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NeuroMooD – Neurofeedback in depression

Submission date	Recruitment status	[X] Prospectively registered
07/12/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/08/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and loss of interest in life. Depression comes in many forms however the most recognised is major depressive disorder (MDD). People suffering from MDD tend to go through periods where they are able to function normally (remittance) and depressive episodes, in which the feelings of depression begin suddenly, lasting for at least two weeks and are serious enough to affect day to day life. Even effective treatments, such as talking therapy and medication, do not guarantee complete remittance in patients with MDD. A possible reason may be that partly remitted patients still experience feelings of “self-blame”, which can lead to further depressive episodes. There is therefore an urgent need to better understand the role self-blame plays in remitted patients and to develop new treatments that improve long-term outcomes of MDD. Previous studies using functional magnetic resonance imaging (fMRI), a type of brain scan which shows what is happening in the brain in real time, suggest that this may be because certain parts of the brain do not function as they should do in patients with MDD. A technique called fMRI-neurofeedback has been developed which works by highlighting abnormal brain activity and teaching a patient how to change it by giving them feedback. The aim of this study is to compare the effects of fMRI-neurofeedback and a new psychological treatment program on reducing self-blame in adults suffering from MDD.

Who can participate?
Right handed adults with MDD who haven't responded well enough to a standard treatment for a depressive episode.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are given a self-guided psychological (mental health) therapy designed to reduce self-blame and increase self-worth. Participants in the second group a have the fMRI neurofeedback treatment as well as the self-guided therapy. At the start of the study and the end of the study, participants in both groups complete a number of questionnaires in order to find out if there has been any improvement in their mood and self-esteem, and if their levels of self-blame have been reduced.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in the study. The FMRI neurofeedback and the psychological therapy are non-invasive procedures which are considered safe, and so risks of taking part in the study are minimal.

Where is the study run from?
Kings College London (UK)

When is the study starting and how long is it expected to run for?
June 2015 to September 2018

Who is funding the study?
Kings College London (UK)

Who is the main contact?
Dr Roland Zahn

Contact information

Type(s)
Public

Contact name
Dr Roland Zahn

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
FMRI neurofeedback treatment of self-blaming emotions in major depressive disorder – a pilot trial

Acronym
NeuroMooD

Study objectives
Patients undergoing active transcranial direct current stimulation (tDCS) or active neurofeedback (ATL-subgenual - correlation decrease) will show reduced depressive symptoms, decreased self-blame and increased self-worth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Camberwell St Giles, 11/06/2015, ref: 15/LO/0577

Study design
Randomised controlled clinical proof-of-concept trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Partially remitted major depressive disorder (MDD)

Interventions
Interventions as of 08/08/2016:
Participants are randomised to two treatment arms which all include 3 treatment sessions:

Arm 1: Psychological self-guided intervention to reduce self-blame and increase self-worth

Arm 2: Anterior temporal lobe-posterior subgenual cingulate correlation fMRI neurofeedback + psychological self-guided intervention to reduce self-blame and increase self-worth

The study involves 5 visits: Pre-trial assessment on visit 1 (day 0), treatment session 1 (visit 2) taking place 1-13 days after visit 1, treatment session 2 (visit 3) taking place 7-13 days after visit 2, treatment session 3 (visit 4) taking place 7-13 days of Visit 3 and the post-trial assessment on visit 5 taking place 7-13 days after the last treatment visit.

Original interventions:
Participants are randomised to three treatment arms which all include 3 treatment sessions:

Arm 1: Right anterior temporal lobe cathodal transcranial Direct Current Stimulation (tDCS) + psychological self-guided intervention to reduce self-blame and increase self-worth

Arm 2: Sham (mock) right anterior temporal lobe tDCS + psychological self-guided intervention to reduce self-blame and increase self-worth

Arm 3: Anterior temporal lobe-posterior subgenual cingulate correlation fMRI neurofeedback + psychological self-guided intervention to reduce self-blame and increase self-worth

The study involves 5 visits: Pre-trial assessment on visit 1 (day 0), treatment session 1 (visit 2) taking place 1-13 days after visit 1, treatment session 2 (visit 3) taking place 7-13 days after visit 2, treatment session 3 (visit 4) taking place 7-13 days of Visit 3 and the post-trial assessment on visit 5 taking place 7-13 days after the last treatment visit.

Intervention Type
Mixed

Primary outcome(s)
Depressive symptoms are assessed using the Beck Depressive Inventory (BDI-II) at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit).

Key secondary outcome(s))
1. Depressive symptoms are assessed using the Montgomery–Asberg Depression Rating Scale (MADRS) at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
2. Self-rated depressive symptoms are assessed using the Quick Inventory of Depressive Symptomatology (QIDS-SR 16) at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
3. Self-rated depressive symptoms are assessed using the Clinical Global Impression Scale at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
4. Withdrawal rates and adverse events are recorded continuously throughout the trial
5. ATL-SCSR correlation in the neurofeedback arm is measured using fMRI and compared between the first and last treatment session (at the start of visit 2 and at the end of visit 4 or at the start and end of visit 1 for patients lost to follow-up, and at the start of visit 2 and the end of visit 3 for patients with missing data from visit 4)
6. Self-contempt bias is assessed using the Brief Implicit Association Test (BIAT) at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
7. Self-esteem is assessed using the Rosenberg Self Esteem Scale at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
8. Changes in mood states are assessed using the Profile of Mood States (POMS) Scale at baseline (Visit 1) and at visit 5 (7-13 days of last treatment visit)
9. Self-blame ratings are obtained using the Moral Emotion Addendum to the AMDP as the sum of all self-blaming emotion scores at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
10. Agency-incongruent self-blame is measured using the short version of the value-related moral sentiment task at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)
11. Clinical global impression is self- & observer rated using the Global Social Functioning Score at baseline (visit 1) and at visit 5 (7-13 days of last treatment visit)

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Recurrent major depressive disorder (MDD) according to DSM-V with at least one major depressive episode (MDE) of at least 2 months duration, insufficiently remitted from current MDE and stable symptoms for at least 6 weeks, level of symptoms that are significantly bothering or impairing
2. If treated with antidepressants, on stable dose for at least 6 weeks prior participation and planning to stay on this dose for the duration of the study

3. Patients have insufficiently responded to at least one course of cognitive behavioural therapy (CBT) or antidepressants or are not amenable to these standard treatments and are not currently undergoing psychotherapy
4. Aged 18 years or over
5. Right-handedness
6. Proficient in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
43

Key exclusion criteria
Exclusion criteria as of 08/08/2016:
1. Greater than low risk of suicidality or violence
2. Current MDE with a duration of more than one year
3. Prior specialist diagnosis of ADHD, antisocial or borderline personality disorder
4. Standard MRI contraindications such as exclusion of participants with any kind of non-removable ferromagnetic devices or implants due to possible dangerous effects of the MRI magnet upon metal objects in the body
5. History of learning disabilities or developmental disorders
6. Impairments of vision or hearing which cannot be corrected during the experiment
7. History of manic or hypomanic episodes, of schizophreniform symptoms or schizophrenia, of substance abuse, neurological disorders such as seizures, loss of consciousness following brain injury or medical disorders affecting brain function, blood flow or metabolism
8. Current intake of benzodiazepines, GABAergic or benzodiazepine receptor agonists
9. Current recreational drug use
10. Pregnancy

Original exclusion criteria:
1. Active suicidal thoughts or history of suicide attempts or aggression
2. Last MDE with a duration of more than one year
3. Prior specialist diagnosis of ADHD, antisocial or borderline personality disorder
4. Standard MRI and tDCS contraindications such as exclusion of participants with any kind of non-removable ferromagnetic devices or implants due to possible dangerous effects of the MRI magnet upon metal objects in the body
5. History of learning disabilities or developmental disorders
6. Impairments of vision or hearing which cannot be corrected during the experiment

7. History of manic or hypomanic episodes, of schizophreniform symptoms or schizophrenia, of substance abuse, neurological disorders such as seizures, loss of consciousness following brain injury or medical disorders affecting brain function, blood flow or metabolism
8. Current intake of benzodiazepines, GABAergic or benzodiazepine receptor agonists, psychostimulants (e.g. Ritalin, and Adderall), or seizure provoking medication (e.g. Bupropion and Theophylline)
9. History of electroconvulsive therapy (ECT)
10. Current recreational drug use
11. Pregnancy

Date of first enrolment
01/09/2016

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
Institute of Psychiatry
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16 De Crespigny Park
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
King's, Collegium Regium apud Londinenses, Collegium Regale Londinense, Collegium Regale Londiniense, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Roland Zahn. No personal data will be shared and the data is fully anonymised. The data management plan stipulates access:
5.1. Suitability for sharing
The anonymised data are suitable for sharing with collaborators.
5.2. Discovery by potential users of the research data
Potential users are pointed to the data through publications and the study website and can apply for data sharing via a collaboration. They will be able to get access to the data directly through data repositories such as the one recently launched at KCL with searchable metadata (www.kcl.ac.uk/library/researchsupport/research-data-management/ DepositPublishPromote /Deposit-your-data-with-Kings.aspx) after an embargo period of 5 years.
5.3. Governance of access
Primary decisions will be made by the PI, and subsequently reviewed by an independent advisor.
5.4. The study team’s exclusive use of the data
There will be an embargo of 5 years after study completion during which only the original research team and new researchers in the PI’s lab or invited collaborators will have access.
5.5. Restrictions or delays to sharing, with planned actions to limit such restrictions
See above
5.6. Regulation of responsibilities of users
People outside the research team who want to collaborate and use data will have to agree to a data sharing agreement in line with MRC principles.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		02/12/2021	03/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed results in preprint	09/08/2019	18/03/2020	No	No
Protocol file	version 11	17/11/2017	10/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes