## Roundtable discussion report on:

# Premenstrual Dysphoric Disorder (PMDD) and transcranial direct current stimulation (tDCS)

**23rd June 2025**

Health Innovation Network South London

# Contents

# 1. Acknowledgements

The Health Innovation Network South London (HIN SL) would like to thank all participants in this roundtable, and our UK wide collaborators who identified, recommended, and introduced potential attendees. A list of participants is provided on page 4. This paper is a synthesis of the roundtable discussion organised and chaired by the Health Innovation Network South London.

# 2. Introduction

Validation of a Non-Invasive Brain Stimulation Device (Nettle™) to Manage Symptoms of Premenstrual Dysphoric Disorder is phase one of a 6-month SBRI Women's health award funded project, led by Dr Paul Faulkner at Queen Mary University of London that aims to improve the mental health of women who experience Premenstrual Dysphoric Disorder (PMDD).

This project has two primary objectives:

1. To validate the at-home use of a novel transcranial direct current stimulation (tDCS) device termed Nettle™ to alleviate the physical and mental symptoms of PMDD.
2. To determine optimal strategies for integrating Nettle™ into NHS treatment protocols for PMDD.

If the project successfully validates the at-home use of Nettle™ in alleviating the psychological and physical symptoms of PMDD, the team led by Queen Mary University of London will be eligible to apply for phase two funding subject to SBRI budget availability. This next phase will support the generation of early clinical evidence over a 12-month period and provide an opportunity for NHS trusts and other organisations to be part of the project.

This roundtable is the second of two held as part of this project. The first roundtable was held on Monday 24th March 2025, to discuss the viability and optimal approach for integrating the Nettle™ device into NHS treatment for PMDD. The discussion was focused on three main areas: understanding the clinical need, the benefits and potential of the technology and barriers to adoption and implementation.

A key conclusion from the roundtable discussion was that with appropriate support, digital treatments like Nettle™ have the potential to improve outcomes for patients while also delivering wider social and economic benefits, particularly among the working-age female population. The following is a summary of the key themes and insights that emerged during the first roundtable discussion:

**Diagnosis**

- There is a growing recognition of the significant unmet need in supporting individuals with PMDD, however barriers remain across diagnosis, treatment, and service provision. Accurate diagnosis is often impacted by the need for prospective symptom tracking over multiple cycles, a process that is difficult for patients to engage with while they are experiencing symptoms. Challenges in diagnosis are further complicated by symptom overlap with other hormonal and mental health conditions, such as ADHD and bipolar disorder, which highlights the need for better clinical awareness.

**Treatment**

- Current treatment options, including the use of Selective Serotonin Reuptake Inhibitors (SSRIs) and hormonal therapies, have limitations including side effects and inconsistent relief. A technology like Nettle™, which offers a non-pharmacological, non-hormonal, and

non-invasive approach, could provide a valuable addition to the PMDD treatment "toolbox," particularly for patients who do not tolerate existing options. However, long-term use considerations, limited awareness of PMDD and of technologies like tDCS among clinicians, could pose barriers to adoption within the NHS.

**Cultural and system change**

- To enable the successful adoption and integration of Nettle™ into the NHS, it would be essential to develop clinician buy-in and patient support. In addition, there is a need to engage clinical champions who could support cultural change and the development of new care pathways. The fragmented nature of current PMDD services across the United Kingdom, combined with broader systemic challenges in the NHS, reinforces the need for a clear, coordinated approach to implementation.

## 3. Roundtable aim

The aim of this second roundtable was to bring together an invited group of academics, NHS clinicians, commissioners, and other relevant organisations, that have an active interest in this area to discuss the most effective strategies for shaping the phase two SBRI funding bid, with a particular focus on evaluation and data collection. Phase one of the study was in progress when this roundtable took place.

The discussion focused on three main areas:

1. Evaluating effectiveness and safety
2. Optimising data collection
3. Engagement for phase two SBRI funding

## 4. Attendance

The Health Innovation Network South London compiled an invite list of approximately 60 stakeholders from across the UK. This list was developed through a combination of desktop research, personal recommendations and introductions from individuals working within the PMDD field. It included a diverse range of stakeholders representing general practices, NHS Trusts, specialist clinics, universities, health innovation and research organisations, national bodies, Integrated Care Boards (ICBs), and charities. All those approached expressed an interest in this study.

The roundtable event took place on 23rd June 2025. An online approach was taken to support attendance from across the UK and remove geographical barriers to attendance.

The event was chaired by Dr Muj Husain, Clinical Director for Mental Health at the Health Innovation Network South London, and Consultant Liaison Psychiatrist at the South London and Maudsley NHS Foundation Trust.

**Roundtable Attendees on 23rd June 2025**

| Name | Organisation | Job Title |
|---|---|---|
| Dr Emma Abery | The Royal London Hospital | Obstetrics and Gynaecology Consultant |
| Lotte Coppieters | NHS England | Senior Project Manager - Digital Mental Health |

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|---|---|---|
| Professor Michael Craig | King's College London | Professor of Psychiatry |
| Paul Faulkner | Queen Mary University of London | Assistant Professor of Cognitive Neuroscience |
| Dr Andrea Ford | The University of Edinburgh | Wellcome Trust Research Fellow (Assistant Professor) |
| Professor Cynthia Fu | King's College London, University of East London and South London and Maudsley NHS Foundation Trust | Professor of Affective Neuroscience & Psychotherapy, Honorary Consultant Psychiatrist |
| Dr Muj Husain (Chair) | Health Innovation Network South London and South London and Maudsley NHS Foundation Trust | Clinical Director, Mental Health, Consultant Psychiatrist |
| Aileen Jackson | Health Innovation Network South London | Head of Mental Health |
| Dr Vera Martins | GP and Trustee | National Association for Premenstrual Syndromes |
| Julie McCullough | Health and Social Care Northern Ireland, and Public Health Agency | Industry Engagement Manager |
| Anthony Mysak | NHS England | Senior Programme Manager – Digital Mental Health |
| Kate Organ | The Menopause Specialists | BMS Menopause Specialist, Consultant Pharmacist MRPharms Hons, MSc |
| Dr Thomas Reilly | University of Oxford | MRC Clinical Research Training Fellow |
| Dr Delali Sefe | Chelsea and Westminster NHS Foundation Trust | Obstetrics & Gynaecology Specialty Registrar |
| Dr Hannah Short | Menopause Care | GP Specialist in Menopause, Premature Ovarian Insufficiency (POI) and Premenstrual Disorder |

## 5. Discussion

The roundtable discussion was centred around three key questions:

1. How should we effectively measure the Nettle™ device's ability to alleviate PMDD symptoms and determine any potential negative effects associated with its use?
2. Considering the measures outlined in the pre-event briefing document (see appendix 2), are there any important measures that may be missing? If so, what would be the most effective way to capture this additional information?
3. What would encourage you or others to join the SBRI phase two bid?

### Question one: How should we effectively measure the Nettle™ device's ability to alleviate PMDD symptoms and determine any potential negative effects associated with its use?

Key points discussed by roundtable attendees were:

- The placebo effect tends to be particularly pronounced in studies focused on PMDD, with many treatments showing short-term effects in alleviating symptoms. The inclusion

of sham stimulation during phase one of the study may help to mitigate this effect. However, it was noted that the participant sample was not randomised, so it was suggested participants could be asked whether they believed they were receiving active or placebo treatment. If responses showed equal likelihood across both arms of the study, this may strengthen the credibility of the findings and support the review process.

- Symptom tracking tools, such as those created by the National Association for Premenstrual Syndromes (NAPS) or the International Association for Premenstrual Disorders (IAPMD), should be used throughout the duration of phase two of the study, to gather subjective responses on the participants response to the Nettle™ device. It would be important to maintain consistency in these measurement tools for comparability and clarity in outcomes.

- Participants in phase one of the study completed the PHQ-9 questionnaire, a tool commonly used to assess the severity of depression and response to treatment. In this study, the PHQ-9 results were also used to evaluate suicidality. A reduction in suicidal thoughts would represent a significant positive outcome from use of the Nettle™ device, particularly in relation to a reduction in engagement with crisis services.

- Other studies focused on the use of tCDS devices have asked participants how acceptable they found the use of the device, via an acceptability scale, to measure safety and potential adverse effects.

- To assess any negative side effects associated with the use of the Nettle™ device, it would be important to document any instances of adverse effects such as dizziness or nausea. It was confirmed the participant questionnaires currently in use in phase one of the study would capture these.

- Clinicians observed that treatments for PMDD are associated with a reduction in either the severity or the duration of symptoms. It was suggested that both should be used as outcome measures in phase two of the study.

- None of the participants enrolled in phase one of the study are using the Nettle™ device as a first line of treatment. While most participants are not actively using other therapies during the study, the Queen Mary University of London (QMUL) team has collected detailed treatment histories. This context could help advocate for the Nettle™ device to be implemented as a viable treatment alternative, particularly for patients who have not responded to first-line treatment options, or for whom such treatments are contraindicated or poorly tolerated.

**Question two: Considering the measures outlined in the pre-event briefing document (see appendix 2), are there any important measures that may be missing? If so, what would be the most effective way to capture this additional information?**

Key points discussed by roundtable attendees were:

- Phase one of the SBRI-funded study recruited a self-defining population of participants. Given the high level of interest in the study, it will be important to apply more clearly defined inclusion and exclusion criteria in phase two.

- PMDD is a highly heterogeneous condition, and the larger sample size in phase two will

offer an opportunity to divide participants into subgroups based on specific characteristics.

- When considering different subgroups for phase two of the study, it may be valuable to collect background information on participants' lifestyles, as this can help inform more appropriate and tailored treatment choices. An example was shared of a treatment framework used in clinical practice that follows three key steps: first, addressing lifestyle factors, given the evidence supporting the impact of exercise on mood; second, considering supplements, particularly vitamin B6 and dietary calcium, which have shown some benefits; and finally, exploring medical treatment options once lifestyle and supplement approaches have been considered.

- A key challenge in the PMDD patient population is distinguishing PMDD from premenstrual exacerbation (PME), especially given the high prevalence of overlapping conditions such as ADHD and autism. Many individuals presenting with PMDD also have coexisting neurodiverse traits, which complicates diagnosis and treatment planning. In phase two of the study there would be value in exploring neurodiversity, as understanding how different subgroups, such as neurotypical versus neurodivergent individuals, respond to interventions could offer meaningful insights.

- Phase two of the study should incorporate the collection of health economic impact data as this information is likely to be a determining factor for device adoption within the NHS. However, the current variability in PMDD treatment pathways across the UK creates a challenge for generating economic comparisons to the current standard of care.

- It is important to balance clinical research needs for NHS/NICE adoption with industry requirements for regulation assessment. Phase two of the study could offer an opportunity to generate health economic data, which would be valuable to Samphire Neuroscience and may support both regulatory and market access.

- Qualitative interviews with participants to explore their experiences of the study should be considered in phase two, with findings written up as part of a qualitative analysis. An example was shared of this approach being used in a study investigating the acceptability of home-based tDCS for bipolar depression.

- Although daily symptom tracking offers rich data, it may be burdensome for participants to complete. A global measure of daily functioning could be introduced in phase two of the study, as a simpler, more meaningful primary outcome, especially given the cyclical nature of PMDD symptoms.

- Weighting symptom severity at specific points in the menstrual cycle should be considered for phase two of the study to better capture the fluctuating impact of the condition.

- In order for research studies on PMDD to be considered valid, a prospective diagnosis is required, involving symptom tracking over a two-month period. While the Daily Record of Severity of Problems (DRSP) used in phase one could support this diagnosis, the IAPMD symptom tracker is currently the most widely recognised and standard tool in this field.

- In phase two of the study, it would be useful to include measures on active substance misuse, as many patients with PMDD sub treat their symptoms with alcohol or illicit substances.

- The upcoming NHS 10-year plan is expected to have an emphasis on equalities, so in phase two of the study it would be important to ensure the Nettle™ device intervention reaches all population groups. This would include capturing data on cultural nuances and the socio-economic status of participants, to help assess equitable access and impact across diverse communities.

- The QMUL team confirmed equity has been a focus for phase one of the study. As the tCDS treatment is delivered via a headband applied to the scalp, there is a possibility that hair type could affect current delivery. To address this, hair type and ethnicity are being recorded.

- Phase two of the study could explore ways to better integrate contextual factors to understand if daily experiences would correlate with the effectiveness of the Nettle™ device. Examples from endometriosis research were shared, which highlighted how fluctuations in stress and pain can affect responsiveness to treatment. This variability could be captured through qualitative measures or the use of wearable devices.

- Stigma can compound menstrual pain and symptoms, so exploring how experiences of stigma may influence the use and effectiveness of the Nettle™ device in phase two of the study could be valuable and offer a richer and more comprehensive understanding of the device's efficacy.

- Caution was expressed about the suitability of Randomised Controlled Trials (RCTs) to evaluate the efficacy of the Nettle™ device, as PMDD patients often require multiple, combined interventions rather than a single solution. Complex conditions, such as PMDD, may be better suited to an alternative approach, such as observational studies in clinical settings. Similar methodologies have been used in chronic pain studies, where varied treatment combinations were explored to identify optimal strategies.

**Question three: What would encourage you or others to join the phase two bid?**

Key points discussed by roundtable attendees were:

- The QMUL team plan to recruit nationwide sites for phase two of the SBRI funded study. They will aim to work with a heterogeneous sample of participants, from a range of socio-economic and educational backgrounds. The QMUL team also intend to seek guidance around the study's design and how the Nettle™ device may be framed for use within the NHS, particularly given the absence of a standard PMDD care pathway.

- Strong involvement from primary care was considered essential for the phase two study as PMDD remains a poorly understood and under-recognised condition, with many patients struggling to access secondary care services.

- The inclusion of Women's Health Hubs was put forward as they serve as a bridge between primary and secondary care. Examples were shared of teaching sessions that have taken place at the Tower Hamlets Women's Health Hub, to improve understanding

of PMDD amongst primary care professionals. Training sessions facilitated by the QMUL team could be an effective way to introduce the Nettle™ device to a wide audience.

- The Menarche, Menstruation, Menopause and Mental Health (4M) consortium could provide a useful platform for broader engagement.

- An Advisory Board to bring together expert input, enable flexible involvement without a significant time burden, and help guide the design and delivery of the phase two study was agreed to be of high value.

## 6. Summary

The roundtable discussion offered rich insights into the design and delivery of the potential second phase of the SBRI-funded study exploring the use of the Nettle™ device for alleviating PMDD symptoms. Attendees emphasised the importance of rigorous and nuanced measurement tools to capture both the therapeutic potential and any adverse effects associated with the Nettle™ device, recommending the continued use of validated symptom trackers, broader data on suicidality, acceptability, and physical side effects, as well as careful consideration of symptom severity and duration.

There was clear consensus that phase two should take a more comprehensive and inclusive approach. This includes clearer inclusion/exclusion criteria, subgroup analyses (particularly regarding neurodiversity), lifestyle and substance use factors, and the integration of both quantitative and qualitative data. The need to collect health economic data was highlighted, not only to inform NHS and NICE adoption pathways but also to support regulatory and commercial development.

Looking ahead, there was strong support for wide-ranging involvement in the phase two bid. This included interest in developing a nationwide network of recruitment sites, collaborating with primary care and Women's Health Hubs, and leveraging established platforms such as the 4M consortium. Establishing an Advisory Board was viewed as a valuable mechanism for ongoing expert input and stakeholder engagement.

## 7. Glossary

| Term | Definition |
|---|---|
| A heterogeneous condition | A disease or condition that has various causes, symptoms, or severity levels among different individuals. |
| Contraindicated | A particular treatment or therapy that is not recommended or should be avoided for a specific patient because it could be harmful or worsen their condition. |

## 8. References


- SBRI Healthcare – Competition 25: Women's health: https://sbrihealthcare.co.uk/competitions/competition-25-women-s-health
- Dr Paul Faulkner: https://paulfaulkner.uk/

- Roundtable discussion report: Premenstrual Dysphoric Disorder (PMDD) and transcranial direct current stimulation (tDCS) – 24th March 2025 https://healthinnovationnetwork.com/projects/validation-of-a-non-invasive-brain-stimulation-device-nettle-to-manage-symptoms-of-premenstrual-dysphoric-disorder/
- The Effect of Physical Activity on Premenstrual Syndrome: A Systematic Review: https://pmc.ncbi.nlm.nih.gov/articles/PMC11647822/#:~:text=A%20systematic%20review%20of%20studies,intervention%20for%20managing%20PMS%20symptoms.
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- Altered sensitivity to alcohol in the late luteal phase among patients with premenstrual dysphoric disorder: https://www.sciencedirect.com/science/article/pii/S0306453003001215#BIB43
- Gendered Worlds of Pain: Women, Marginalization, and Chronic Pain: https://www.jpain.org/article/S1526-5900%2824%2900567-4/fulltext
- The Syndemic of Endometriosis, Stress, and Stigma: https://www.researchgate.net/publication/319831427_The_Syndemic_of_Endometriosis_Stress_and_Stigma
- The efficacy of an interdisciplinary pain management program for complex regional pain syndrome compared to low back pain and chronic widespread pain: an observational study: https://academic.oup.com/painmedicine/article/26/4/180/7922563
- The Menarche, Menstruation, Menopause and Mental Health (4M) consortium: https://4mhealth.uk/

## About us

Health Innovation Network (HIN) South London is one of 15 HINs across England. As the only bodies that connect NHS and academic organisations, local authorities, the third sector and industry, we are catalysts that create the right conditions to facilitate change across whole health and social care economies, with a clear focus on improving outcomes for patients.

This means we are uniquely placed to identify and spread health innovation at pace and scale; driving the adoption and spread of innovative ideas and technologies across large populations. Our staff bring together a broad range of skills including clinical and lived experience partners, and subject matter expertise in commercial, digital transformation, quality improvement, user involvement, communications and engagement, community and capacity building, research and data analytics, project, and programme management.

# Appendix one: Roundtable agenda

| Time | Item | Lead |
|---|---|---|
| 12.30 | **Welcome and introductions** | Dr Muj Husain |
| 12.40 | **Phase one project update** | Paul Faulkner |
| 12.50 | **Questions and attendees' opening thoughts** | Dr Muj Husain facilitating |
| 13.00 | **Question 1 – discussion** | Dr Muj Husain facilitating |

| | | |
|---|---|---|
| | **Evaluating effectiveness and safety**<br>• *How should we effectively measure the Nettle™ device's ability to alleviate PMDD symptoms and determine any potential negative effects associated with its use?* | |
| 13.15 | **Question 2 – discussion**<br>**Optimising data collection**<br>• *Considering the measures outlined in the briefing document, are there any important measures that may be missing? If so, what would be the most effective way to capture this additional information?* | Dr Muj Husain facilitating |
| 13.30 | **Question 3 – discussion**<br>**Engagement for phase two**<br>• *What would encourage you or others to join the phase two bid?* | Dr Muj Husain facilitating |
| 13.45 | **Summary and reflections from the chair**<br><br>**Next Steps**<br><br>**Close** | Dr Muj Husain |

## Appendix two: A list of measures currently being implemented during phase one of the project.

The below table provides a list of measures currently being implemented during phase one of the project. These were shared in the attendee pre-event briefing document to support the discussion around question two, which focused on optimising data collection strategies for phase two of the project.

| Area of focus | Measures |
|---|---|
| Demographics | • Age<br>• Gender<br>• Education<br>• Ethnicity/race<br>• Drug use history<br>• Psychiatric diagnoses<br>• PMDD history<br>• PMDD diagnosis |
| PMDD | • Daily Record of Severity of Problems (DRSP)<br>• Premenstrual Screening Symptoms Tool (PSST) |
| Depression | • Beck Depression Inventory<br>• Patient Health Questionnaire-9 (PHQ-9) |
| Anxiety | • Generalized Anxiety Disorder-7 (GAD-7) |
| Emotion Regulation | • Difficulties in Emotion Regulation Scale (DERS) |

| | |
|---|---|
| | • Emotion Regulation Task (Cognitive Task) |
| Sleep | • Sleep Quality Scale |