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Assessment of the effect of transcranial direct current stimulation on insomnia in primary care patients

Submission date
07/08/2025

Recruitment status
Recruiting

Registration date
14/08/2025

Overall study status
Ongoing

Last Edited
08/08/2025

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
Insomnia (difficulties falling or staying asleep) is a common, distressing, and impairing sleep disorder and is linked to poor mental and physical health. Clinical guidelines recommend cognitive behavioural therapy for insomnia (CBT-I) (which can be effective for some people, but is costly and there can be long wait times) and medication (which has negative side effects and creates dependency). Therefore, an alternative effective, acceptable and affordable treatment is required to relieve insomnia. Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation (NIBS) which delivers low-voltage electric currents applied through two pads on the forehead. tDCS is safe to use at home and has rare and minor side effects (for example, tingling sensation, mild skin irritation or redness, short headache or dizziness). It is currently used for treating mental health conditions. Recent studies suggested that tDCS could also improve sleep quality and reduce insomnia. Evidence about the improvement with tDCS could expand NHS treatment for millions of people who experience insomnia. Having a new effective treatment in the NHS that can be used at home could be life-changing for people with insomnia.
Aim: To investigate if insomnia is reduced in primary care participants who receive tDCS

Who can participate?
Patients aged from 18 to 110 years reporting insomnia symptoms.

What does the study involve?
Participants will be recruited from primary care practices. They are required to read the participant information sheet (PIS) and sign a consent form. At the start and end of treatment, participants will complete five 'tick box' health assessments. Optionally, participants may take part in an interview via phone or computer video, with a duration of less than one hour.

Participants will read the information given about the device and use the device as per protocol: 30 minutes, 5 times a week for 4 weeks. They will complete a participant usage questionnaire and provide feedback. Participants may also be contacted by Northamptonshire Healthcare NHS Foundation Trust project researchers for optional verbal feedback via an audio-recorded interview. Using Flow entails downloading a free app to a mobile phone, connecting the headset

to the phone via Bluetooth, opening the app, and starting stimulation by pressing a button titled: START STIMULATION.

What are the possible benefits and risks of participating?
Possible benefits: Evidence shows that tDCS can treat symptoms of insomnia.
Possible risks: tDCS has been used in humans for over 40 years. These stimulation techniques use battery-powered current generator devices that have a built-in circuitry to limit the current above a certain level, typically 2 mA, which is a very low level of current. The most common sensations/side effects are only experienced by some people and include: mild skin redness (54%) at the site of the electrodes, which resolves following stimulation, itching (39%), and tingling (22%), temporary headache (16%), discomfort (13%) and heating sensation (10%), which resolve following use. In the optional interview, participants may or may not find discussing issues related to insomnia uncomfortable or distressing.

Where is the study run from?
The General Practice Alliance (GPA), UK

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

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

Who is the main contact?
Dr Chris Griffiths, chris.griffiths@nhft.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
359630

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Flow-Insomnia2025

Study information

Scientific Title
Assessment of the effect of transcranial direct current stimulation (tDCS) on insomnia in primary care patients

Acronym
Flow-Insomnia

Study objectives
Aims, Objectives and Outcomes
• Evaluate the impact of tDCS on insomnia, depression, cognition, quality of life and functioning.
• Understand correlations between scores on the self-report measures.
• Understand experiences, views, feedback, and recommendations of patients and GPs through in-depth semi-structured interviews.

Research Questions
R1. What is the impact of tDCS on insomnia, depression, cognition, quality of life, and functioning?
R2. What is the association between insomnia, depression, cognition, quality of life and functioning, and patient factors?
R3. What are the experiences, views, feedback, and recommendations of patients and GPs?

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 22/07/2025, London – Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8105; camberwellstgiles.rec@hra.nhs.uk), ref: 25/PR/1011

Study design
Single-centre open-label patient cohort design with no control group

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Insomnia

Interventions

Design

The study has an open-label patient cohort design with no control group. Patients complete pre- and post-intervention self-report measures. In-depth interviews will be undertaken with patients and NHS GPs.

Participants

Approximately 100 primary care patients will use tDCS and complete outcome measures. Approximately 14 patients will complete in-depth interviews, purposely recruited to be representative in terms of gender and age. Approximately 8 GPs will also complete in-depth interviews.

Setting

Participants will be recruited through a primary healthcare general practice (GP). Flow will be self-administered at home by participants living in the community. Flow Neuroscience AB (manufacturer of the Flow device) provides GPs and other healthcare staff with training.

Procedure

Patients' records will be reviewed/screened by NHS staff with permission to access to identify those meeting the inclusion criteria. Patients selected by their GP if they meet the inclusion /exclusion criteria will be provided with PIS. Participants can choose to stay on the same medication and continue any current psychological interventions they were undertaking (this will be recorded). Informed consent will be obtained before beginning treatment. Participants can withdraw consent or stop treatment at any point without the need to provide a reason. The research team will keep any data supplied before this, and this is noted on the PIS and consent forms. Following informed consent, a note will be made on the patient's records, participants will collect the Flow device and instructions from the GP reception and complete the self-report measures. Participants are informed about Flow Neuroscience AB's website, which provides information, training on use, and email-based support. Follow-up measures will be collected after treatment.

For the professionals' interviews, GPs will be given a PIS and consent form, and they will be provided with the opportunity to ask questions. If they agree to participate, a consent form will be completed, one copy will be given or sent back to the participant, and one completed copy securely stored. GPs will be invited to be interviewed via phone or computer (video call).

Intervention

Flow Neuroscience FL-100 is a BSI UKCA-certified and Conformité Européenne (CE) marked Class IIa medical device (UKCA 776047). The tDCS treatment will consist of 5 tDCS sessions of 30 minutes per week for 4 weeks. The tDCS device is a headset placed over the forehead with two pre-positioned soft-padded electrodes, each 23cm2. Anode and cathode electrodes are placed over the left and right DLPFC, EEG F3 and F4 positions, respectively (16,21). Active tDCS stimulation is 2mA for 30 minutes. Flow treatment can be implemented concurrently with any existing insomnia treatment, e.g., medication, face-to-face psychotherapy, or any online psychotherapy. The Flow mobile phone software app is used to control the Bluetooth-connected Flow FL-100 tDCS headset via the user's smartphone.

Measures

1. Insomnia Severity Index (ISI)
2. Patient Health Questionaire-9 (PHQ-9)

3. Perceived Deficits Questionnaire (PDQ-5)
4. Quality of Life (EQ-5D-5L)
5. Work and social adjustment (WASA)

Data collection
The questionnaires will be filled in by the participants themselves or through the staff asking the questions and marking their score, with support as necessary.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Flow Neuroscience FL-100

Primary outcome(s)
The severity and impact of insomnia symptoms will be measured using the self-reported Insomnia Severity Index (ISI) pre- and post-intervention

Key secondary outcome(s))
The following secondary outcome measures will be self-reported pre- and post-intervention:
1. Severity of depression will be measured using the Patient Health Questionnaire-9 (PHQ-9)
2. Cognitive dysfunction, particularly in the context of depression, will be measured using the Perceived Deficits Questionnaire (PDQ-5)
3. Health-related quality of life will be measured using the EuroQol Group Quality of Life measure (EQ-5D-5L)
4. Daily functioning will be measured using the Work and Social Adjustment (WASA)

Completion date
26/03/2027

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Patients reporting insomnia symptoms
3. Able to provide written informed consent
4. Have a smart mobile phone with internet access and a data download contract

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
1. Epilepsy (or having a history of seizures)
2. Having a defect in the neurocranium and/or a cranial implant
3. Having an active, implanted medical device (e.g., cardiac pacemaker, spinal cord stimulator, vagal nerve stimulator, auricular stimulator, deep-brain-stimulating electrodes, cochlear implant, implanted hearing aid or defibrillator) or other implanted, metallic, or electronic device
4. A neurological condition
5. A history of hypomanic/manic episodes
6. Do not have the capacity to consent
7. Open wound in the area of pad contact on the forehead
8. Pregnant

Date of first enrolment
15/08/2025

Date of final enrolment
23/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
General Practice Alliance (GPA)
3 Adelaide Street
Northampton
United Kingdom
NN2 6AL

Sponsor information

Organisation
General Practice Alliance

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 are not expected to be made available due to a lack of funding beyond the study duration.

IPD sharing plan summary
Data sharing statement to be made available at a later date