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At-home brain stimulation for chronic pelvic pain in endometriosis: a randomised controlled trial

Submission date
02/03/2025

Recruitment status
No longer recruiting

Registration date
04/03/2025

Overall study status
Ongoing

Last Edited
07/11/2025

Condition category
Urological and Genital Diseases

[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
Endometriosis is a common condition where tissue similar to the lining of the uterus grows outside the womb, often causing chronic pelvic pain (CPP) and negatively impacting quality of life. Current treatments, such as pain medication and hormone therapy, may not be effective for all patients and can have side effects. This study aims to investigate whether a non-invasive, at-home brain stimulation device (transcranial Direct Current Stimulation, tDCS) can help reduce pain and improve mood symptoms in women with endometriosis-related CPP.

Who can participate?
Women aged 18 to 50 years who have been diagnosed with endometriosis and experience chronic pelvic pain for more than three months are eligible to participate.

What does the study involve?
Participants will be randomly assigned to one of two groups:
1. Active treatment group – Participants will use the Nettle tDCS device at home for 20 minutes per day for 20 days.
2. Sham control group – Participants will use the same device, but it will not deliver active stimulation.
The study is double-blind, meaning neither participants nor researchers will know which group a participant is in. All participants will complete daily symptom assessments on pain and mood through a smartphone app and attend follow-up assessments after one menstrual cycle.

What are the possible benefits and risks of participating?
- Potential benefits: If effective, the device may help reduce pain and improve mood symptoms in women with endometriosis without the side effects of medication.
- Possible risks: tDCS is considered safe, but some participants may experience mild skin irritation, tingling, or headaches at the electrode sites.

Where is the study run from?
The study is being conducted at University College London Hospital (UCLH) (UK)

When is the study starting and how long is it expected to run for?
March 2024 to September 2027.

Who is funding the study?
Samphire Neuroscience Ltd. (UK)

Who is the main contact?
Professor Ertan Saridogan, uclh.gynaeresearch@nhs.net

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
350170

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 64649

Study information

Scientific Title
At-home transcranial direct current stimulation on endometriosis-related chronic pelvic pain: randomised, double-blind, sham-controlled trial

Acronym
ENHANCE

Study objectives
At-home transcranial direct current stimulation (tDCS) using the Nettle device reduces chronic pelvic pain (CPP) intensity in women with endometriosis compared to a sham stimulation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/12/2024, London - Riverside Research Ethics Committee (2 Redman Pl, Stratford Cross, London, E20 1JQ, United Kingdom; 44207 104 8243; riverside.rec@hra.nhs.uk), ref: 24/PR/1445

Study design
Single-centre interventional double-blind randomized sham controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of endometriosis-related chronic pelvic pain (CPP).

Interventions
The study is a randomised, double-blind, sham-controlled trial evaluating the effectiveness of at-home transcranial direct current stimulation (tDCS) for chronic pelvic pain (CPP) in women with endometriosis. Participants will be randomised into two arms:
1. Active tDCS Group – Participants will receive daily 20-minute sessions of active tDCS using the Nettle device for 20 consecutive days. The device targets the primary motor cortex (M1) and

dorsolateral prefrontal cortex (DLPFC) to modulate pain perception and mood symptoms.
2. Sham Control Group – Participants will use the same device for 20 minutes daily for 20 days, but without active stimulation, ensuring blinding.

Randomisation was carried out using the Excel randomisation formula, by a senior member of the team.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nettle

Primary outcome(s)
Pain is measured using the Numerical Rating Scale (NRS) at baseline, daily during the 20-day intervention, post-intervention (Day 20), and one menstrual cycle post-intervention.

Key secondary outcome(s))
1. Pain catastrophising measured using the Pain Catastrophising Scale (PCS) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.
2. Quality of life measured using the Endometriosis Health Profile-30 (EHP-30) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.
3. Positive and negative affect measured using the Positive and Negative Affect Schedule (PANAS) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.
4. State and trait anxiety measured using the State-Trait Anxiety Inventory (STAI) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.
5. Depressive symptoms measured using the Beck Depression Inventory (BDI) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.
6. Premenstrual symptom severity measured using the Daily Record of Severity of Problems (DRSP) continuously throughout the intervention and one menstrual cycle post-intervention.
7. Daily medication use recorded using the Daily Medication Diary daily during the intervention and one menstrual cycle post-intervention.

Added 07/11/2025:
8. Health-related quality of life measured using the EuroQol 5-Dimension 5-Level (EQ-5D-5L) at baseline, post-intervention (Day 20), and one menstrual cycle post-intervention.

Completion date
17/09/2027

Eligibility

Key inclusion criteria
1. Women aged 18 to 50 years.
2. Confirmed diagnosis of endometriosis based on previous surgery, histology, MRI, or ultrasound findings.
3. Experiencing chronic pelvic pain (CPP) associated with endometriosis, defined as pain persisting for more than three months in the past six months with an intensity of at least 3 out

of 10 on the Numerical Rating Scale (NRS).
4. Ability to complete symptom questionnaires and follow study procedures.
5. Capacity to provide informed consent for medical investigation and treatment.
6. Access to a compatible smartphone (Android or Apple) capable of hosting the study application.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Key exclusion criteria
1. Severe or untreated neurological disease, such as subarachnoid haemorrhage or multiple sclerosis.
2. History of brain surgery, brain tumors, or intracranial metal implants.
3. History of stroke or head trauma.
4. History of epilepsy.
5. Active skin lesions, infections, open wounds, or cuts on the scalp.
6. Scalp conditions such as dermatitis, eczema, psoriasis, significant scarring, burns, or other forms of skin damage in areas where electrodes are placed.
7. Presence of brain implants.
8. Severe and/or untreated psychiatric illness, such as schizophrenia.
9. Metal implants or pacemakers, including implanted cardiac devices.
10. Pregnancy or plans to become pregnant within the next 12 months.
11. Currently breastfeeding.
12. Lack of capacity to consent.

Date of first enrolment
04/03/2025

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
Samphire Neuroscience Ltd

Funder(s)

Funder type
Industry

Funder Name
Samphire Neuroscience Ltd

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 patient confidentiality considerations, ethical restrictions, and data protection regulations (including GDPR and the UK Data Protection Act 2018).

All collected participant-level data will be securely stored and used solely for study analysis and regulatory compliance. Aggregated, de-identified results will be shared through peer-reviewed publications and conference presentations, but individual participant data (IPD) will not be publicly available. If future amendments allow for data sharing, appropriate consent and anonymisation measures will be implemented.

IPD sharing plan summary
Not expected to be made available

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