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A study of home-use brain stimulation to treat bipolar depression

Submission date
22/01/2026

Recruitment status
Recruiting

Registration date
26/01/2026

Overall study status
Ongoing

Last Edited
29/06/2026

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
Bipolar depression is a long-lasting and disabling condition, and many people continue to experience depressive symptoms despite standard treatments. Transcranial direct current stimulation (tDCS) is a non-invasive form of brain stimulation that uses a very small electrical current applied through the scalp and has shown promise as a treatment for depression. This study aims to find out whether a home-based tDCS device is effective and safe in reducing symptoms of bipolar depression when compared with a placebo (sham) treatment. The study will also look at how acceptable the treatment is to participants and how well people are able to use the device at home.

Who can participate?
Adult patients aged 18 years and over who have a diagnosis of bipolar disorder and are currently experiencing a depressive episode.

What does the study involve?
Participants must meet specific eligibility criteria, which will be assessed by the research team. People who do not meet the study criteria or for whom tDCS is not suitable will not be able to take part. Participants will be randomly assigned to receive either active tDCS or a placebo (sham) treatment. Neither the participant nor the researchers assessing outcomes will know which treatment has been assigned.

Participants will use a study device at home over a defined treatment period and will complete a series of assessments at set time points. These include clinician-rated interviews and self-reported questionnaires about mood and well-being. Device use and adherence data will be collected electronically. Participants will also be monitored for any side effects throughout their involvement in the study.

Although the study is multi-site, participation is primarily remote, with most study activities completed from the participant's home.

What are the possible benefits and risks of participating?
Participants may experience an improvement in depressive symptoms. Information gained from this study may help improve future treatments for bipolar depression.

tDCS is generally well tolerated. Possible side effects include mild and temporary sensations such as tingling, itching, headache, or skin irritation at the electrode sites. All participants will be monitored for adverse events, and appropriate support will be available if needed.

Where is the study run from?
The study is run from King's College London in collaboration with NHS research sites across the UK.

When is the study starting and how long is it expected to run for?
April 2026 to October 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Professor Cynthia Fu, the Chief Investigator at King's College London, cynthia.fu@kcl.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Cynthia Fu

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
348113

Central Portfolio Management System (CPMS)
64255

National Institute for Health and Care Research (NIHR)
167361

Study information

Scientific Title
Home-based transcranial direct current stimulation in bipolar depression: a randomised, double-blind, placebo-controlled trial

Acronym
BDEP

Study objectives
To determine clinical efficacy of a 10-week course of home-based tDCS for bipolar depression in terms of depressive symptoms as measured by clinician-rated MADRS score in active and sham treatment arms at week 10.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/03/2026, London - Dulwich Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JO, United Kingdom; +44 0207 104 8144; dulwich.rec@hra.nhs.uk), ref: 26/LO/0035

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control

Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bipolar Disorder; Mental health

Interventions
Randomisation:
Following confirmation of eligibility to participate in the trial, written consent and baseline assessment, participants will be randomly allocated to receive either active tDCS in addition to treatment as usual (active treatment arm) or sham tDCS in addition to treatment as usual (sham treatment arm) in a 1:1 ratio. Randomisation will be at the participant level, stratified by recruitment site, using randomly varying block sizes within the site.

Randomisation will be implemented via an online system provided by King's College London (KCL) Clinical Trial Unit (KCTU). This bespoke randomisation system will be created in collaboration with the trial analyst/s and the Cl and maintained by the King's Clinical Trials Unit for the duration of the project. It will be hosted on a dedicated server within KCL.

Randomisation will be at the level of the individual, and the system will employ block randomisation with randomly varying block sizes and will be stratified by site. The details needed for randomisation (study site, date of birth (dd/mm/yyyy), initials and unique patient identity number)) will be held in a dedicated database. Research assistants, senior trial manager, project coordinator, Pls and CI will have access to the randomisation system. Randomisation will be undertaken by research assistants, senior trial manager, project coordinator and Cl onto the randomisation system by going to www.ctu.co.uk and clicking the link to access the randomisation system. A full audit trail of data entry will be automatically date and time-stamped, alongside information about the user making the entry within the system. Research assistants will have access to randomise participants at the research site where they are based. Research assistants at KCL, senior trial manager, project coordinator and Cl will have access to randomise participants at all research sites.

Treatment arm allocation data will be automatically sent to the tDCS device manufacturer, and this information will be linked to participant ID in the tDCS device portal. When research assistants sign participants up to the study app, the app will automatically deliver either active or sham tDCS based on treatment arm allocation. Research team members will remain blinded to group allocation.

Study visits:
Below we describe study visits from week -3 (the first screen, up to three weeks before randomization), through to baseline assessment, randomisation and intervention start at week 0 through to month 9 as the final visit.

Once identified through different recruitment sources (e.g., referral by a clinician who obtained consent for contact, direct express of interest in the study by a person), potential participants will be first contacted regarding the study by a researcher who will email them a list of some inclusion/exclusion criteria to assess potential eligibility, this will be followed by a brief telephone screen. Potentially eligible participants will be emailed a copy of the Participant Information Sheet (PIS). The researcher will encourage potential participants to spend as much time as they need asking questions about the study (via email or phone call) and consider whether they wish to participate or not.

As a minimum, study information will be provided to potential participants at least 24 hours prior to initial screening. After reading the PIS and having any questions answered, if the participant is happy to take part in the study, an appointment for screening will be arranged.

Week -3 to 0: Screening session - Usually conducted via video conference, but can take place in person if preferred by the participant. Study information will be discussed, the Informed Consent to participate in the trial and screening visit will be obtained. If the potential participant is willing, screening will provide an initial determination of eligibility. Specifically, eligibility will be assessed via screening procedures as follows:

Eligible age range: 18 years old or older.

Diagnosis of bipolar disorder in a current depressive episode based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria, assessed by structured clinical assessment, Mini-International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998)

Symptom severity: Montgomery-Asberg Depression Rating Scale (Montgomery and Åsberg, 1979) will be administered, with moderate severity defined as a score of 18 or more, covering the past 7 days.

Assessment of suicide risk: Columbia Suicide Severity Rating Scale Screen is a rating scale to evaluate suicide risk (Posner et al., 2011) will be administered, with a response of 'yes' to questions 4, 5 or 6 considered exclusion criteria.

Assessment of manic symptoms: measured with the Young Mania Rating Scale (Young et al., 1978)

Assessment of alcohol and substance abuse: Audit-C, Alcohol use disorders identification test consumption (Khadjesari et al., 2017; NICE, 2023) will be administered, with a score of 5 or more considered an exclusion.

Current pharmacological treatments (type, dose, frequency of use, duration of use), current non-pharmacological treatments (type, provider, attendance frequency), past treatments (number of pharmacological, psychological, and other treatments)

Questions assessing other potential exclusion criteria: comorbid diagnoses (also assessed using MINI), current and previous depression treatments, current physical health conditions, neurological disorder, history of cardiac issues, history of migraines, current medications, any cognitive disorder, any implanted devices, any metal in the head, healthcare professional contact details, concurrent enrolment in another interventional study, lack of capacity to consent.

If a participant reports information during the screening assessment that is a clear exclusion for participation, the screening assessment will be paused, and a discussion with the CI regarding the exclusion will be conducted.

Other information that will be collected at the screening visit includes:

Socio-demographic data: age, gender, ethnicity, marital status, level of education, current occupation, IMD as measured by postcode

Clinical data: duration of current treatment, duration of current episode, past psychiatric history, including previous treatments, initial onset of depression, number of previous episodes, hospital admissions, history of self-harm and suicide attempts, and past medical history.

Adverse events (AEQ)

Pre-baseline administrative procedures - Before the assessment begins, a copy of the consent form alongside a letter of notification is sent to the contact Healthcare Professional (who also receives an information sheet about the study) for that participant. The letter asks the professional to note in the patient's health record confirming that they are participating in this interventional study.

An IDCS device will be ordered by the research team and delivered directly to the participant's home. They will be advised to charge the device and not to download the Flow app and make an account, as they will use a study-specific app that we will guide them through during the study visit.

Baseline study visit:

Prior to the randomisation the following measures will be assessed:

Clinical symptom severity: MADRS, QIDS-SR, HAMA, GAD-7, YMRS

Suicide risk: C-SSRS

Quality of life measure: EQ-5D-5L

Treatment acceptability: TAQ (Qualitative interview using TAQ if consent given)

Participants will also be asked about general health, medication/psychotherapy treatments or any changes to treatments. If the participant no longer meets the inclusion criteria (MADRS score of 18 or above), they will not proceed in the trial.

Subsequently, randomisation will be conducted. The group assignment will be blinded. The information entered by the researcher into the study app portal will instruct the study app whether to administer active or sham IDCS. This information will not be available to the research team or the participant.

The participant will have received their tDCS device. During the study visit, the research team member will invite the participant to install the dedicated study app. The participant's email will be entered into the study app portal, which will send an email to the participant with a link to download the app. Once downloaded, the participant will create a password to log in to the app. Once logged in, the research team will be able to view the participant in the study app portal,

where the stimulations can be tracked. The research team member will support the participant to use the IDCS device for their first stimulation session. During the stimulation session, the researcher will maintain a discreet presence on the video call or in person without interacting with the participant, unless they are responding to the participant related to the stimulation.

After the stimulation session, participants will be administered the AEQ.

The participant will be given the following information/advice about what to do whilst having the stimulation:

Sit or lie down while using the headset.

Use the headset on your head as shown.

Do not use the headset if you have a skin wound.

Do not apply the headset over areas of skin that lack normal sensations.

Do not use the headset on other parts of the body.

Do not apply the headset without the supplied headset pads.

Do not apply the headset with dried-out headset pads (pads are single-use).

Do not apply the headset outdoors or close to water.

Do not apply the headset while driving.

Do not apply the headset during any activity that could lead to a significant risk of injury.

Do not apply the headset while intoxicated or incapacitated.

Do not apply the headset in environments with strong magnetic fields.

The tDCS headset is for you and should not be shared with others.

Intervention period - Participants will be directed to use the headset according to the study protocol, 5 times per week for weeks 1 to 3, then three times per week for weeks 4 to 10. The participant will be reminded of the common side effects and asked to contact the study team should they experience any less common side effects or have any concerns or questions about any side effects or the stimulations. They will be reminded of the study mobile number should they experience the need to speak to someone urgently.

Weeks 1, 4 and 7: the following assessments will be completed at the study visit:

Clinical symptom severity: MADRS, QIDS-SR, HAMA, GAD-7, YMRS

Suicide risk: C-SSRS

Adverse events: AEQ

Participants will also be asked about general health, medication/psychotherapy treatments or any changes to treatments.

Week 10-post intervention:

All outcome measures listed at the baseline visit are repeated. The post-intervention assessment will take place at the end of week 10, after tDCS sessions for that week have been completed. The following assessments are completed:

Clinical symptom severity: MADRS, QIDS-SR, HAMA, GAD-7, YMRS

Suicide risk: C-SSRS

Quality of life measure: EQ-5D-5L

Treatment acceptability: TAQ

Adverse events: AEQ

Participants will also be asked about general health, medication/psychotherapy treatments or any changes to treatments.

Participants will be invited to take part in a qualitative interview.

After the week 10 visit, participants will be able to continue with 3 maintenance IDCS sessions per week if they would like to. This is optional and is up to the participant to decide. If they choose to continue, they will be reminded that they can stop at any time should they wish to.

Month 4: Follow-up - All measures listed above in week 10 are repeated except the qualitative interviews.

Month 6: Follow -up - All measures listed above in week 10 are repeated.

After all assessments have been completed, participants will be asked which treatment arm they thought they were in. The responses will be active, sham, or don't know.

Once this information has been recorded, the researcher will unblind the participant and inform them if they had been receiving the active or sham treatment.

Optional open-label extension follow-up phase begins:

After the 6-month follow-up visit, the open-label extension follow-up phase of the trial will begin.

Participants who were receiving sham tDCS will be given the opportunity to try the active IDCS intervention if they wish. The research team member will edit the settings that have been made available in the study app portal to direct the device to provide active IDCS. Participants will start with 5 sessions per week for 3 weeks, then 3 sessions per week for 7 weeks. They will be informed that they can contact the study team if they experience side effects or require an unscheduled study visit.

Participants who were in the active treatment arm can continue with 3 tDCS sessions per week if they would like to.

Month 9: Follow-up - All measures listed above in month are repeated.

Intervention Type
Other

Primary outcome(s)
1. Clinical efficacy, based on depressive symptoms measured using the Montgomery–Åsberg Depression Rating Scale (MADRS) score at baseline and week 10-post intervention

Key secondary outcome(s)
1. Selfrated depressive symptoms measured using Quick Inventory of Depressive Symptomatology – SelfReport (QIDSSR) at baseline, and weeks 1, 4, 7, and 10 (postintervention), and the 4- and 6-month followups

2. Clinicianrated anxiety symptoms measured using Hamilton Anxiety Rating Scale (HAMA) at baseline, and weeks 1, 4, 7, and 10 (postintervention), and the 4- and 6-month followups

3. Selfrated anxiety symptoms measured using Generalized Anxiety Disorder 7item questionnaire (GAD7) at baseline, and weeks 1, 4, 7, and 10 (postintervention), and the 4- and 6-month followups

4. Quality of life measured using EuroQol 5Dimension 5Level questionnaire (EQ5D5L) at baseline, and weeks 1, 4, 7, and 10 (postintervention), and the 4- and 6-month followups

5. Clinicianrated depressive symptoms (6month outcome) measured using Montgomery–Åsberg Depression Rating Scale (MADRS) at baseline and 6-month followup

6. Selfrated depressive symptoms (6month outcome) measured using Quick Inventory of Depressive Symptomatology – SelfReport (QIDSSR) at baseline and 6-month followup

7. Clinicianrated anxiety symptoms (6month outcome) measured using Hamilton Anxiety Rating Scale (HAMA) at baseline and 6-month followup

8. Selfrated anxiety symptoms (6month outcome) measured using Generalized Anxiety Disorder 7item questionnaire (GAD7) at baseline and 6-month followup

9. Quality of life (6month outcome) measured using EuroQol 5Dimension 5Level questionnaire (EQ5D5L) at baseline and 6-month followup

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over.
2. Diagnosis bipolar disorder in a current depressive episode based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria assessed by structured clinical

assessment, Mini-International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998).
3. Having at least a moderate severity of depressive symptoms as measured by a score of at least 18 in MADRS (Montgomery and Åsberg, 1979).
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 in ongoing psychotherapy for at least 6 weeks before enrolment.
6. Being under care of GP
7. Agreeable for GP to be regularly informed by research team about participation
8. Able to provide written, informed consent.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 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 (Posner et al., 2011).
2. Primary comorbid psychiatric disorder (e.g. obsessive compulsive disorder) based on DSM-5 criteria as assessed in MINI (Sheehan et al., 1998).
3. Having a Young Mania Rating Scale (Young et al., 1978) score of 20 or more.
4. Current daily use of medications that affect cortical excitability (e.g. benzodiazepines).
5. Current illicit drug use or heavy alcohol use with high risk of alcohol use disorder as measured by a score of ≥8 in Alcohol use disorders identification test consumption (AUDITC) (Khadlesari et al., 2017; NICE, 2023).
6. History of electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), cranial electrotherapy stimulation (CES), transcranial direct current stimulation (tDCS), deep brain stimulation (DBS), other brain stimulation, or psychosurgery for depression.
7. History of esketamine / ketamine for treatment of depression.
8. Medical disorder that may mimic mood disorder (e.g. hormonal disorder).
9. History of myocardial infarction, coronary artery bypass graft (CABG), coronary heart failure (CHF), or history of other cardiac issues.
10. Have cognitive impairment (e.g. dementia).
11. History of a neurological disorder (e.g., cerebrovascular events, stroke, structural lesion, epilepsy, seizures, Parkinson's disease).
12. History of migraines or intractable headaches.
13. Implant in brain, neurocranial defect or active implantable medical device.

14. Shrapnel or any ferromagnetic material in head.
15. If female and of child-bearing potential, currently pregnant or planning to become pregnant during the study
16. Concurrent enrolment in another interventional study.

Date of first enrolment
27/04/2026

Date of final enrolment
27/02/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre
St Nicholas Hospital (newcastle upon Tyne)
Jubilee Road, Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre
Warneford Hospital
Warneford Lane
Headington
Oxford
England
OX3 7JX

Study participating centre

The Uffculme Centre
52 Queensbridge Road
Moseley
Birmingham
England
B13 8QY

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
Wales
CF14 4HH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

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
Deidentified individual participant data and the data dictionary will be made available on request to academic researchers. A data request and brief analysis plan will be required in accordance with Ethics Committee requirements. These will be reviewed by the lead (Professor Cynthia Fu, cynthia.fu@kcl.ac.uk), study steering committee and study sponsor. A data transfer agreement (DTA) will have to be completed prior to any data being shared. Following completion of the DTA, data will be shared as password-protected files. Data sharing will abide by the rules and policies defined by the sponsor, relevant institutional review boards, and local, state and federal laws and regulations. The rights and privacy of individuals participating in the research will be protected at all times. Approval will not be provided for commercial use of the data.

IPD sharing plan summary
Available on request