

Testing a non-invasive brain stimulation device (Nettle™) to reduce symptoms of premenstrual dysphoric disorder

Submission date 19/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/10/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/10/2026	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Premenstrual dysphoric disorder (PMDD) is a severe form of premenstrual disorder that can cause marked changes in mood, anxiety, irritability and daily functioning during the second half of the menstrual cycle. This study investigated whether a non-invasive form of brain stimulation called transcranial direct current stimulation (tDCS), delivered at home using the Nettle device, could help reduce symptoms of PMDD. The study compared active stimulation with sham stimulation, which was designed to feel similar but did not deliver the same active stimulation.

Who can participate?

Women with PMDD who met the study eligibility criteria were invited to participate. Participants were required to have regular menstrual cycles and to be able to use the stimulation device at home over three menstrual cycles.

What does the study involve?

Participants took part over three menstrual cycles. They were assigned to receive either active tDCS or sham stimulation and remained in the same group throughout the study. Participants did not know whether they were receiving active or sham stimulation.

The stimulation was delivered at home using the Nettle device for 20 minutes per day during the luteal phase of each menstrual cycle, beginning the day after estimated ovulation and continuing until the day before menstruation.

Participants completed questionnaires measuring anxiety, depression, difficulties with emotion regulation and PMDD symptoms. Some questionnaires were completed at the beginning and end of the study and at specific points during each menstrual cycle. Participants also completed a daily questionnaire about premenstrual symptoms throughout the three study cycles.

A total of 42 participants took part: 22 received active stimulation and 20 received sham stimulation.

What are the possible benefits and risks of participating?

Participants may or may not have experienced an improvement in their PMDD symptoms. The stimulation was non-invasive and participants were monitored throughout the study and had regular contact with the research team. The possible risks and side effects associated with use of the device were explained to participants before they took part.

Where is the study run from?

The study was run from Queen Mary University of London, UK, with participants using the stimulation device at home.

When is the study starting and how long is it expected to run for?

The study began in March 2025. Recruitment continued during 2025 and participants were followed across three menstrual cycles, with study activity completed in December 2025.

Who is funding the study?

The study was funded by Small Business Research Initiative for Healthcare (SBRI), with additional funding provided through Queen Mary University of London's Flexible Research Fund.

Who is the main contact?

Dr Paul Faulkner, Queen Mary University of London, p.faulkner@qmul.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Paul Faulkner

ORCID ID

<https://orcid.org/0000-0003-4475-3568>

Contact details

Room 2.25, GE.Fogg Building, Bancroft Road, Queen Mary University of London
London

United Kingdom

E1 4DQ

+44 (0)7949069012

p.faulkner@qmul.ac.uk

Additional identifiers

Study information

Scientific Title

Validation of a non-invasive brain stimulation device (Nettle™) to manage symptoms of premenstrual dysphoric disorder

Study objectives

Premenstrual dysphoric disorder (PMDD) is a severe premenstrual disorder characterised by marked mood, cognitive and physical symptoms that occur during the luteal phase of the menstrual cycle and improve after menstruation begins. Symptoms can include depression, anxiety, irritability, emotional lability and impaired daily functioning. Current treatments include selective serotonin reuptake inhibitors (SSRIs) and hormonal treatments, but these are not effective or suitable for all patients and may produce unwanted side effects. There is therefore a need to investigate additional treatment options for PMDD.

This study will evaluate the effects of repeated at-home transcranial direct current stimulation (tDCS) during the luteal phase across three menstrual cycles in women with PMDD. The study aimed to determine whether active tDCS, compared with sham stimulation, reduced anxiety, depressive symptoms and core PMDD symptoms, and improved emotion regulation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 11/02/2025, Queen Mary University of London Ethics Committee (Queen Mary University, Mile End Road, London, E1 4NS, United Kingdom; +44 (0)20 7882 7915 / 6947; research-ethics@qmul.ac.uk), ref: QME25.0811

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Premenstrual dysphoric disorder (PMDD)

Interventions

Participants are allocated in a non-randomised manner to receive either active transcranial direct current stimulation (tDCS) or sham stimulation using Nettle™, a wearable, home-use neurostimulation device by Samphire Neuroscience (<https://www.samphireneuro.com>). Nettle™ delivers stimulation at 2.0 mA via anode and cathode electrodes. The device contains two electrode pairs, with one pair positioned over the prefrontal cortex (PFC) and one pair positioned over the motor cortex.

Participants remain in the same intervention group throughout the study. In both groups, the device is used at home for 20 minutes per day during the luteal phase of each menstrual cycle, beginning the day after estimated ovulation and continuing until the day before menstruation, across three consecutive menstrual cycles.

In the active group, Nettle™ delivers active tDCS at 2.0 mA according to the device stimulation protocol. In the sham group, the device follows a sham stimulation procedure designed to mimic the initial sensation of active tDCS. The current ramps up over approximately 30 seconds and then stops, so participants experience the initial stimulation sensation without receiving the full active stimulation protocol. Participants are blinded to treatment allocation.

Ovulation is estimated individually using the midpoint of each participant's typical menstrual-cycle duration rather than being confirmed using objective ovulation testing. Participants therefore begin device use on the day after estimated ovulation and continue daily until the day before menstruation.

Participants complete the Generalized Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9) at baseline and at specified follicular and luteal timepoints during each menstrual cycle, and again at endpoint. Participants complete the Daily Record of Severity of Problems (DRSP) daily throughout all three menstrual cycles. Difficulties in emotion regulation are assessed using the Difficulties in Emotion Regulation Scale (DERS) at baseline and endpoint. A total of 42 participants are included: 22 in the active group and 20 in the sham group.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Nettle™

Primary outcome(s)

1. Anxiety symptom severity measured using the Generalized Anxiety Disorder-7 (GAD-7) questionnaire at baseline (luteal phase before trial initiation), and day 8 and day 21 of each menstrual cycle (with day 21 of menstrual cycle 3 being termed 'endpoint')
2. Depression symptom severity measured using the Patient Health Questionnaire-9 (PHQ-9) questionnaire at baseline (luteal phase before trial initiation), and day 8 and day 21 of each menstrual cycle (with day 21 of menstrual cycle 3 being termed 'endpoint')
3. PMDD symptom severity measured using the Daily Record of Severity of Problems (DRSP) at baseline (luteal phase before trial initiation), and everyday of each of the three menstrual cycles
4. Difficulties in emotion regulation measured using the Difficulties in Emotion Regulation Scale (DERS) at baseline (luteal phase before trial initiation) and late luteal phase of menstrual cycle three (termed 'endpoint')

Key secondary outcome(s)

Completion date

19/12/2025

Eligibility

Key inclusion criteria

1. Participants were all aged 18-45 years old
2. Assigned female at birth and who menstruate, who either self-endorse or have been clinically diagnosed with PMDD or score >70/144 on the Daily Record of Severity of Problems (DRSP) questionnaire within the luteal phase (i.e. days 14-28) of their menstrual cycle

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Total final enrolment

42

Key exclusion criteria

1. More than 14 units of alcohol per week
2. Current illicit drug use, nicotine or tobacco use
3. A neurological condition
4. Pregnancy
5. Use of antidepressant or hormonal treatment for PMDD, or any other non-PMDD-related psychiatric condition

Date of first enrolment

06/03/2025

Date of final enrolment

26/09/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Queen Mary University of London
327
Mile End Road
London
England
E1 4NS

Sponsor information

Organisation
Queen Mary University of London

ROR
<https://ror.org/026zzn846>

Funder(s)

Funder type

Funder Name
Small Business Research Initiative for Healthcare (SBRI)

Funder Name
Queen Mary University of London

Alternative Name(s)
Queen Mary Uni of London, Queen Mary, Queen Mary and Westfield College, The London Hospital Medical College, St Bartholomew's Hospital Medical College, Westfield College, East London College/Queen Mary College, QMUL, QM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available