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Home-based transcranial direct current stimulation for the treatment of major depressive disorder

Submission date
03/10/2025

Recruitment status
Recruiting

Registration date
10/10/2025

Overall study status
Ongoing

Last Edited
20/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression is a prevalent and disabling disorder. The most common treatments are antidepressant medications and talking therapies, however, after a full course of treatment with antidepressant medication or psychotherapy, over one third continue to be unwell. As well, for many individuals, they would prefer to not take antidepressant medications or be involved in talking therapy. Studies have shown that transcranial direct current stimulation (tDCS) could be a possible treatment for major depression
tDCS is a form of brain stimulation that produces a small electric current (2 mA) which affects how easily brain cells can discharge. Our meta-analysis found that depressive symptoms improved better with active tDCS as compared to inactive tDCS and that individuals were back to their usual self more often with active tDCS as compared to inactive tDCS.
In our recent trial, we looked at whether we could give tDCS at home and we compared active tDCS with inactive tDCS, which was the same device but did not have a current. We found that participants with depression who had received the active tDCS treatment had more improvements in their depressive symptoms than those who had received the inactive tDCS. Additionally, more participants showed an improvement in most or all of their depressive symptoms in those who had received the active tDCS as compared to inactive tDCS.
In this study, we will look at how we can provide tDCS in day-to-day care and we will look at whether giving tDCS in addition to usual care can lead to greater improvements in depressive symptoms as compared to usual care.

Who can participate?
Adults aged 18 years and over who are currently feeling depressed for at least 2 weeks. You can be taking antidepressant medication or be in talking therapy, but you will need to have been having the same treatment for at least 6 weeks. You can also participate if you are not receiving any treatment for your depression. You will need to be registered with a GP in England or Wales and willing for us to contact them about your participation in the trial.

What does the study involve?
Your participation in the study would be expected to last up to 10 months and would include

screening activities and 9 months for the study, as we would like to contact you after the treatment to see how you are doing.
A randomised, controlled trial is a study where some participants are given a treatment (the treatment group) and some participants are given a standard treatment, a placebo, or no treatment at all (the control group). For this tDCS study, the control group receives their standard care for depression, or Treatment as Usual (TAU).
The first part of the study involves a 10-week course of either tDCS or TAU, followed by two follow up visits at 4-months and 6-months after the start of the treatment. During this part of the study, we would have appointments with you after 1, 4, 7 and 10 weeks and at 4 and 6 months.
You will be randomly allocated to either the tDCS group or the TAU group. In the TAU group you will continue with the depression treatments prescribed by your GP or psychiatrist, and you will not receive the tDCS treatment. In the tDCS group, you will receive active tDCS treatment in addition to your standard care from your GP or psychiatrist.
Each tDCS session is for 30 minutes. The number of sessions would be 5 times a week for the first 3 weeks and then 3 times a week for the next 7 weeks, for a total of 36 sessions. You will have the tDCS sessions at home. The first tDCS session will take place with supervision from a researcher via video call, or in person at your local research site if you would prefer.
After the10-week treatment period, we would like to see you again after 4 and 6-months from the start of the study. During the follow up period between week 10 and the 4-month and 6-month follow up visits, the TAU group will continue with their standard care, and the tDCS group will continue with their standard care and can choose to continue with maintenance tDCS sessions (3 per week) if they would like.
In the second part of the study, everyone will be offered to receive the active tDCS treatment if they would like. If you were in the TAU group and your depressive symptoms are not feeling better, you can start the tDCS treatment. You would have 5 sessions per week the first 3 weeks and then 3 sessions per week for 7 weeks. If you were in the tDCS group, you can continue with up to 3 sessions per week for the next 3 months. We would then see you for a final study visit after 3 months, which would be 9 months from when your participation in the trial started. This would be the final study visit and then your participation in the trial would be completed.

What are the possible benefits and risks of participating?
In the study, you will receive treatment with tDCS, which has shown to improve depressive symptoms in individuals with major depression, and you will receive regular assessments. It's important to understand that you may not directly benefit from participating in research. Your condition may get better; it may stay the same or it may even get worse as a result of your participation.
The information from this study may help us improve the treatment of depression in the future. You may receive information about your symptoms of depression after the research member completes the questions about your depression.
There may be risks to you if you take part in this study. Some of the questions may cause you some emotional discomfort or distress. You may also experience side effects from the tDCS treatment. The most common side effects are redness where the electrodes are, tingling sensation, itchiness and headache.

Where is the study run from?
The study will take place in six research sites across England and Wales. All study activates have been designed to be conducted remotely via video call, which means you can take part from anywhere in England or Wales. If you would like to be seen in person, we can arrange for you to be seen in-person at one of our NHS research sites.
1. Cardiff and Vale Health Board (CAVUHB)
2. Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (CNTW)

3. Northamptonshire Healthcare NHS Foundation Trust (NHFT)
4. Nottinghamshire Healthcare NHS Foundation Trust (NOTTS)
5. South London and Maudsley NHS Foundation Trust (SLaM)
6. Hampshire and Isle of Wight Healthcare NHS Foundation Trust (HIOWH)

When is the study starting and how long is it expected to run for?
May 2025 to November 2027

Who is funding the study?
National Institute for Health and Care Research Health Technology Assessment (NIHR) (UK)

Who is the main contact?
Prof. Cynthia H.Y. Fu, cynthia.fu@kcl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
344318

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 62581, NIHR165425

Study information

Scientific Title
Home-based transcranial direct current stimulation in major depressive disorder: a multi-centre, two-parallel group, superiority randomised controlled trial (HOME)

Acronym
HOME

Study objectives
The overall objectives of the trial are to evaluate the effectiveness and cost-effectiveness of home-based tDCS as a treatment for MDD in the NHS. We will evaluate the real-life clinical effectiveness and cost-effectiveness of tDCS combined with treatment as usual (TAU) as compared to TAU alone following a 10-week treatment period and at a 6-month follow up. We will evaluate changes in depressive symptoms using the clinician-rated Montgomery-Åsberg Depression Rating Scale (MADRS). We will further assess impact on self-report depressive symptoms, anxiety symptoms, remission, acceptability and quality of life. We will conduct in-depth process evaluation, economic evaluation, and implementation work to investigate operational challenges of integrating home-based tDCS into existing NHS care pathways and to inform scalability in primary care settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2025, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, Health Research Authority, E20 1JQ, UK; +44 (0)207 104 8012; Leedseast.rec@hra.nhs.uk), ref: 25/YH/0166

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Participants will be randomly allocated to one of two groups:

Treatment as usual (TAU): half of participants will continue with their standard care, such as psychotherapy and/or antidepressant medication or no treatment, as decided by participant and treating clinician.

TAU + transcranial direct current stimulation (tDCS) intervention: half of participants will be allocated to receive the tDCS treatment in addition to their standard care. The tDCS treatment consists of five tDCS sessions per week for 3 weeks followed by three tDCS sessions per week for 7 weeks, for a total of 36 sessions in 10 weeks. The tDCS device is headset with a bifrontal montage. The anode electrode is over the left dorsolateral prefrontal cortex (DLPFC) and cathode over right DLPFC (EEG positions F3 and F4, respectively). Stimulation is 2 mA for 30 minutes with a gradual ramp up over 120 seconds. The electrode area is 23 cm2.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial direct current stimulation

Primary outcome(s)
Clinician-rated depressive symptom severity measured by the Montgomery-Åsberg Depression Rating Scale (MADRS) at 10-week end of treatment period

Key secondary outcome(s))
Key secondary outcome:
Clinician-rated depressive symptoms measured by the Montgomery-Åsberg Depression Rating Scale (MADRS) at 6 months

Additional secondary outcomes:
1. Self-rated depressive symptoms measured by Montgomery-Åsberg Depression Rating Scale-Self report (MADRS-S). at 10-week end of treatment period
2. Clinician-rated depressive symptoms, as measured by the Hamilton Depression Rating Scale (HDRS). at 10-week end of treatment period
3. Clinician-rated anxiety symptoms measured by the Hamilton Anxiety Rating Scale (HAMA). at 10-week end of treatment period
4. Treatment response at 10-week end of treatment period, measured by participants with 50% or more improvement on MADRS rating from baseline

5. Treatment remission at 10-week end of treatment period, as measured by participants with a MADRS rating of 10 or less
6. Self-rated depressive symptoms measured by Montgomery-Åsberg Depression Rating Scale-Self report (MADRS-S) at 6 months
7. Clinician-rated depressive symptoms measured by the Hamilton Depression Rating Scale (HDRS) at 6 months
8. Clinician-rated anxiety symptoms measured by the Hamilton Anxiety Rating Scale (HAMA) at 6 months
9. Sustained treatment response at 6 months, measured by participants with 50% or more improvement on MADRS rating from baseline
10. Sustained treatment remission at 6 months, measured by participants with a MADRS rating of 10 or less.

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over
2. Current episode of depression based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria (APA, 2013) for major depressive disorder (MDD) as assessed by structured clinical assessment, Mini-International Neuropsychiatric Interview (MINI)
3. Having at least a moderate severity of depressive symptoms as measured by a score of at least 18 in MADRS
4. Either not taking antidepressant medication or taking a stable dose of antidepressant medication for at least 6 weeks before enrolment.
5. Either not currently in psychotherapy or engaged in ongoing psychotherapy for at least 6 weeks before enrolment.
6. Being under the care of a GP
7. Agreeable for GP to be regularly informed about study participation
8. Able to provide written, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Significant suicide risk as measured by answering 'yes' to questions 4, 5 or 6 on the Columbia Suicide Severity Rating Scale (C-SSRS) Screen
2. Primary comorbid psychiatric disorder (e.g. obsessive compulsive disorder) based on DSM-5 criteria as assessed in MINI
3. Current daily use of medications that affect cortical excitability (e.g. benzodiazepines)
4. Current illicit drug use or heavy alcohol use with high risk of alcohol use disorder as measured by a score of 5 or more (corrected 04/11/2025: previously > 5) in the Alcohol Use Disorders Identification Test consumption (AUDIT-C)
5. History of electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), cranial electrotherapy stimulation (CES), transcranial direct current stimulation (tDCS), deep brain stimulation (DBS), or other brain stimulation
6. History of esketamine / ketamine for treatment of depression
7. History of psychosurgery for depression
8. Having cognitive impairment (e.g. dementia)
9. Current medical disorder or neurological disorder that may mimic mood disorder (e.g. hormonal disorder, unstable heart disease)
10. Have any implants in the brain or neurocranial defect
11. Have shrapnel or any ferromagnetic material in the head
12. Have any active implantable medical device (e.g. pacemaker)
13. If female and of child-bearing potential, currently pregnant or planning to become pregnant during the study
14. Concurrent enrolment in another interventional study

Date of first enrolment
18/11/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiff and Vale U H B
St. Davids Hospital
Cowbridge Road East
Cardiff
Wales
CF11 9XB

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
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NN15 7PW

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
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NG3 6AA

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
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SO40 2RZ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Cynthia Fu (cynthia.fu@kcl.ac.uk). Appropriate data-sharing requests will be considered by the study management group. Only anonymous data will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes