

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

| | | |
|--|--|---|
| Submission date 02/03/2025 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 04/03/2025 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 07/01/2026 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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.gynaereseach@nhs.net

Contact information

Type(s)

Scientific, Principal investigator

Contact name

Prof Ertan Saridogan

ORCID ID

<https://orcid.org/0000-0001-9736-4107>

Contact details

University College London Hospital, 250 Euston Road
London
United Kingdom
NW1 2BU
+44 20 3447 2611
uclh.gynaereseach@nhs.net

Type(s)

Public

Contact name

Ms Emile Radyte

ORCID ID

<https://orcid.org/0000-0002-2460-8016>

Contact details

85 Great Portland Street
London
United Kingdom
W1W 7LT
+44 7500114946
research@samphireneuro.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

350170

Central Portfolio Management System (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

Total final enrolment

0

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

01/03/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London Hospitals NHS Foundation Trust

250 Euston Road

London

England

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

IPD sharing plan summary

Not expected to be made available