method is now experiencing a research revival and there is a growing body of evidence that it can be used as a treatment for disorders such as depression and anxiety, as well as producing subtle changes in the responses of healthy people.
We are interested in understanding more about how tDCS works when it is used on a particular region of the brain related to information processing, attention control and mood. We are also interested in understanding how the brain is organised, processes information and performs skills such as thinking and speaking. We can investigate this using MRI brain scans, which are safe and non-invasive. Using many different techniques available on a MRI scanner, we can gain information about brain structure and brain function, for example, which parts of the brain are important for certain types of information processing (using a technique called functional MRI). We would like to explore the effect of tDCS on brain activity, at rest and when participants are completing a series of computerised information processing tasks. Specifically, we want to investigate if tDCS can subsequently change behavioural and brain responses to visual information in healthy people.

Who can participate?
Healthy right-handed females aged 18-45

What does the study involve?
All participants will receive active and sham (placebo) tDCS; however, the order in which these will be received is randomly allocated. Active tDCS is where the brain will be stimulated using weak electrical currents through electrodes placed on the scalp. Sham tDCS appears the same; however no current is delivered.
The two sessions will occur 30-60 days apart. At each session, participants will receive either active or sham tDCS for 20 minutes. They will then go into an MRI scanner and will be asked to

complete an attention-based task. Before and after tDCS, participants will be asked to complete questionnaires.

What are the possible benefits and risks of participating?
There is no direct benefit to participants from taking part in this study; however, participants are paid £10 per hour for their time and any inconvenience caused by participating in this study. Reasonable travel expenses are also reimbursed. There are no known risks to participants taking part in this study. As with all techniques that directly stimulate the brain, tDCS has the possibility to induce seizures in people who are more susceptible to them (although there are no known reports of this in healthy subjects). Therefore, participants with a personal or family history of epilepsy, or other neurological/psychiatric disorders will not be able to participate.

Where is the study run from?
1. Warneford Hospital, Oxford
2. John Radcliffe Hospital, Oxford

When is the study starting and how long is it expected to run for?
June 2013 to October 2015

Who is funding the study?
The Medical Research Council of England (UK)

Who is the main contact?
Dr Maria Ironside
maria.ironside@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Maria Ironside

Contact details
McLean Hospital
Belmont
United States of America
02478

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MS-IDREC-C2-2015-003

Study information

Scientific Title
A Functional Magnetic Resonance Imaging investigation into the effects of Transcranial Direct Current Stimulation on information processing and and neural activity in healthy volunteers with trait anxiety

Acronym
FMRI TDCS

Study objectives
The present study uses behavioural and neuroimaging results to examine how transcranial direct current stimulation (tDCS) affects emotional processing relevant to trait anxiety. Our working hypothesis is that tDCS will alter activity in cortical regions relevant to attentional control and anxiety. Specifically, that compared to sham stimulation, tDCS will improve accuracy in an attentional control task, reduce neural activity in regions relevant to fear processing (e.g. amygdala) and increase neural activity in regions relevant to attentional control (e.g. prefrontal cortex). This has implications for our understanding of the use of tDCS in the treatment of mood and anxiety disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Science Interdivisional Research Ethics Committee, University of Oxford, 04/02/2015, MS-IDREC-C2-2015-003

Study design
Interventional single-centre double-blind placebo-controlled order randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Mood disorders, anxiety disorders, trait anxiety

Interventions

Participants are randomised into two arms using a list generated by an Excel spreadsheet of randomly generated numbers between 0 and 1, where numbers below 0.5 represent the sham-active order and numbers above 0.5 represent the active-sham order. Participants will take part in both arms of the study; however, the order in which they do is randomised. Double-blinding is achieved using a study mode on the tDCS (transcranial direct current stimulation) device with blinding codes assigned by a party not otherwise working on the study.
The intervention delivers 20 minutes of 2 mA bipolar balanced tDCS, with anodal tDCS delivered to the left dorsolateral prefrontal cortex (DLPFC) and cathodal tDCS delivered to the right DLPFC simultaneously. In the sham condition, 40 seconds of stimulation is delivered with a placebo tDCS.
Participants in arm 1 receive sham (placebo) tDCS for 20 minutes in session 1. At least 1 month later, this group receives the intervention (active) tDCS for 20 minutes in session 2.
Participants in arm 2 receive intervention (active) tDCS for 20 minutes in session 1. At least 1 month later, this group receives sham (placebo) tDCS for 20 minutes in session 2.
Following tDCS, participants in both arms were asked to complete an attentional control task whilst in an MRI scanner. Participants were shown visual stimuli, where a 6 letter string superimposed on a task-irrelevant, non-familiar face was presented for 200 ms. The face stimuli comprised 4 different individuals with fearful or neutral expressions. The task was to decide whether the letter string contained an "X" or an "N" and respond with a key press. In half the blocks – the “high attentional load” condition – the string comprised a single target letter (N or X) and 5 non-target letters (H, K, M, W, Z) arranged in random order. In the other half of blocks—the ‘‘low attentional load" condition—the letter string comprised 6 Xs or 6 Ns, removing attentional search requirements. The task ran in 3 separate blocks, with a total duration of 15 minutes.

Intervention Type
Other

Primary outcome measure
The change in neural activity during an attentional control task after sham and active tDCS, assessed using blood oxygenation level dependent-response measured using functional magnetic resonance imaging, taken after each tDCS treatment (sham and active). The time period between each measurement is no less than 30 days and no more than 60 days.

Secondary outcome measures
The following were measured after active and sham tDCS treatment (the time period between measurements is no less than 30 days and no more than 60 days):
1. Change in accuracy in the attentional control task, assessed by comparing the behavioural test results (accuracy in task) after active and sham tDCS
2. Change in reaction time in the attentional control task, assessed by comparing the behavioural test results (mean reaction time in milliseconds in task) after active and sham tDCS
3. Difference in anxiety symptoms, assessed by the change in self-reported anxiety scores using the State-Trait Anxiety Inventory (STAI) after active and sham tDCS
4. Change in sadness and happiness, assessed by the change in self-reported visual analogue scale (VAS) ("sad" indicated by 0 and "happy" indicated by 100) after active and sham tDCS
5. Difference in hostility and friendliness, assessed by the change in self-reported visual analogue scale (VAS) ("hostile" indicated by 0 and "friendly" indicated by 100) after active and sham tDCS
6. Difference in calmness/tenseness, assessed by the change in self-reported visual analogue scale (VAS) ("calm" indicated by 0 and "tense" indicated by 100) after active and sham tDCS

Overall study start date
10/06/2013

Completion date
06/10/2015

Eligibility

Key inclusion criteria
1. Aged 18-45 years old
2. Female
3. Willing and able to provide informed consent
4. Healthy
5. Right-handed
6. Normal range on trait anxiety (based on State-Trait Anxiety Index (STAI) pre-screening online anxiety questionnaire)
7. Fluent in English

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
1. Current significant medical condition
2. Current or past psychological disorder (e.g. depression, anorexia)
3. Any family history of extreme mood fluctuations (e.g. elated mood states)
4. Current medications (except for contraceptive treatment) or herbal remedies such as St John's wort
5. Current pregnancy or likelihood of becoming pregnant during the study
6. Participation in any other psychological or medical experiment involving taking any kind of drugs, within the last 3 months
7. Previous participation in a brain stimulation study will be taken into account and advice will be sought from the secondary supervisor on whether they should be included, based on the type of

stimulation received, the location of the stimulation and the number of sessions. If the secondary supervisor advises that the nature of the stimulation previously received could affect the results of this study, the participant will not be included
8. Any other contraindication to magnetic resonance imaging or transcranial current stimulation
9. Claustrophobic
10. Metal within the body:
10.1. Pacemaker
10.2. Mechanical heart valve
10.3. Mechanical implant (e.g. aneurysm clip)
10.4. Hip replacement
10.5. Any other pieces of metal that have accidentally entered the body

Date of first enrolment
20/04/2015

Date of final enrolment
25/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warneford Hospital
Warneford Lane,
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Block 60
Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LE

+441865572228
heather.house@admin.ox.ac.uk

Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
Medical Research Council of England

Results and Publications

Publication and dissemination plan
The neuroimaging and behavioral results are currently under revision at a psychiatry journal and thus under embargo until the publication date

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Maria Ironside, maria.ironside@gmail.com. Data available includes fMRI data, behavioural data and questionnaire data. Data will be available indefinitely upon request to academic and medical researchers only, and data will be fully anonymised as per consent obtained from participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/10/2018		Yes	No
Protocol (other)		17/10/2018	06/09/2023	No	No