

Thesis Submitted in Partial Fulfilment of the Degree of Doctor of Clinical Psychology (DClinPsych)

Louise Nolan

Student Number: 1579886

Oxford Institute of Clinical Psychology Training and Research

Harris Manchester College

University of Oxford

August 2025

Word counts

Systematic Review of the Literature – 7,037

Service Improvement Project – 5,100

Theory Driven Research Project – 6,547

Executive Summary – 756

Connecting Narrative – 982

Total – 20,422

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Abstracts

Systematic Review of the Literature

The Association between Trauma and Premenstrual Disorders: A Systematic Review with Narrative Synthesis

Background: Trauma is receiving increasing attention as a potential aetiological factor for Premenstrual Disorders (PMDs). Despite this, the extent to which trauma is associated with PMDs, in the absence of post-traumatic stress disorder (PTSD), remains unclear. We therefore aimed to summarise all available studies examining the association between trauma and PMDs, in the absence of PTSD. **Methods:** Electronic databases MEDLINE, Embase, PsycINFO and CINAHL were systematically searched. Meta-analysis was precluded due to methodological heterogeneity, and narrative synthesis was conducted. **Results:** 19 individual studies were included examining Premenstrual Syndrome (PMS; *n*=12) or Premenstrual Dysphoric Disorder (PMDD; *n*=7) and their association with a variety of trauma types at various developmental stages. **PMS:** 92% (11/12) of studies reported a significant positive association between trauma and PMS likelihood and/or severity, of which 33% demonstrated a dose-response relationship. Findings largely support an independent association, owing to control for PTSD and other methodological strengths. **PMDD:** 86% (6/7) of studies reported a significant positive association between trauma and PMDD likelihood and/or severity but owing to methodological drawbacks, provide only equivocal evidence of an independent association. **Conclusions**: This review provides mixed evidence that trauma, in the absence of PTSD, is a risk factor for the development and severity of PMDs. Nevertheless, the consistency of positive results suggests trauma, even in the absence of PTSD, should be routinely considered in clinical practice and research relating to PMDs. The predominance of cross-sectional studies means causation cannot be inferred.

Service Improvement Project (SIP)

How can Oxfordshire Psychosexual Therapy Service improve psychological provision for people with vaginismus?

Background: Vaginismus is a common sexual disorder, and psychosexual therapy is a highly effective treatment approach. Despite this, the Oxfordshire Psychosexual Service noticed that adherence to certain aspects of therapy was low and there was limited research to draw on to understand factors influencing treatment adherence in vaginismus. Therefore, the aim of this project was to identify barriers and facilitators to treatment adherence, as well as treatment preferences, in patients with vaginismus in this service. **Methods:** This project utilised a mixed-methods approach, across three phases. Phase A involved an audit of existing outcome data and staff consultation to identify key issues. Phase B involved a patient survey (N=17) examining barriers, facilitators, and treatment preferences. Phase C entailed staff (N=5) and patient (N=2) interviews to further explore these issues. **Results:** Overall, this project identified several barriers and facilitators to adherence at all levels of the WHO Multidimensional Adherence Model (e.g., patient-related factors), although there was some divergence in staff and patient views regarding where responsibility for adherence lies. The current therapeutic offer within the service is highly valued by patients and staff, and there were significant reservations regarding the introduction of group-based support. **Implications:** Based on the findings, six recommendations for service improvement were developed, emphasising that any changes to service provision would require careful consideration and additional evaluation to monitor effectiveness.

Theoretically Driven Research Project (TDRP)

Obsessive Compulsive Disorder across the Menstrual Cycle: A Prospective Within-Subjects Design

Background: Research has identified that some women with OCD experience a worsening of symptoms in the week preceding menstruation, known as premenstrual exacerbation (PME). However, these symptom changes are poorly understood and it remains unclear whether some OCD dimensions, such as contamination, are more vulnerable to such exacerbations. The aim of this study was therefore to address this gap by prospectively measuring several dimensions of OCD alongside theoretically relevant mood factors across the menstrual cycle. **Method**: This online study utilised a prospective within-subjects design. Participants completed the Dimensional Obsessive-Compulsive Scale (DOCS: contamination, harm, unwanted thoughts, symmetry) alongside measures of pathogen disgust sensitivity (PDS), anxiety and depression at three time points across one menstrual cycle including T1: early-follicular (days 4-7), T2: mid-luteal (days 19-22) and T3: premenstrual phase (days 24-27). **Results**: Contrary to expectations, across the whole sample ($N = 61$) OCD symptom severity, anxiety and depression significantly *improved* from T1 to T3. DOCS-Contamination scores remained relatively stable and DOCS-Harm demonstrated the most change. PDS did not change significantly across the cycle, however, within-person variations in PDS were significantly associated with concurrent changes in DOCS-Contamination scores. Exploratory analyses identified that 23% of the sample experienced clinically meaningful symptom change (≥30%) across the cycle. **Conclusion:** OCD symptoms demonstrated significant premenstrual improvement rather than exacerbation and there appears to be a complex and heterogenous relationship between hormonal fluctuations and OCD symptom changes. The implications for clinical practice and future research are considered.

Systematic Review of the Literature (SRL)

The Association between Trauma and Premenstrual Disorders: A Systematic Review with Narrative Synthesis

Louise Nolan (louise.nolan@hmc.ox.ac.uk)

Student Number: 1579886

Internal Supervisor:

Dr Susannah Jenner

August 2025

Word count: 7037

Proposed Journal: This report is intended to be published in the Journal of Clinical Psychology (see Appendix E for Author Guidelines). This was selected given the relevance of menstrual cycle related to clinical psychology generally.

Abstract

Background: Trauma is receiving increasing attention as a potential aetiological factor for Premenstrual Disorders (PMDs). Despite this, the extent to which trauma is associated with PMDs, in the absence of post-traumatic stress disorder (PTSD), remains unclear. We therefore aimed to summarise all available studies examining the association between trauma and PMDs, in the absence of PTSD. **Methods:** Electronic databases MEDLINE, Embase, PsycINFO and CINAHL were systematically searched. Meta-analysis was precluded due to methodological heterogeneity, and narrative synthesis was conducted. **Results:** 19 individual studies were included examining Premenstrual Syndrome (PMS; *n*=12) or Premenstrual Dysphoric Disorder (PMDD; *n*=7) and their association with a variety of trauma types at various developmental stages. **PMS:** 92% (11/12) of studies reported a significant positive association between trauma and PMS likelihood and/or severity, of which 33% demonstrated a dose-response relationship. Findings largely support an independent association, owing to control for PTSD and other methodological strengths. **PMDD:** 86% (6/7) of studies reported a significant positive association between trauma and PMDD likelihood and/or severity but owing to methodological drawbacks, provide only equivocal evidence of an independent association. **Conclusions**: This review provides mixed evidence that trauma, in the absence of PTSD, is a risk factor for the development and severity of PMDs. Nevertheless, the consistency of positive results suggests trauma, even in the absence of PTSD, should be routinely considered in clinical practice and research relating to PMDs. The predominance of cross-sectional studies means causation cannot be inferred.

Introduction

Premenstrual Disorders (PMDs) describes a group of disorders characterised by the onset or worsening of emotional, psychological, behavioural and somatic symptoms of varying severity and impact, during the perimenstrual phase of the menstrual cycle, the days before and during menstrual bleeding (menses) (IAPMD, 2024). These disorders include Premenstrual Syndrome (PMS), Premenstrual Dysphoric Disorder (PMDD) and Premenstrual Exacerbation (PME) (Standeven et al., 2024).

PMS refers to recurrent psychological and/or physical symptoms (e.g., such as anxiety, bloating) during the luteal phase of the menstrual cycle and affects approximately 20% to 50% of women (Pearlstein & Steiner, 2012; Kwan & Onwude, 2015). If these symptoms are more severe and cause significant distress and interference with functioning, a diagnosis of PMDD may be conferred. According to the DSM-5, PMDD is cyclical, hormone-based mood disorder with symptoms (e.g., depressed mood, anxiety, irritability) present only in the luteal phase, after which they remit completely (APA, 2013). PMDD is less common and affects 3% to 8% of women (Yonkers, O'Brien, & Eriksson, 2008). PME is distinct in that it refers to the worsening of an *existing* mental health disorder during the perimenstrual phase, after which symptoms return to baseline (Hsiao, Hsiao, and Liu, 2004). PME has received relatively little attention with no reliable overall prevalence estimates, but a recent systematic review found that multiple disorders, such as psychotic disorders and depression, are vulnerable to premenstrual worsening of symptoms (Tiranini et al., 2022; Nolan & Hughes, 2022). This review will focus on PMS and PMDD (here forth referred to as PMDs), owing to PME being conceptually and clinically distinct such that it refers to the

worsening of an existing disorder rather than constituting a primary premenstrual disorder.

Notably, for individuals with PMDD or PMS, the luteal phase is associated with an increased risk of suicidal thoughts and behaviours (Eisenlohr-Moul et al., 2018). Importantly, an estimated 30% of women with PMDD will attempt suicide (Eisenlohr-Moul et al., 2018). A recent study identified that individuals with PMDD with a history of trauma demonstrate significantly higher rates of suicidal ideation compared to those without trauma (Machado et al., 2024). This highlights the importance of understanding the aetiological and maintenance factors in PMDs.

The pathophysiology of PMDs is not fully understood and there remains a pervasive misunderstanding that hormonal abnormality is responsible for the negative emotional and/or behavioural outcomes (Eisenlohr-Moul, 2019). The now well-stablished 'hormone sensitivity hypothesis' proposes that symptoms likely result from abnormal sensitivity to normal fluctuations in hormones (Schmidt et al., 1998). There is significant between-person variation in sensitivity to cyclical hormone changes and relatively little is known about what factors might explain such differences (Eisenlohr-Moul et al., 2016).

Recently, trauma has received increasing attention as a potential risk factor for hormone sensitivity (Tonon et al., 2024; Kulkarni et al., 2022). Multiple types of trauma occurring at various developmental stages have been implicated in both the development and severity of PMS and PMDD. For example, women reporting the highest level of childhood emotional abuse and physical abuse were 2.6 times and 2.1 times, respectively, more likely to develop PMS than those reporting no abuse (Bertone-Johnson et al., 2014). Similarly, a recent study found a significant positive correlation between severity of childhood trauma

and PMDD symptom severity, including increased negative affect and stress appraisal (Nayman et al., 2023). Notably, the association between trauma and PMDs may be bidirectional, such that having a PMD could increase the likelihood of subsequent trauma. Indeed, PMDD has been associated with increased risk of suicide attempts, interpersonal conflict and relationship breakdowns (Westermark et al., 2024; Prasad et al., 2021). Additionally, PMDs are associated with significant mood changes and research on mood-congruent memory suggests negative mood states may influence memory retrieval and perception of past events (Faul & LeBar, 2023). These considerations are particularly important when interpreting findings from cross-sectional studies.

Various mechanisms have been proposed to explain how trauma exposure may contribute to the onset or severity of PMDs, though this remains relatively poorly understood. The Hypothalamic-Pituitary-Adrenal (HPA)-axis is frequently implicated, with trauma thought to disrupt its function and dysregulate response to stress, contributing to hormone sensitivity. Lower cortisol levels and blunted cortisol response to acute stress has been demonstrated in individuals with PMDD (Huang et al., 2015; Hou et al., 2020). Recent research has proposed that trauma-induced HPA-axis dysregulation may contribute to emotion dysregulation, a hallmark of PMDD (see Tonon et al., 2024).

To date, three reviews have attempted to elucidate the association between trauma and PMDs. A recent meta-analysis by Islas-Precadio et al. (2021) reported that experience of either of physical and/or sexual violence in childhood or adolescence was associated with almost twice the odds (OR=1.9) of developing a Menstrually Related Mood Disorder. However, only five studies were included in this meta-analysis, and whilst other abuse types (e.g., neglect, emotional abuse) were excluded conceptually, the included papers did not

adequately control for them. Given the context of polyvictimisation, whereby individuals often experience multiple types of trauma, authors may have drawn unwarranted conclusions about the unique influence of physical and sexual abuse.

These limitations were somewhat overcome by a recent meta-analysis (Bencker et al., 2024; preprint), which included 22 studies and found that experience of any trauma was associated with 2.5 times higher odds of developing PMS. However, this review also has several methodological shortcomings. For example, the review lacked a coherent definition of PMS, leading to the inclusion of studies focussing on PMDD (e.g., Segebladh et al., 2011) and studies classifying PMS against unvalidated thresholds (e.g., experience of at least one symptom in Ito et al., 2021). As such, it remains unclear whether trauma is associated with PMDD, PMS, or broader premenstrual symptoms.

A more recent review by Grewal et al. (2024) included 16 studies and found that women with PMDD were 1.99 times more likely to have a trauma history than those without PMDD. Whilst this is highly valuable, this review did not consider the severity or likelihood of developing PMDD as a function of experiencing trauma, leaving this yet to be explored.

Importantly, prior research has indicated that those with both a trauma history and diagnosis of PTSD are at higher risk of developing PMDD than those with a trauma history without PTSD (Pilver et al., 2011). One study found that individuals with PMDD were nine times more likely to have PTSD compared to those without PMDD (Hong et al., 2012). However, previous reviews have inconsistently considered PTSD, and none have explicitly examined the influence of non-PTSD trauma. Beckner et al. (2024) conducted a moderator analysis and found the largest effect sizes in studies linking premenstrual symptoms to PTSD. Grewal et

al. (2024) included an additional analysis examining the prevalence of PTSD (and not trauma) in PMDD populations, with a pooled prevalence of 23%. However, in their main analysis focusing on trauma, the possible inclusion of PTSD wasn't considered and therefore the relative role of non-PTSD trauma remains unclear. Islas-Precadio et al. (2021) did not consider PTSD at all. Consequently, none of these reviews provide clarity on the association between non-PTSD trauma and PMDs. Elucidating this association is clinically important, as trauma may otherwise go unrecognised in individuals with PMDs not presenting with PTSD, despite its potential aetiological relevance. Numerous other methodological considerations have generally been overlooked in these reviews. For example, use of hormonal contraception and retrospective assessment for classifying PMDs or measuring symptom severity. Further, whilst these reviews have drawn attention to the association between trauma and PMDs, none have considered whether evidence demonstrates a dose-response relationship.

The considerable impact of PMDs on the life of sufferers and need for evidence-based interventions underscores the importance of drawing warranted conclusions on the role of risk factors such as non-PTSD trauma in their development. As such, there remains a need for a systematic review considering the association between all PMDs and trauma across the lifespan, in the absence of PTSD.

Thus, the aim of this review is to summarise the available evidence on the association between lifetime trauma and PMDs, independent of PTSD. The questions this review aims to address include:

- What is the association between trauma and PMDs?
- Is there an association between trauma and PMDs, in the absence of PTSD?

- Is there a dose-response relationship between trauma and PMDs?

Methods

Protocol and registration

PRISMA guidelines were followed, and the review protocol was published on the PROSPERO website on the 13th July 2023. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023420708)

Eligibility was defined around the PICOS framework (Higgins & Green, 2011). Studies were eligible for inclusion if they met the following criteria:

a. included individuals between menarche and menopause
b. with a current diagnosis of PMDD based on standard diagnostic criteria (DSM-5/ICD)
c. or a current diagnosis of a PMS or clinically significant premenstrual symptoms measured using a validated outcome measure or diagnostic interview based on standard diagnostic criteria
d. included a suitable comparison group of individuals *without* PMDs or comparing severity of symptoms
e. measured trauma as an exposure factor – defined according to WHO's criteria (physical abuse, sexual abuse, emotional abuse, and neglect), DSM Criterion A stressors (APA, 2013) or Adverse Childhood Experiences (Felitti et al., 1998) and/or measured trauma using a validated trauma scale (e.g., Childhood Trauma Questionnaire)
f. measuring PMDs as the outcome variable
g. with the primary aim of examining the relationship between trauma and PMDs or where trauma has been sufficiently considered prior to analysis

h. cross-sectional, descriptive, case-control, cohort studies, qualitative or mixed-methods (published or grey literature)
i. English language.

Studies were excluded against the following criteria:

a. only includes participants with PMS/PMDD and a current diagnosis of PTSD. To be included, a study must also include individuals without PTSD and provide separate analyses examining the unique association between PMDs and trauma without PTSD, and/or statistically control for PTSD (e.g., include PTSD as a covariate in multivariate analysis)
b. experimental design (e.g., Randomised Controlled Trials) unless inclusion criteria was satisfied outside of experimental component
c. non-human research studies
d. review papers, letters, comments, or books.

Search strategy

Search terms were defined around psychological trauma (concept 1) and premenstrual disorders (concept 2). Key words and subject headings were used alongside Boolean operators 'AND', 'OR'. Four electronic databases Embase (Ovid), PsycINFO (Ovid), Medline (Ovid), and CINAHL were searched from inception. See Appendix A for full search terms. The search was conducted between January and May 2024 and repeated in February 2025 prior to submission. The repeated search identified 101 additional articles, of which two were included in the final synthesis. Backwards searching of reference lists and forward searching via Google Scholar was conducted for included studies. A supplementary grey literature search was conducted using the term "trauma and premenstrual disorders" in

Google Scholar and ResearchGate. Grey literature was searched to reduce publication bias which could overestimate the impact of trauma on PMDs (McDonagh et al., 2013).

Data Extraction (selection and coding)

Database references were first exported into Endnote for deduplication. References were then imported into Rayyan for titles and abstracted to be independently screened by two reviewers. All were screened by LN and 25% were screened by a second reviewer (NN). A Cohen's kappa statistic of 0.977 was achieved suggesting an almost perfect level of agreement (Landis & Koch, 1977). For grey literature, the title and abstract of the first 100 papers were screened for inclusion by LN only.

After screening, the full text of articles was assessed for eligibility by LN, and exclusion reasons were recorded. Data for individual studies was extracted by LN and cross-checked by NN for 30% of studies and no discrepancies were found. Data extraction comprised author/s, publication year, title, study design, setting, sample size, age, primary diagnosis, measurement tool/s, diagnostic criteria, PTSD status, key findings, statistical controls, hormonal contraception status and evidence of dose-response relationships.

Risk of Bias (quality) assessment

To assess risk of bias for each included study, the Critical Appraisal Skills Programme (CASP) tool was utilised (CASP, 2018). CASP is a validated tool with versions tailored to assess each study design. CASP for cohort studies includes 14 items and for cross-sectional studies includes 11 items. CASP appraises research in three overall steps: (a) is the study valid? (b) what are the results? and (c) are the results useful? For each item, 2 points is awarded for 'yes', 0 for 'no' and 1 for 'can't tell' and then the total score is calculated. For

the purpose of this review, a score of 1 was also awarded if conditions were partially met, this reflects the additional methodological considerations in menstrual cycle and trauma research (e.g., gold-standard prospective measurement; see Appendix B for details). The use of a single tool was preferred over the application of separate tools for each study design (e.g., Newcastle Ottawa Scale for cohort studies and AXIS for cross-sectional studies). This balances the need to appraise quality according to concerns specific to each study design whilst facilitating clearer comparisons between studies. As scores are subjective and 'quality' is poorly defined in the literature, CASP scores were not used as a basis for study exclusion (Sterne et al., 2019).

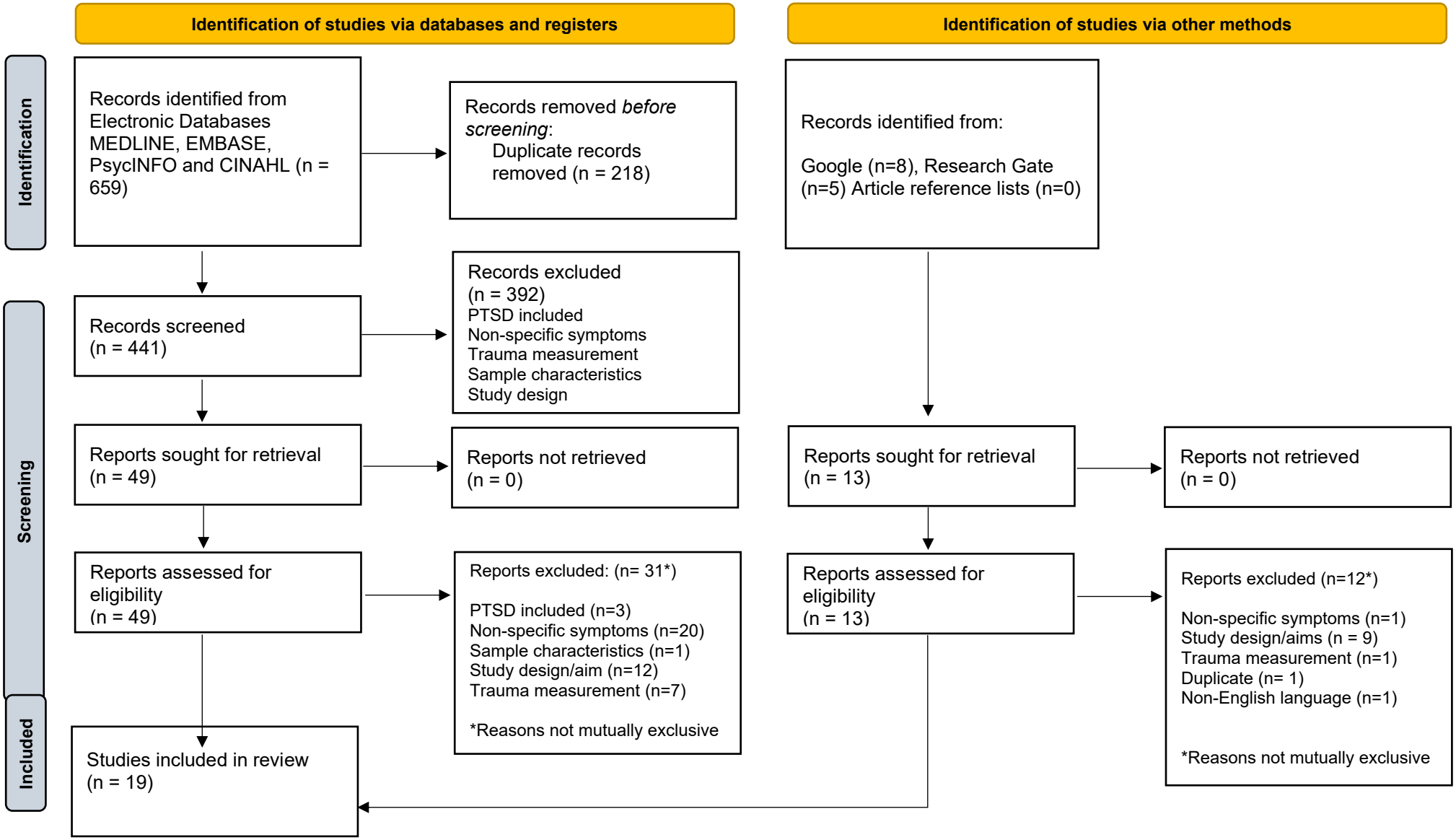
A maximum score of 28 was available for cohort studies and 22 for cross-sectional studies. There is no agreed way of categorising scores on the CASP, so percentage-based thresholds were applied, allowing for consistency across designs (≥80% = high, 60-79%=moderate, <60%=low). This specified that for cohort studies a total score of ≥23 is high quality, 17-22 moderate quality and ≤16 low quality. For cross-sectional studies a total score of 18+ is high quality, 14-17 moderate quality and ≤13 low quality.

Data analysis

Narrative synthesis of individual studies was conducted, with consideration for Systemic Review without Meta-analysis guidance (SWiM; Campbell et al., 2020). The scope for meta-analysis was limited by heterogeneity in outcome measures, analytical methods and definitions and/or analysis of trauma (e.g., binary, ordinal, continuous) and PMDs (e.g., severity or likelihood). Studies were arranged into subgroups according to their category of PMD: Premenstrual Dysphoric disorder (PMDD) or Premenstrual Syndrome (PMS; see Appendix C for classification criteria). Synthesis included tabulation of data, vote counting

and narrative description of the direction of effect. Findings were ordered according to three key variables which considerably influence the interpretability of evidence when addressing the current review questions: control for PTSD, prospective symptom measurement and exclusion of hormonal contraception (HC; see Appendix D). Notably, whilst these factors relate to study quality, they are conceptually distinct, with 'interpretability' referring only to the degree to which a study considered these factors thereby permitting conclusions to be drawn on the *independent* association between trauma and *confirmed* PMDs.

Fig. 1 PRISMA diagram of search strategy



Results

Study selection

Study selection followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance, and search results are detailed in Figure 1 (Moher et al., 2009). A total of 19 papers were included in the review.

Study characteristics

The 19 studies included a total of 22,349 participants (range 52 to 8640) with a diagnosis or classification of the PMS (N=16,870; 12 papers) or PMDD (N=5,479; 7 papers).

The following types of trauma were measured: physical, emotional, sexual, psychological abuse; neglect (unspecified), emotional, physical and parental neglect, corporal punishment, household dysfunction, DSM-criteria A events (e.g., sexual assault, natural disasters, war/combat exposure), combat and non-combat related traumatic experiences, adverse childhood experiences (ACES; e.g., neglect, parental death, parental divorce, poverty, bullying) and childhood traumatic events (e.g., extreme illness, major upheaval, physical violence). The developmental stage of trauma exposure (childhood and/or adolescence or lifetime) was measured retrospectively in all studies.

Across studies, the outcomes relevant to elucidating the association between trauma and PMDs included:

1. Severity of PMDs as a function of trauma exposure status or severity

2. Likelihood of PMDs as a function of trauma exposure (trauma is the grouping variable e.g., high versus low trauma),
3. Likelihood, prevalence or severity of prior trauma as a function of PMD status or severity (PMD is the grouping variable e.g., PMS vs. no PMS group).

The majority (16/19) utilised a cross-sectional study design or cross-sectional data collection for the results of interest, and three utilised a cohort design. Individual study characteristics are detailed in Tables 3 and 4.

Risk of bias (quality) assessment

A quality score was ascertained for all individual studies (N=19) according to CASP cross-sectional or cohort study criteria. All quality scores are presented in Table 1 and 2. Overall, cross-sectional studies (N=16) were classified as moderate quality, with a mean total score of 16.6 and range of 14 to 20. Cohort studies (N=3) were also classified as moderate quality, with a mean total score of 22.3 and range of 21 to 24. Recurring quality issues across studies were lack of prospective symptom measurement with reliance on cross-sectional data collection methods, failure to ascertain reproductive status and cycle phase at time of measurement, failure to screen and exclude PTSD, and lack of representative samples owing to sampling methods (e.g., university students) or small sample sizes.

Table 1. Quality Scores for individual studies using a CASP tool for cross-sectional studies

Author	Focused Issue	Appropriate Method	Recruitment Acceptable	Bias Reduced	Data Collection	Power	Results	Rigorous analysis	Clear findings	Local application	Value	Total	Rating
Azoulay et al. (2020)	2	2	1	1	1	1	2	1	2	1	2	16	Mod
Crowley et al (2015)	2	2	2	2	1	1	2	1	2	1	2	18	High
Eisenlohr-Moul et al (2016)	2	2	1	1	1	1	1	2	2	1	2	16	Mod
Girdler et al. (2003)	2	1	1	1	2	0	2	1	2	1	1	14	Mod
Girdler et al. (2007)	2	2	1	1	1	0	2	1	2	1	1	14	Mod
Gumussoy et al. (2021)	2	2	1	1	1	2	2	1	2	1	1	16	Mod
Kanamori et al. (2025)	2	2	1	1	1	2	2	2	2	1	2	18	High
Kfoury et al. (2024)	2	1	1	1	0	2	2	2	2	1	1	15	Mod
McKinnon (2009)	2	2	2	1	2	2	2	2	2	1	2	20	High
Nayman et al. (2023)	2	2	2	1	1	1	2	2	2	1	2	18	High
Pilver et al. (2011)	2	2	2	1	2	2	2	2	2	1	2	20	High
Saglam et al. (2025)	2	2	1	1	1	2	2	1	2	1	2	17	Mod
Segebladh et al. (2011)	2	2	1	1	1	2	1	1	2	1	1	15	Mod
Soydas et al. (2014)	2	2	1	1	2	1	2	1	2	1	1	16	Mod
Standeven et al. (2024)	2	2	1	1	0	1	2	1	2	1	1	14	Mod
Yang et al (2022)	2	2	1	1	1	2	2	2	2	2	2	19	High

Table 2. Quality Scores for individual studies using a CASP tool for cohort studies

Author	**Focused Issue**	**Recruitment Acceptable**	**Exposure measures**	**Outcome measures**	**Confounds identified**	**Confounds addressed**	**Follow-up complete**	**Follow-up duration**	**Study results**	**Result precision**	**Results credible**	**Apply locally**	**Evidence alignment**	**Implications**	**Total**	**%**
Bertone-Johnson et al. (2014)	2	1	1	1	1	2	2	2	2	1	2	1	2	2	22	Mod
Jung et al. (2019)	1	1	1	1	2	2	1	2	2	1	2	1	2	2	21	Mod
Perkonigg et al. (2004)	2	2	2	1	0	2	2	2	2	1	2	2	2	2	24	High

Note. All studies were categorised according to their score: ≥80% = High, 60-79%=Moderate (Mod), <60%=Low.

PMDD

Seven individual studies examining PMDD were included (see Table 3). Three studies utilised gold-standard prospective methods for PMDD classification, four prospectively measured symptom severity, and the remaining studies employed retrospective methods for classification and/or severity. The mean CASP score of studies examining PMDD was 16.2 (cross-sectional; moderate) and 24 (cohort; high).

Most studies (6/7) found a significant positive association between trauma and PMDD severity and/or likelihood. No studies attempted to identify a dose-response relationship or conducted analysis allowing for this (e.g., use of correlational analysis and continuous data).

PMDD severity

Four studies examined the severity of PMDD in relation to trauma exposure (Girdler et al., 2007; Nayman et al., 2024; Segebladh et al., 2011; Soydas et al., 2014).

Two studies examined the independent effect of trauma history (PTSD excluded) on PMDD symptom severity in hormonal contraception free women with prospectively measured PMDD symptom severity. Girdler et al. (2007) found no significant differences in symptom severity between women with PMDD in the abused versus non-abused group, during the luteal phase (6 days before menses). However, abuse history was associated with higher severity of anger, irritability, depression and headache during the follicular phase (days 4 to 9; $p<0.05$). Similarly, a cross-sectional study by Segebladh et al. (2011) which prospectively measured PMDD, found no association between PMDD severity and lifetime physical, emotional and sexual abuse.

Two studies provided marginally less interpretable evidence, based on the aforementioned criteria, with one failing to account for PTSD (Nayman et al., 2024) and one failing to prospectively measure PMDD severity (Soydas et al., 2014), although both included HC-free women. Soydas et al. (2014) found a significant positive correlation between PMDD symptom severity and both overall trauma severity and all trauma subscales including childhood emotional abuse/neglect, physical abuse and sexual abuse. Notably, other trauma types were not controlled for in analysis of subscales. Similarly, a recent study by Nayman et al. (2024) prospectively assessed PMDD symptom severity and found overall childhood trauma severity was significantly associated with greater increases in negative affect and stress appraisal, alongside greater decreases in positive affect, from the follicular to the luteal phase ($p<0.001$ level).

PMDD likelihood

Two studies examined PMDD likelihood as a function of lifetime trauma exposure (Perkonigg et al., 2004; Pilver et al., 2011). Both provide the least interpretable evidence, using retrospective methods to classify PMDD and including HC users, although PTSD was controlled for. In a large prospective longitudinal cohort study (N=1251) spanning 42 months, Perkonigg et al. (2004) found that compared to women with no trauma, those with a history of any traumatic event at baseline were 4.2 times more likely to develop PMDD at follow-up, after controlling for PTSD and other mental disorders (OR= 4.3, 95% CI: 1.2–12.0). Notably, as PTSD was not excluded and only statistically controlled for, residual or unmeasured effects of PTSD cannot be entirely ruled out. Similarly, in another large study (N=3,698) utilising cross-sectional methods, Pilver et al. (2011) found that women with history of any trauma (and no PTSD) were 2.84 times more likely to have PMDD (OR = 2.84, 95% CI: 1.26–6.42) than those with no trauma.

Trauma likelihood

Three studies measured likelihood of reporting trauma as a function of PMDD status, all of which classified PMDD using strict prospective methodology (Girdler et al., 2003; Girdler et al., 2007; Segebladh et al., 2011).

In the aforementioned study controlling for HC and PTSD, Girdler et al. (2007) found that compared to non-PMDD women, those with PMDD were significantly more likely to have experienced physical abuse (44% vs. 21%, p=0.05) but not sexual abuse (32% vs. 14%, p=0.08).

In another study with a verified HC-free sample, Girdler et al. (2003) found that women with PMDD were significantly more likely than women without PMDD to have experienced sexual abuse (36% vs. 11%; $p<0.05$), physical abuse (61% vs. 29%; $p<0.05$), or any abuse (71% vs. 36%; $p<0.01$). Notably, whilst individuals with current psychiatric disorders were excluded, the PMDD group scored significantly higher on the PTSD scale; despite not meeting diagnostic thresholds, subclinical symptoms may still have influenced findings. Furthermore, individual abuse types were not controlled for.

Finally, Segebladh et al. (2011) found that those with PMDD did not report a significantly higher rate of lifetime physical, emotional, or sexual abuse than non-PMDD groups (ObGyn: 39%, PMDD: 31%, Healthy: 21.3%). On the contrary, obstetric gynaecological controls were significantly more likely to report lifetime abuse than women with PMDD or healthy controls ($p<0.05$). Notably, this study provides the least interpretable evidence, as PTSD and HC use were only excluded in the PMDD group. This may have inflated trauma prevalence in controls by including individuals with PTSD and allowed for

misclassification of PMDD cases as non-PMDD due to potential for symptom masking or improvement with HC.

Table 3. Characteristics of studies measuring PMDD

Study	Diagnosis Measure	Sample	Design	Trauma Measurement	Trauma characteristics	Key Findings	Controlled Variables	Dose-response
Girdler et al (2003) United States	PMDD **Classification** PRISM Prospective DSM-IV	**N=56** (28 PMDD, 28 non-PMDD) Mean age across groups 32.9 to 34.3 years (SD 1.3 to 2.1)	Cross-sectional data (nested within an experimental study).	Modified validated interview (Leserman et al., 1996)	**Type:** Sexual and physical abuse **Age:** Lifetime	**Trauma likelihood** Women with PMDD were significantly more likely to have experienced sexual abuse (36% vs. 11%, $p<0.05$), physical abuse (61% vs. 29%, $p<0.05$), any abuse (71% vs. 36%; $p<0.01$) Abused PMDD women exhibited heightened luteal norepinephrine (NE) reactivity, greater adrenergic receptor responsivity, and lower baseline NE levels compared to non-abused PMDD women ($p<0.05$).	**PTSD** Partially – excluded current Axis-1 disorders using SCID for DSM-III-R. PTSD symptoms (measured separately) were significantly higher in the PMDD group and not controlled in analysis. or PTSD scores. **HC** Excluded **Trauma types** Did not control for individual abuse types **Other** Demographic variables tested for group differences; no significant differences found.	Dose response not studied Positive association between PMDD presence and likelihood of previous trauma

Girdler et al (2007) United States	PMDD **Classification** PRISM Prospective (one or two cycles) DSM-IV	**N=67** (25 PMDD; 42 non-PMDD) Mean age across groups 31.0 to 35.0 years (SDs 1.2 to 1.9)	Cross-sectional data (nested in an experimental study).	Modified validated interview (Leserman et al., 1996)	**Type:** Sexual and physical abuse **Age:** Lifetime	**Symptom severity** Symptoms of anger irritability, depression and headache (ps<0.05) were significantly greater in abused PMDD women compared to non-abused PMDD women during the follicular phase (days 4 to 9) but **not** the luteal phase (6 days before menses). No significant influence of abuse on symptoms during the luteal phase in PMDD women. **Trauma likelihood** Women with PMDD were significantly more likely to have experienced physical abuse compared to non-PMDD women (44% vs. 21%, p=0.05). Sexual abuse was reported more often by PMDD women compared to non-PMDD women (32% vs. 14%, p=0.08, but not statistically significant. Any abuse (combined) was reported more often by PMDD women compared to non-PMDD women (48% vs. 29%; p=0.10, not statistically significant).	**PTSD** Yes (they did a SCID and excluded *current* Axis-1 disorders, but sample included those with *histories* of PTSD) **HC** Excluded **Trauma types** Did not control for individual abuse types **Other** None reported	Dose response not studied Positive association between PMDD status and likelihood of previous physical abuse No significant association between trauma presence and PMDD symptom severity.
Nayman et al. (2023) Germany	PMDD* **Classification** SCID-PMDD DSM-5 criteria Retrospective **Severity** PSST	**N=52** (all with PMDD) Age: 30.54 (5.59)	Prospective cohort study	Childhood Trauma Questionnaire (CTQ; Bernstein et al., 1994).	**Type:** Physical, emotional, and sexual abuse, neglect **Age:** Childhood (prior to age 18)	**Symptom severity** Higher childhood trauma scores (total) were associated with greater increases in negative affect (mean difference = 1.106, SE = 0.031, p < .001) and stress appraisal (mean difference = 0.395, SE = 0.050, p < .001) and greater decreases in positive affect (mean difference = -1.269, SE = 0.034, p < .001), from the follicular to luteal phase.	**PTSD** No Controlled for recent stressful life events, assessment day, weekday/ weekend, time since first assessment in analysis of interest	Dose response not studied Positive association between trauma severity and PMDD severity

	Prospective (4 days during both follicular and late luteal phase)						**HC** Excluded hormonal medication **Other**	
Perkonigg et al (2004) Germany	PMDD* **Classification** M-CIDI Retrospective DSM IV criteria	**N=1251** Age: 14-28 (baseline) and18-28 (second follow-up)	Prospective longitudinal cohort Study 3 timepoints across 42 months (1995 to 1999)	M-CIDI	Lifetime Traumatic events according to DSM-IV A1 and A2 criteria (e.g., such as rape, childhood sexual abuse, severe accidents, or witnessing similar events).	**PMDD likelihood** Individuals with a history of any traumatic event at baseline had a 4.2 times higher likelihood of developing PMDD at follow-up compared to those without trauma, even after controlling for PTSD and other mental disorders (95% CI: 1.2–12.0).	**PTSD** Yes, PTSD controlled in regression model, examines the effect of trauma *over and above* any effect due to PTSD. **HC** Hormonal contraceptives included in sample **Other** Age at follow-up, subthreshold PMDD at baseline, any qualifying trauma, low self-competence, number of negative life events, increased daily hassles, substance use disorder, nicotine dependence, any anxiety disorder, any mood disorder, any somatoform disorder or syndrome, and any eating disorder	Dose response not studied Positive association between trauma presence and likelihood of developing PMDD.

							included in multiple regression analysis.	
Pilver et al. (2011) United States	PMDD **Classification** WMH-CIDI Retrospective DSM-IV	**N=3,698** Age: 28.74 (0.24)	Cross-sectional	Diagnostic interview	Lifetime trauma 22 lifetime trauma types (e.g., rape, combat, assault) both primary (direct) and secondary (witnessed) trauma	**PMDD likelihood** Women with history of trauma (but no PTSD) were 2.84 times more likely to have PMDD (OR = 2.84, 95% CI: 1.26–6.42) and 1.43 times more likely to have PMS (OR = 1.43, 95% CI: 1.09–1.87) than those with no trauma. In those that did **not** meet criteria for PMDD, history of trauma (without PTSD) was associated with a 43% increased likelihood of premenstrual symptoms (OR = 1.43, 95% CI: 1.09–1.87).	**PTSD** Yes PTSD assessed via interview based on DSM-IV criteria. Separated analysis for those with and without PTSD (Histories) **HC** Included but controlled for oral contraceptives **Other** Controlled for race, age, smoking, oral contraceptive use, education, income, BMI, mood disorder history, trauma severity, trauma type.	Dose response not studied Positive association found between trauma and likelihood of PMDD.

Segebladh et al (2011) Sweden	PMDD **Classification and severity** Cyclicity Diagnoser Scale Prospective (one or two cycles) DSM-IV criteria	**N=207** 58 (PMDD), 102 (gynaecological controls), 47 (healthy controls) Age PMDD – **36.5** (7.5) Obgyn – **33.6** (7.9) Healthy – **33.6** (7.6)	Cross-sectional	Modified Abuse Assessment Screen (AAS) interview – Swedish version	Lifetime Sexual abuse and physical/ emotional abuse (combined) Ages specified for sexual abuse (0-12, 13-19, 20 or older)	**Symptom severity** No significant differences in PMDD severity based on abuse exposure. **Trauma likelihood** PMDD patients did not report higher prevalence of lifetime physical, emotional, or sexual abuse than healthy controls. ObGyn controls (e.g., abdominal pain, bleeding disturbance, no PMS/PMDD) were significantly more likely to report lifetime abuse than PMDD or healthy controls (ObGyn: 39%, PMDD: 31%, Healthy: 21.3%; $p<0.05$).	**PTSD** Partially MINI used to exclude current psychiatric diagnoses in PMDD group only (*histories* not excluded) **HC** Excluded PMDD group only **Other** Demographic variables tested for group differences; no significant differences found.	Dose response not studied No significant association between trauma and PMDD severity; or between PMDD status and likelihood of previous trauma
Soydas et al (2014) Turkey	PMDD* **Classification** SCID-I (Turkish) Retrospective DSM-IV-TR **Severity** PMSS Retrospective	**N=148** 70 (PMDD), 78 (control) Age PMDD - 29.3 (5.3) Control - 30.7 (6.0)	Cross-sectional	Childhood Trauma Questionnaire (CTQ; Bernstein et al)	Childhood (before age 18) Emotional abuse and neglect; Physical abuse; Sexual abuse	**Symptom severity** Significant positive correlations were found between the CTQ total score ($r = 0.281$, $p<.001$), emotional abuse and emotional neglect subscale ($r = 0.233$, $p<.001$), physical abuse subscale ($r = 0.221$, $p<.001$), and sexual abuse subscale ($r = 0.222$, $p<.001$) and PMSS total score. **Trauma severity** PMDD group scored higher than control group on total CTQ (M=59.39 vs 68.02; $F = 5.42$; $p=.002$) and subscales for emotional abuse/neglect ($F = 6.92$; $p=.004$), physical abuse ($F = 0.99$; $p=.009$), and sexual abuse ($F = 29.01$; $p=.012$).	**PTSD** Yes, SCID used to exclude current and past psychiatric diagnoses **HC** Excluded **Other** None reported (beyond exclusion criteria). Did **not** statistically control for significant group differences in education level, occupation, family psychiatric history,	Dose response not studied Positive association between trauma severity and PMDD severity; and PMDD status and trauma severity

							postpartum disorder history, or history of suicide attempts.	

Note. PMDD = Premenstrual Dysphoric Disorder; PRISM = Prospective Record of the Impact and Severity of Menstrual Symptoms (Reid, 1985); SCID = Structured Clinical Interview for DSM Disorders (First et al., 1997); SCID-I = Structured Clinical Interview for DSM-IV Axis I Disorders (First et al., 1997); SCID-PMDD = Structured Clinical Interview for PMDD (American Psychiatric Association, 2013); CIDI = Composite International Diagnostic Interview (WHO, 1997); M-CIDI = Munich-Composite International Diagnostic Interview (Wittchen & Pfister, 1997) WMH-CIDI = World Mental Health Composite International Diagnostic Interview (Kessler & Üstün, 2004); PSST = Premenstrual Symptoms Screening Tool (Steiner et al., 2003); PMSS = Premenstrual Syndrome Scale (Gencdogan, 2006); HC = Hormonal Contraception; PTSD = Post-Traumatic Stress Disorder; ACEs = Adverse Childhood Experiences.*PMDD marked with an asterisk indicate studies that used retrospective screening tools rather than prospective confirmation as required by DSM-5.

Premenstrual Syndrome (PMS)

Twelve individual studies examined PMS (see Table 4). Ten employed retrospective assessment for PMS classification and/or severity, and two utilised prospective methods for both (Crowley et al., 2015; Eisenlohr-Moul et al., 2016). The majority (11/12) studies identified a significant association between trauma and PMS severity and/or likelihood, either as a positive association or dose-response relationship. The average CASP score was 16.9 (cross-sectional; moderate) and 21.5 (cohort studies; moderate).

PMS severity

Six studies examined the severity of PMS in relation to trauma exposure (Azoulay et al., 2020; Crowley et al., 2015; Eisenlohr-Moul et al., 2016; Gumussoy et al., 2021; Saglam et al., 2025; Standeven et al., 2024).

Three studies examined this association whilst controlling for PTSD in a sample of HC-free women, providing the most interpretable evidence (Eisenlohr-Moul et al., 2016; Azoulay et al., 2020; Crowley et al., 2015). The strongest associations were reported by Eisenlohr-Moul et al. (2016), who found that in women with prospectively measured Menstrually Related Mood Disorder (MRMD), physical abuse predicted a stronger association between cyclical increases in *progesterone* and mood symptoms (e.g., depression, interpersonal conflict; $p<0.0083$) than sexual abuse. By contrast, sexual abuse predicted a stronger association between *oestradiol* levels and anxiety symptoms ($p<0.0083$) than physical abuse. This suggests that specific types of abuse may sensitise individuals to distinct hormone fluctuations. Similarly, Azoulay et al. (2020) found that childhood sexual abuse ($r = .243$, $p < 0.01$) and emotional neglect ($r = .198$, $p < 0.05$) were significantly associated with

retrospectively assessed PMS severity, although their independent effects were not assessed. This association was fully mediated by emotion regulation difficulties, with trauma and emotional regulation accounting for 37% of PMS variance, suggesting emotional dysregulation is a potential mechanism through which trauma influences PMS severity. By contrast, Crowley et al. (2015) found no significant difference in prospectively measured symptom severity between MRMD women with and without a history of early sexual abuse.

Two studies examined the independent effect of trauma history (excluding PTSD) on current PMS symptoms in samples with unmeasured HC use. Standeven et al. (2024) found that both the severity ($R = 0.41$, $p = 0.015$) and frequency ($R = 0.42$, $p = 0.013$) of childhood trauma were significant predictors of PMS symptom severity. This trend persisted in groups, including healthy controls. Similarly, Saglam et al. (2025) found that total childhood trauma scores (measuring abuse and neglect), significantly predicted PMS severity ($\beta = 0.266$, $p < 0.001$), with emotional neglect ($\beta = 0.163$, $p = 0.006$) and physical abuse ($\beta = 0.121$, $p = 0.039$) emerging as significant individual predictors. Emotional abuse, sexual abuse and physical neglect were not significant predictors of PMS severity ($ps>0.05$). However, the overall regression model indicated overall childhood trauma as a significant predictor of PMS severity ($F = 32.989$, $p < 0.001$).

One study provided the least interpretable evidence, failing to account for either HC use or PTSD. In an adolescent sample, Gumussoy et al. (2021) reported a significant positive association between severity of overall childhood abuse and neglect and PMS severity ($r = 0.216$, $p = 0.001$), however, associations between individual trauma subscales were not examined.

PMS likelihood

Six studies examined the association between trauma exposure and PMS likelihood, with four providing evidence of a dose-response effect (Bertone-Johnson et al., 2014; Kanamori et al., 2025; Yang et al., 2022; McKinnon, 2009), and the remaining two studies identifying a positive association (Jung et al., 2019; Kfoury et al., 2024).

The most interpretable evidence was provided by one study examining trauma history (PTSD excluded) in a verified HC-free sample of 2000 women. Kanamori et al. (2025) found that those experiencing 4+ ACEs had a 2.81 times greater odds of severe premenstrual symptoms compared to those with 0 ACEs (*aOR* = 2.81, 95% CI [2.12–3.72]).

Three studies provided less interpretable evidence, controlling for PTSD but failing to account for HC use. Jung et al. (2019) found that trauma-exposed women had 31% higher odds of PMS (*OR:* 1.31, 95% CI [1.05–1.63]), but this association became non-significant when adjusting for childhood trauma, indicating that early-life trauma may be a stronger predictor of PMS than lifetime trauma exposure. Yang et al. (2022) provided additional support for a dose-response effect, reporting that for each additional ACE, PMS risk increased by 12% (*PR* = 1.12, 95% CI [1.10–1.14]). Notably, when comparing groups, this association was stronger in individuals without PTSD, suggesting that trauma exposure itself may drive PMS risk independent of PTSD. Similarly, McKinnon (2009) identified a dose-response effect for non-combat-related trauma, where each additional trauma increased PMS risk by 22% (*OR:* 1.22, 95% CI [1.06–1.40]).

The least interpretable evidence came from two studies which failed to account for either HC use or PTSD. Bertone-Johnson et al. (2014) found that women reporting multiple

or severe forms of abuse had 2.8 times greater odds of PMS (*OR* = 2.8, 95% CI [1.5–5.3]) compared to women reporting no abuse, with emotional and physical abuse showing the strongest effects. Similarly, Kfoury et al. (2024) found that psychological abuse ($p < 0.001$), physical abuse ($p = 0.024$), and neglect ($p = 0.007$) significantly predicted the presence of PMS, however, sexual abuse did not ($p = 0.198$). Nevertheless, all trauma types were found to indirectly predict PMS via suicidal ideation.

Trauma severity and likelihood

Four studies examined trauma severity according to PMS status (Azoulay et al., 2020; Gumussoy et al. 2021; Saglam et al., 2025; Standeven et al., 2024).

One study by Azoulay et al. (2020) provided the most interpretable evidence by controlling for both HC and PTSD, finding that compared to controls, those with PMS were significantly more likely to have experienced trauma (p=0.015) and reported significantly more severe trauma (p=0.005).

Two studies provided less interpretable evidence, controlling for PTSD but not HC use (Saglam et al., 2025; Standeven et al., 2024). Saglam et al. (2025) found that compared to those without PMS, women with PMS reported significantly higher severity of total childhood trauma, emotional abuse, physical abuse, sexual abuse and emotional neglect but not physical neglect. By contrast, Standeven et al. (2024) found no significant differences in number or severity of traumatic events in the PMD group compared to all other groups.

Finally, Gumussoy et al. (2021) provided the least interpretable evidence, failing to control for PTSD or HC use. They found that compared to those without PMS, the PMS

group reported significantly higher severity of overall trauma, emotional, physical and sexual abuse (all $p = .001$), but not emotional or physical neglect.

Table 4. Characteristics of studies measuring PMS

Study	Diagnosis	Sample Size	Design	Trauma Measurement	Trauma age + type	Key Findings	Controlled Variables	Dose-response?
Azoulay et al (2020) Israel	PMS and PMDD* **Classification and severity** PSST DMS-5 criteria Retrospective	**N=118** **Age**: 23.4 (3.25)	Cross-sectional	Childhood Trauma Questionnaire (CTQ; Bernstein & Fink, 1998)	Childhood (before age 18). Sexual abuse Emotional abuse Physical abuse. Emotional neglect Physical neglect Trauma was treated as a binary variable (present/absent) for result 1. Trauma treated as a continuous (scores) variable for result 2, 3, 4 and 5.	**Trauma likelihood and severity** 1. PMS/PMDD group significantly more likely to report trauma compared to no/mild-PMS group (28.9% vs. 10%; χ^2 (1) =5.52; p=0.015). 2. Trauma scores significantly higher in PMS/PMDD group compared to no/mild-PMS group (t=2.96 p=0.005; d=0.62). **Symptom severity** 3. Sexual abuse (r=.243; p<0.01) and emotional neglect (r=.198; p<0.05) significantly associated with symptoms severity across groups 4. The relationship between childhood trauma and premenstrual symptoms was completely mediated by emotion regulation difficulties (κ^2=0.16; medium effect size). Mediation effect was only observed for abuse, not neglect.	**PTSD** Yes SCID used to exclude past/ present psychiatric disorders. **HC** Excluded **Trauma types** Did not control for other trauma types **Other** Demographic variables tested for group differences but not included in regression models.	Dose response not studied Positive association between trauma *presence* and PMS/ PMDD *presence* and trauma *severity* and PMS/ PMDD *presence* and trauma *severity* and PMS/ PMDD *severity*

						5. Trauma scores and emotion regulation difficulties accounted for 37% of the variance in premenstrual symptoms ($R^2 = 0.37$; $p<0.001$.		
Bertone-Johnson et al (2014) United States	PMS (moderate to severe) **Classification** COPE Validated measure but not based on DSM criteria Retrospective	**N=1,018** (PMS) N=2,277 (controls) **Age** PMS: 33.9(4.3) Controls: 34.4(3.9)	Longitudinal prospective cohort study from 1989 to 2005 Trauma identified at baseline	'Violence questionnaire' (idiosyncratic measure including items from the CTQ-SF, Revised Conflict Tactics Scale, Sexual Experience-es Survey). All trauma subtypes treated as ordinal variable, categorised according to severity (none, mild, moderate severe). Overall (combined) trauma treated as ordinal variable.	Childhood (<11) and adolescence (11–17). Emotional, physical, sexual abuse, corporal type punishment	**PMS likelihood** Women reporting severe chronic and multiple types of abuse had 2.8 times greater odds of PMS (OR = 2.8, 95% CI: 1.5–5.3) compared to those reporting no abuse Women reporting the highest emotional abuse: OR = 2.6 (95% CI: 1.7–3.9; pTrend < 0.0001); severe childhood physical abuse: OR = 2.0 (95% CI: 1.5–2.8; pTrend < 0.0001); and severe adolescent physical abuse: OR = 1.8 (95% CI: 1.3–2.5; pTrend < 0.0001) were significantly greater odds of PMS than those reporting no abuse. **Dose response** Mild/moderate single-type abuse had **1.5** times greater odds of PMS (OR = 1.5, 95% CI: 1.2–1.9) whereas severe chronic and multiple types of abuse had **2.8** times greater	**PTSD** No **HC** No – did not exclude HC use **Trauma types** Yes **Other** Adjusted for age, demographics, income, BMI, smoking, physical activity, oral contraceptive use and duration, depression history, adult physical/sexual abuse, alcohol intake, and dietary intake of calcium, vitamin D, vitamin B2,	**Yes** Multiple statistics reported (see Key Findings).

						odds of PMS (OR = 2.8, 95% CI: 1.5–5.3). Sexual abuse had weaker, non-significant associations.	vitamin B6, and potassium.	
Crowley et al (2015) United States	MRMD **Classification and severity** DRSP Prospective over two cycles DSM-5 criteria	**N=60** ESA (N=20) No-ESA (N=40) **Age** Mean ages ranged from: 32.9 (6.8) to 34.7 years (8.0)	Secondary analysis of experimental study (Fleischman et al., 2013)	Standard interview (Leserman, et al., 1996).	Early Sexual Abuse (ESA; <17 years) Physical abuse also recorded With ESA (N=20) Without ESA (N=40)	**Symptom severity** No significant differences in premenstrual symptom severity between MRMD women with and without a history of early sexual abuse (ESA), t(53) = –0.42, p = .68. No group differences in core emotional symptom domains (depression, anxiety, anger/irritability, labile mood), t(58) = 1.05, p = .30. Oxytocin was inversely associated with symptom severity only in women with ESA	**PTSD** Yes - MINI used and current PTSD excluded **HC** Yes – excluded prescribed medications, hormone testing used. **Trauma types** Partially – not adjusted for, however, no statistically significant difference between physical abuse between groups. **Other** Participants matched on key demographics. Did not	Dose response not studied No significant association between trauma presence and symptom severity

							statistically adjust for potential confounders	
Eisenlohr-Moul et al. (2016) United States	Menstrually Related Mood Disorder (MRMD)* (prospectively confirmed) **Severity** DRSP DSM-5 criteria Prospective	**N=66** **Age**: 30.34 (6.75)	Prospective observational	Standardized interview (Leserman et al., 1997)	Lifetime Physical abuse Sexual abuse	**Symptom severity** Physical abuse predicted a stronger association between cyclical increases in progesterone and mood symptoms, including depression ($\beta = 2.29$, $p < .0083$), interpersonal conflict ($\beta = 2.64$, $p < .0083$) mood lability ($\beta = 4.82$, $p < .0083$), and rejection sensitivity ($\beta = 2.76$, $p < .0083$). Sexual abuse predicted a stronger association between oestradiol levels and anxiety symptoms ($\beta = 0.18$, $p<0.0083$) Abuse history strengthened hormone-symptom links in MRMD.	**PTSD** Yes – MINI used to exclude current PTSD **HC** Yes - excluded prescription medication use (**Trauma types** Yes **Other** Controlled for menstrual cycle day, centred hormone levels (oestradiol, progesterone), trauma type (physical vs. sexual abuse), abuse-hormone interactions	Dose response not studied Positive association between presence of physical and sexual abuse and PMDD severity

Gumussoy et al (2021) Turkey	PMS **Classification and severity** PMSS; score ≥111 out of 220 for PMS classification; based on DSM-III/IV-R criteria. Retrospective	**N=702** **Age**: 18.37 (1.14)	Cross-sectional	Childhood Trauma Questionnaire (CTQ; Bernstein et al., 1994) - Turkish version (Sar et al., 2012).	Childhood physical abuse, emotional abuse, sexual abuse, emotional neglect, and physical neglect Age not specified	**Symptom severity** Significant association between PMSS score and overall trauma scores (r = 0.216, p = .001) **Trauma severity** PMS group scored significantly higher on emotional abuse (t = -6.329, p = .001), physical abuse (t = -5.342, p = .001), and sexual abuse (t = -3.911, p = .001) and total score (t = -4.239, p = .001). No group differences on emotional or physical neglect scores. PMS group also reported significantly higher scores on all mental health comorbidities (e.g., depression, anxiety, phobic anxiety; p=0.001)	**PTSD** No **HC** No mention of hormonal contraceptives **Trauma types** Not applicable **Other** None stated	Dose response not studied. Positive association between trauma severity and PMS severity and PMS presence and trauma severity
Jung et al (2019) United States	PMS **Classification** Questionnaire based on the COPE Retrospective Not based on diagnostic criteria or widely validated	**N= 2021** (in analysis of interest) Overall sample N=2924 (PMS= 857 controls= 2067) **Age**	Cross sectional data collection for result of interest (Within Nurses' Health Study II Longitudinal	**Brief Trauma Questionnaire (BTQ) (Schnurr et al. 2005)** used in analysis of interest as primary measure for trauma exposed classification – this is not entirely clear from wording in paper. Two other measures were used for childhood trauma specifically	Lifetime Traumas included in BTQ: sexual abuse/assault, physical abuse/assault, emotional abuse, serious accident/injury natural disasters, war/combat	**PMS likelihood** Trauma-exposed non-PTSD women had an increased likelihood of PMS (OR=1.31, 95% CI=1.05–1.63) compared to non-trauma exposed non-PTSD group. When childhood trauma was adjusted for, this was no longer statistically significant (OR=1.24, 95% CI=0.99–1.54)	**PTSD** Yes – analysis separated for trauma-exposed with and without PTSD **HC** No mention of hormonal contraceptives **Trauma types** Not applicable	Dose response not studied for trauma exposure alone Positive association between trauma exposure and likelihood of PMS.

	based on modified use	Mean age ranged from 33.9 (4.2) 34.4 (3.9) years	cohort study)	and were controlled for in analysis of interest suggesting they were not the exposure variables. Score based on presence perceived life threat and physical injury	exposure, sudden unexpected death of loved one, serious illness, witnessing serious illness or injury, and other/open text.		**Other** Adjusted for age, parental education, BMI, smoking, alcohol use, oral contraceptive use, antidepressant use, dietary intake (riboflavin, B6, potassium, calcium, vitamin D).	
Kanamori et al (2025) Japan	Premenstrual symptoms and 'PMDD' **Classification** Premenstrual Dysphoric Disorder (PMDD) scale (Miyaoka et al., 2009 DSM-IV criteria and **Severity** MDQ – Japanese version (Miyaoka et al., 2009)	**N=2000** **Age**: 33.73 (6.42)	Cross-sectional	The Adverse Childhood Experiences (ACEs) – Japanese version (Fujiwara, 2022)	Childhood (before age 18) 15 types of trauma: parental death, parental divorce, mental illness in the household, substance abuse in the household, mother treated violently, physical abuse, physical neglect, emotional abuse, emotional neglect, childhood	**Symptom severity** Women with 4+ ACEs were 2.81 times more likely to experience severe premenstrual symptoms (adjusted odds ratio = 2.81, 95% CI:2.12–3.72), compared to women with 0 ACEs. Increasing ACEs was associated with higher odds of severe premenstrual symptoms: 1 ACE (aOR = 1.59, 95% CI: 1.20–2.10, p = 0.001), 2 ACEs (aOR = 1.66, 95% CI: 1.19–2.30, p = 0.003), 3 ACEs (aOR = 3.04, 95% CI: 2.31–4.02, p < 0.001), and 4+ ACEs (aOR = 2.81, 95% CI: 2.12–3.72, p < 0.001), compared to women with 0 ACEs **PMS likelihood**	**PTSD** Yes Controlled for current psychiatric illness in analyses but self-report with no verification and PTSD not explicitly addressed **HC** Excluded 'contraception' (presumably hormonal but not specified) **Trauma types** N/A	**Yes** Increasing ACEs was associated with higher odds of severe premenstrual symptoms Positive association between 4+ ACE presence and likelihood of PMDD

	Both retrospective				poverty, overcontrol, bullying, sexual abuse, hospitalization due to chronic disease, and natural disaster. (yes/no)	Women with 4+ ACEs had a 5.61 times higher odds of meeting PMDD criteria (aOR = 5.61, 95%CI: 2.65–11.89) compared to women with fewer than 4.	**Other** Age, BMI, smoking, education, marital status, income, current psychiatric illness in all analyses of interest.	
Kfoury et al (2024) Lebanon	PMS PSST – Arabic version (Younes et al., 2021) DSM-IV criteria Retrospective	**N=915** **Age**: 27.09 (9.28)	Cross-sectional	Child Abuse Self Report Scale (CASRS-12) – Arabic version (Fekih-Romdhane et al., 2022).	Childhood (age not specified) Physical abuse Psychological abuse Sexual abuse Neglect Trauma treated as continuous variable (scores for each subtype) no total score	**PMS likelihood** 1**. Unadjusted model:** participants with PMS reported higher levels of psychological abuse (OR: 1.27, 95% CI: 1.16-1.39), physical abuse (OR: 1.18, 95% CI: 1.08-1.29), and sexual abuse (OR: 1.14, 95% CI: 1.03-1.25) compared to those without PMS. However, neglect was higher in the non-PMS group (OR: 0.95, 95% CI: 0.91-0.99). 2. **Direct effects:** Psychological abuse (β = 0.17, p < 0.001), neglect (β = -0.06, p = 0.007) and physical abuse (β = 0.11, p = 0.024) significantly directly predicted PMS. Sexual abuse (β= 0.07, p = 0.198) did not significantly directly predict PMS, however, it did indirectly predict PMS via	**PTSD** No **HC** No – hormonal contraceptives included in sample and not controlled for **Trauma types** No – did not control for other abuse types (mediation analysis for each type separately) **Other** Age, education, financial burden and marital status (for result 2 and 3 only)	Dose response not studied Positive association between abuse (except neglect) and PMS presence Abuse (except sexual abuse) directly predicted PMS presence All subtypes of abuse indirectly predicted PMS presence

						suicidal ideation (β = 0.10, 95% CI 0.05-0.18). 3. **Indirect effects:** all trauma significantly indirectly predicted PMS and suicidal ideation significantly mediated this relationship: Psychological abuse (β=0.08,95% CI:0.03−0.15), neglect (β=0.01,95%CI:0.004−0.03), physical abuse (β=0.09,95% CI:0.04−0.16), sexual abuse (β=0.10,95% CI:0.05−0.18).		
McKinnon (2009) United States	PMS **Classification** Diagnosis of PMS by healthcare provider (current self-reported moderate to severe symptoms) not verified **or** Questionnaire based on the COPE	**N=502** (cases=72; controls= 430) **Mean age**: 38.6 (PMS) 35 (non-PMS)	Cross-sectional data (Case-control elements in design)	Sexual Violence exposure: based on National Violence Against Women Survey (NVAWS; Kilpatrick et al,1992) and National Women's Study (NWS) **and** Childhood/adolescent sexual and physical abuse: seven questions based on the Childhood Trauma Questionnaire (Bernstein et al., 2003)	Lifetime Sexual violence/ assault Childhood sexual and physical abuse Non-sexual traumatic experiences Combat-related traumatic experiences Non-combat related trauma	**PMS likelihood** In multivariate analysis, there was a significant association between lifetime completed sexual assault (OR:2.42, 95% CI= 1.33-4.40) **and number of Non-Combat Related Traumas** (OR = 1.22, 95% CI = 1.06-1.40) and PMS. All other trauma (e.g., childhood sexual/physical abuse and combat-related trauma) were not significantly associated with PMS in analyses.	**PTSD** Yes Measured via self-report diagnosis (current & historical) **and** PTSD subscale (DIS-IV; current) Not controlled for in final analysis as its effect on PMS became non-significant when adjusted for other predictors **HC**	**Yes** For non-combat related traumas with each additional trauma there was an 22% increased odds of PMS

	Retrospective			**and** Non-sexual traumatic experiences: the Diagnostic Interview Schedule (DIS-IV) subscale for PTSD **plus** nine questions for combat-related trauma			No mention of hormonal contraceptives **Trauma type** Isolated each trauma type by controlling for other trauma types (see table 2)! **Other** Age, body mass index (BMI), smoking status migraine headaches anxiety disorder, current depression (assessed with CIDI-SFMD), number of chronic medical problems.	
Saglam et al (2025) Turkey	PMS **Severity and classification** PSS Retrospective DSM-III and DSM-IV criteria	**N=437** **Age**: 26.44 (5.75)	Cross-sectional	Childhood Trauma Scale (Bernstein et al., 1994) – Turkish version (Sar er al., 2012)	Childhood (age not specified) Emotional, physical and sexual abuse; physical and emotional neglect	**Trauma severity** Total childhood trauma score was significantly higher in individuals with PMS compared to those without PMS ($t(435) = 5.000$, $p < 0.001$). Emotional neglect ($t = 4.306$, $p < 0.001$), physical abuse ($t = 3.563$, $p < 0.001$), emotional abuse ($t = 4.197$, $p < 0.001$), and sexual abuse ($t = 3.083$, $p < 0.001$) scores were	**PTSD** Yes – excluded self-reported psychiatric disease however, no verification, and PTSD not explicitly addressed. **HC** No mention of hormonal contraceptives	Dose response not studied. Positive association between total trauma score and PMS severity and likelihood

						significantly higher scores in the PMS group compared to the non-PMS group. However, physical neglect scores were not significantly different between groups (t = 0.745, p = 0.457). **Symptom severity** **Total childhood trauma score (B = 0.904, p < 0.001,** β=0.266**), e**motional neglect score (B = 1.640, p = 0.006 β = 0.163) and physical abuse score (B = 1.775, p=0.039; β = 0.121) significantly predicted PMS severity. However, emotional abuse sexual abuse and physical neglect were not significant predictors of PMS severity (p>0.05). Total childhood trauma score explained 6.8% of the variance in PMS severity (R2=0.068). The overall regression model indicated childhood trauma is a statistically significant predictor of PMS severity (F=32.989, p<0.001).	**Trauma types** Yes – all abuse types entered into single regression model **Other** None specified.	

Standeven et al. (2024) United States	PMDD*/PMS **Classification and severity** PSST Retrospective	**N = 391** (PMDD/ PMS= 34; PME= 38; Healthy controls= 217; Psychiatric controls= 102) **Age**: 32.7 (4.38)	Cross-sectional (secondary analysis of data from a prospective cohort study)	Childhood Traumatic Events Scale (CTE-S; Pennebaker et al., 1988)	Childhood (before age 17). **6 trauma types:** 1) Death of close person, 2) Parental upheaval (divorce, separation), 3) Traumatic sexual experience, 4) Physical violence, 5) Extreme illness/injury6) Other major upheaval Trauma treated as continuous variable (number and severity of events) for analysis of interest PMS treated as continuous (severity) and binary variable (PMD, PME, control groups)	**Symptom severity** Within PMD group, the number (R=.42, p = .013) and severity (R = .41, p = .015) of childhood traumatic events predicted premenstrual symptom severity Across groups, positive correlation between number (R = .18, p < .001) and severity (R = .22, p < .001) of childhood traumatic events and premenstrual symptom severity across all groups. **Trauma likelihood and severity** No significant differences in number or severity of traumatic events in PMD group compared to all other groups (p>0.05).	**PTSD** Yes (for all groups except PME) SCID conducted and all comorbid disorders excluded from PMS/ PMDD group. **HC** No mention of hormonal contraceptives **Trauma types** N/A **Other** Group-level ANOVA models controlled for medication use, race, income, and education. However, correlational analyses and pairwise comparisons were not.	Dose response not studied. Positive association between number and severity of traumatic events and PMS/PMDD symptom severity but not likelihood trauma.

Yang et al (2022) Iceland	PMDs (including PMS and PMDD*) **Classification** Modified PSST DSM-IV criteria Retrospective	**N= 8640** (in analysis of interest) **Age**: 35.6 (SD=9.4) reported for larger sample of 11,973	Cross-sectional cohort study	ACE-International Questionnaire (ACEIQ; WHO, 2020) – Icelandic version Trauma treated as a categorical variable (1, 2, 3, 4+ ACEs) in analyses of interest.	Childhood (before age 18) Abuse (sexual, physical, emotional); Neglect (emotional and physical); Household dysfunction (e.g., witnessing family violence); Other (e.g., bullying, exposure to war)	**PMS likelihood** For each additional ACE, the prevalence of PMDs (PMS and PMDD) increased by 12% for those without PTSD (PR = 1.12 (95% CI: 1.10–1.14). This was a stronger effect than for those with PTSD (1.03 (95% CI= 1.02–1.05)	**PTSD** Yes, separated analysis for those with and without PTSD **HC** No mention of hormonal contraceptives **Trauma types** Controlling for other trauma types is not applicable here, not drawing conclusions on specific trauma types) **Other** Analyses of interest adjusted for age at survey, childhood deprivation, educational level, marital status, employment status, income, age at menarche, parity, alcohol intake, smoking status, and BMI	**Yes** PMD prevalence increased by 12% for each additional ACE.

Note. PMDD = Premenstrual Dysphoric Disorder; PMS = Premenstrual Syndrome; PSST = Premenstrual Symptoms Screening Tool (Steiner et al., 2003); DSM = *Diagnostic and Statistical Manual of Mental Disorders*; MRMD = Menstrually Related Mood Disorder; DRSP = Daily Record of Severity of Problems; PMSS = Premenstrual Syndrome Scale (Gençdoğan, 2006); MDQ = Menstrual Distress Questionnaire (Moos, 1968); HC = Hormonal Contraceptives; PTSD = posttraumatic stress disorder. *PMDD marked with an asterisk indicate these are not considered PMDD diagnoses according to the standards of this review.

Discussion

This review aimed to examine the association between trauma and premenstrual Disorders (PMDs), focusing on non-PTSD trauma. A total of 19 studies were included following a systematic search of published and grey literature. Based on the findings, several inferences can be drawn.

PMS

Studies relating to PMS provide the most convincing evidence of an association with trauma, independent of PTSD. The majority of studies found a significant association between trauma and PMS likelihood and/or severity, with the majority of these controlling for PTSD. The most evidence was observed for the likelihood of PMS as a function of trauma exposure, and several studies demonstrated a dose-response relationship, such that as trauma severity or incidence increased, the odds of PMS increased. For PMS severity, beyond the consistency of findings, evidence was bolstered by one study identifying that different types of abuse corresponded with increased sensitivity to distinct hormones, and each was associated with distinct symptoms, offering a potential pathways via which abuse influences PMS. It is notable that the only study finding no association utilised group-level analysis, which may have obscured within-person variations in symptom severity. This analytic approach is made less meaningful in the context of a whole sample with a MRMD classification, where between-person differences are expected to be minimal given the shared diagnosis. Across most studies, retrospective assessment limited methodological robustness. However, the consistency of findings, which are mostly maintained when isolating the most interpretable and high-quality studies, suggests it can be concluded with moderate confidence that trauma, independent of PTSD, is a risk factor for the development and severity of PMS.

PMDD

Studies relating to PMDD demonstrated less consistent results. Whilst the majority of studies found a significant positive association between trauma exposure and PMDD severity and/or likelihood, two reported non-significant findings. For PMDD likelihood, all studies demonstrated that trauma, independent of PTSD, significantly increased the odds of PMDD, however, all were rated low for interpretability. Notably, one study examining the likelihood of both PMS and PMDD as a function of trauma found that the association was almost twice as strong for PMDD. In contrast, studies relating to PMDD severity provide less convincing evidence of an independent association owing to more mixed findings and less strict control for PTSD. Only half of studies demonstrated a significant positive association between trauma and PMDD severity and it is notable that the studies of highest interpretability reported non-significant results. Overall, the mixed findings and variability in study quality and interpretability limit the ability to draw firm conclusions. However, findings suggest that trauma, independent of PTSD, may be a risk factor for PMDD, particularly the likelihood of developing PMDD.

Trauma according to PMD status

Across both groups, the trauma-PMD association was also examined by comparing likelihood or severity of trauma according to PMD status (i.e., PMD versus. no PMD). The consistency of results across groups and varying study quality provides convincing evidence that women with PMDD are more likely to have experienced trauma, whilst women with PMS are more likely to have experienced more severe trauma. These findings further support the consideration of trauma as a risk factor for PMDs. However, as half of the studies did not adequately control for PTSD or HC, this does not provide strong support of an association between trauma and PMDs, independent of PTSD

Mechanisms

Whilst this review focused on ascertaining the direction and strength of the independent association between trauma and PMDs, several included studies also highlighted mediators and moderators, providing clues on potential mechanisms. These include emotional regulation, depression, trait anger, harm avoidance, suicidal ideation, oxytocin and stress appraisal. Notably, many of these have been independently linked to altered HPA-axis activity, suggesting that results largely support current theoretical frameworks that an interaction between HPA axis dysfunction and emotion regulation difficulties may mediate the heightened sensitivity to hormonal fluctuations seen in trauma-exposed individuals with PMDs (Tonon et al., 2024). Importantly, not all studies examining potential mechanisms controlled for PTSD and therefore this review does provide further clarity on whether these pathways are independent of PTSD.

Overall, these findings are largely consistent with prior reviews suggesting an overall association between trauma and PMDs (Bencker et al., 2024; Grewal et al., 2024; Islas-Precadio et al., 2021). For PMDD, findings relating to trauma prevalence according to PMDD status are largely consistent with Grewal et al.'s (2024) recent review. Our review extends these findings by demonstrating that trauma is also associated with PMDD severity and likelihood. By contrast, unlike Islas-Precadio et al., this review has been cautious in drawing conclusions about the independent impact of individual trauma types or development stages. Across groups, a variety of trauma types and classifications were included (e.g., severity of lifetime emotional neglect, duration of childhood sexual abuse, severity of total trauma exposure). Notably, across studies, trauma was operationalised in various ways (e.g., as a binary or continuous variable) which has been shown to result in diverging effects of

specific trauma types on PMD outcomes (see Runtz et al, 2000). As such, cautious interpretation is required. Further, many studies failed to statistically control for co-occurring trauma types, it is therefore unclear whether observed associations reflect the unique impact of a specific trauma type or the cumulative effect of multiple, possibly unmeasured, traumas.

Strengths and Limitations

Strengths

There are several strengths to this review. Firstly, a systematic search strategy was employed, utilising electronic databases, grey literature and forward/backward searching of references, allowing for comprehensive results. This reviews extends findings of prior reviews by applying the requirement that all included studies align with diagnostic criteria or utilise a validated measure. This allowed for a clear distinction between PMDD and PMS and ensured consistency in their definition across studies, increasing validity of conclusions. Bencker et al. (2024) used an inconsistent definition of PMS, and the current review therefore builds on this by enabling disorder-specific associations. Further, the current review extends Grewal et al.'s (2024) findings through its broader focus, beyond trauma prevalence, allowing for the disentangling and distinguishing of PMD likelihood and severity outcomes, allowing for more meaningful conclusions on the trauma-PMD association. In addition, this review included trauma across the lifespan, rather than focusing on specific developmental periods (e.g., Islas-Precadio et al., 2021).

Limitations

There are several important limitations to address. Notably, the majority of studies utilised cross-sectional methodology and the implications for this are three-fold. Firstly, research has identified that negative mood at assessment can significantly influence trauma recall, an

important consideration in a population that experiences frequent fluctuations in mood (Faul & LaBar, 2023). Indeed, research has identified that women with PMDD were more likely to appraise an event as more stressful, undesirable and horrifying than controls (Fontana & Palfai, 1994). No studies controlled for this, so it remains unclear if observed associations merely reflect the increased trauma recall in this group. Further, only two studies utilised longitudinal methods with the remaining cross-sectional studies preventing conclusions on directionality. As such, the potential for a bidirectional association cannot be ruled out, such that PMDs may increase subsequent trauma; notably, this is relevant only for trauma experienced in adulthood, or following menarche. Second, cross-sectional designs most often coincide with retrospective measurement of PMDs with no hormonal assays or confirmation of symptom onset during the luteal phase. This substantially undermines validity, and likely overestimates prevalence and severity outcomes, which may have inflated observed associations with trauma. Third, in this review, the cross-sectionally derived prevalence of PMDs was considered a proxy to the likelihood of developing PMDs and it is noted that the conflation of these distinct variables may be misleading.

Another notable limitation was this review's approach to PTSD with the aim of identifying the influence of non-PTSD trauma. Firstly, the review excluded studies that explicitly measured and included individuals with PTSD alongside including studies that did not consider PTSD at all. Whilst this decision reflects the desire to exclude *known* cases of PTSD, it is noted that in reality, there may be no differences in the actual rates of PTSD between these studies. Therefore, we may have excluded studies on this basis that could have added valuable contributions. Second, a liberal definition was applied to 'control' of PTSD. For example, whilst some studies used a SCID to identify and exclude all mental health disorders, others only excluded self-reported disorders or statistically controlled for them. As

such, even with careful consideration for this when interpreting findings, the extent to which results truly reflect the influence of trauma, independent of PTSD, is unclear.

Research implications

This review highlights the lack of methodologically robust evidence examining the association between trauma and PMDs, which likely contributed to the mixed findings. Further high-quality research longitudinally examining the onset of prospectively assessed PMDs is required to further unpick and understand their association with trauma. Based on the state of the current evidence, this review proposes several recommendations for future research: (1) utilisation of longitudinal within-subject designs with prospective assessment of PMS/PMDD for classification and severity (2) explicit measurement and control for current and historical PTSD, either via exclusion or separating analyses in those with/out PTSD (3) accurate assessment of reproductive status via hormonal assays and exclusion of hormonal medication (4) controlling or matching for mood and cycle phase at the time of trauma recall (5) measurement of and control for multiple trauma types if drawing conclusions about the unique impact of a single trauma type (e.g., controlling for sexual trauma when examining the impact of emotional neglect) (6) adequate control for well-established confounding variables including recent stress, age, obesity and alcohol use.

There remains little understanding of the factors explaining this relationship, and future research should further explore potential mediators, particularly those malleable to psychological intervention (e.g., emotion regulation) to support progress in treatment for PMDs. Research should also examine potential moderators to identify protective factors that buffer against PMD onset or severity.

Clinical practice and policy implications

The results of this review also generate several recommendations for clinical practice that extend those of prior reviews, by specifying the association between non-PTSD trauma and PMDs (e.g., Grewal et al., 2024). The current findings suggest that services should not rely on the exhibition of PTSD symptoms to prompt enquiry into trauma and point to the need for routine enquiry, for example, through a screening tool such as the Trauma and Life Events Checklist (Carr et al., 2018). Prior research has indicated that trauma is often missed within this population, for example, Al-Manteen et al. (1999) identified that despite many women having experienced profound and multiple instances of sexual abuse, none had trauma documented in their medical records, underscoring the importance of standardised and routine enquiry. Clinicians working with individuals with PMDs should be aware of the association with non-PTSD trauma and PMDs and adopt a universal trauma-informed approach to assessment and intervention. Although more research is required, several mediators were highlighted including emotional regulation difficulties, depression, trait anger, harm avoidance, low self-directedness which could guide treatment targets. Interestingly, recent research has identified that early-maladaptive schemas, considered to be formed by early experiences such as trauma, fluctuate across the menstrual cycle and may therefore also be of clinical relevance (Sanayeh et al., 2023). Overall, the context of limited research and individual differences highlights the importance of developing idiosyncratic formulations to understand an individual's vulnerability, precipitating and maintaining factors, to guide treatment. Notably, given the results of the current review, treatment for PMDs in the absence of PTSD may include directly addressing past traumas if they are present and therefore clinicians should be appropriately trained in trauma-focused therapies.

Conclusions

To our knowledge, this is the first review attempting to examine the association between PMDs and trauma in the absence of PTSD. Findings overwhelmingly support an independent association between non-PTSD trauma and PMS likelihood and severity, with particularly strong evidence for PMS likelihood. By contrast, whilst findings relating to PMDD also demonstrate mostly positive associations, they provide equivocal evidence of an independent association. Notably, given the complexity of all findings owing to high heterogeneity in methodology, a level of nuance is required when interpreting findings with heavy consideration for study quality. Notably, the predominance of cross-sectional studies prevents conclusions on causation or direction, and a bidirectional relationship is possible. Nevertheless, findings suggest that a history of trauma, in the absence of PTSD, may lead to increased sensitivity to hormones fluctuations across the menstrual cycle. Results underscore the importance of non-PTSD trauma being routinely considered in PMDs and highlights the need for additional research.

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Service Improvement Project

How can Oxfordshire Psychosexual Therapy Service improve psychological provision for people with vaginismus?

Word Count: 5100

Candidate**:**

Louise Nolan

louise.nolan@hmc.ac.uk

Internal Supervisor:

Dr Susannah Jenner

External Supervisor:

Dr Eike Adams and Dr Emma Evans (Maternity Leave cover)

Doctorate in Clinical Psychology

Department of Psychology, University of Oxford, Isis Education Centre, Warneford Hospital, Oxford, OX3 7JX

Proposed Journal: This report is intended to be published in BMJ Sexual and Reproductive Health (see Appendix N for Author Guidelines). This was selected given the relevance of vaginismus and its treatment to sexual and reproductive health.

Abstract

Vaginismus is a common sexual disorder, and psychosexual therapy is a highly effective treatment approach. Despite this, the Oxfordshire Psychosexual Service noticed that adherence to certain aspects of therapy was low and there was limited research to draw on to understand factors influencing treatment adherence in vaginismus. Therefore, the aim of this project was to identify barriers and facilitators to treatment adherence, as well as treatment preferences, in patients with vaginismus in this service. **Methods:** This project utilised a mixed-methods approach, across three phases. Phase A involved an audit of existing outcome data and staff consultation to identify key issues. Phase B involved a patient survey (N=17) examining barriers, facilitators, and treatment preferences. Phase C entailed staff (N=5) and patient (N=2) interviews to further explore these issues. **Results:** Overall, this project identified several barriers and facilitators to adherence at all levels of the WHO Multidimensional Adherence Model (e.g., patient-related factors), although there was some divergence in staff and patient views regarding where responsibility for adherence lies. The current therapeutic offer within the service is highly valued by patients and staff, and there were significant reservations regarding the introduction of group-based support. **Implications:** Based on the findings, six recommendations for service improvement were developed, emphasising that any changes to service provision would require careful consideration and additional evaluation to monitor effectiveness.

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Introduction

Summary of literature

Vaginismus is a common sexual disorder defined as persistent or recurrent difficulties in allowing vaginal entry of a penis, a finger, and/or any object, despite an expressed wish to do so (Bhasin & Basson, 2011). In the DSM-5, vaginismus is combined with dyspareunia (painful intercourse) and classified under Genito-Pelvic Pain/Penetration Disorder (American Psychological Association, 2013). Prevalence rates are difficult to establish but estimated to be 0.5-1% in a community setting and 5-30% in primary care settings (Fugl-Meyer & Sjogren, 1999; Gaber et al., 2021).

Vaginismus is considered within the National Institute for Health and Care Excellence (NICE) guidance for Pelvic Floor Dysfunction, which encompasses a broad range of conditions (e.g., vaginismus, bowel dysfunction, pelvic organ prolapses) (NICE, 2021). In this guidance, no specific psychological treatment is recommended and notably, vaginismus may be considered unique from other conditions in this category due to the significant role of psychosocial factors in its development and maintenance (Banaei et al., 2021). As such, there is little guidance to draw on for services attempting to meet the psychological needs of women with vaginismus.

There remains relatively little research into vaginismus and efficacy of psychological treatment, nevertheless, a systematic review found a ‘success’ rate of 79% across studies examining psychosexual treatments including Cognitive Behavioural Therapy, Psychoeducation, and Behavioural Sex Therapy (Maseroli et al., 2018). Notably, there are several barriers to seeking and receiving appropriate treatment such as lack of awareness of

vaginismus and stigma (Pithavadian et al., 2024). Given these challenges, it is especially important that sufferers are supported to fully adhere to treatment when it is sought.

Barriers and facilitators to treatment adherence

Treatment adherence refers to the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider (Sabate, 2003). In vaginismus, an internet-based intervention study found that only 32.5% of patients with vaginismus adhered to all psychological treatment sessions (Zarski et al., 2017). As expected, those adhering to protocol and completing all treatment sessions demonstrated significantly higher improvements across multiple outcomes. Barriers are defined as characteristics of an individual or system that serve as obstacles to the person initiating or adhering to treatment (Xu et al., 2007; Tucker et al., 2004). Examples of barriers in psychological therapy include stigma, lack of motivation and time constraints (Mohr et al., 2010). Facilitators are personal or structural factors that encourage uptake or adherence in treatment (Farhoudian et al., 2022). Examples of facilitators in psychological therapy include clinician characteristics (e.g., attitude and empathy), support from significant others, societal attitudes, flexibility of service delivery (e.g., online therapies) (Carroll et al., 2021; Baker et al., 2022). Barriers and facilitators to adhering to psychological treatment for vaginismus remain unexplored and are crucial to ensuring optimal outcomes and the accessibility of services.

Treatment preferences

Treatment preferences refer to the relative desirability or acceptability of interventions compared to their alternatives (U.S. Food & Drug Administration, 2020). Preferences such as those relating to mode of psychological therapy, time, place and therapist can ensure more cost-effective use of available resources and have been shown to influence adherence and

outcomes in psychological treatment (Williams et al., 2016). Research on treatment preferences in vaginismus is scant and likely relates to rates of adherence (Losi et al., 2021).

Service Improvement

The service

The Oxfordshire Sexual Health Clinic has a Psychosexual Therapy Service (PTS) commissioned to provide assessment, advice and short-term treatment (6-8 sessions) to outpatients with a variety of presentations (e.g., vaginismus, erectile dysfunction) including both individual and couples' work. Of the women on the waitlist, 76% have vaginismus. Currently, the service primarily offers behaviourally focused psychosexual therapy, involving psychoeducation, relaxation exercises, and gradual exposure to dilators between sessions.

Staffing capacity is relatively low, totalling 1FTE across 3 permanent clinical staff, including two Psychosexual Therapists (both 0.4FTE) and one Principal Clinical Psychologist (0.2FTE), as well as one fixed-term Trainee Clinical Psychologist (0.2FTE) and one fixed-term Psychosexual Therapist (0.2FTE).

Rational for service improvement

Rationale 1: Anecdotally, the lead psychologist has reported an issue with adherence with certain aspects of treatment offered (e.g., homework tasks). This is despite initial uptake being high, with approximately 80% of those referred subsequently commencing treatment. Given the importance of treatment adherence in improving outcomes, the service is seeking to understand the barriers and facilitators to treatment adherence.

Rationale 2: the service has recognised an increase in demand for vaginismus treatment, leading to longer waitlist times of 9 to 12 months. The service would like to improve this and has scope to diversify psychological provision within the boundaries of service capacity. Given the lack of specific NICE recommendations to guide such decisions, the service wants to identify treatment preferences of service users with vaginismus. Identifying alternative ways of meeting treatment needs may reduce waitlist times, for example, group therapy may be a cost-effective and appropriate alternative for some clients (Malhotra & Baker, 2019). Oxford University Hospitals NHS Trust identified *'Increasing patient and public involvement'* a key strategic priority, emphasising the importance of service-users in the development of services.

To address both issues, it is important to first identify how well the service is currently doing via a service audit using existing outcome measures, which has not yet been conducted within the PTS. Given the scarcity of research regarding adherence to vaginismus treatment, methodology will consider the WHO Multidimensional Adherence Model, which emphasizes 5-levels influencing treatment adherence including patient-related factors, social/economic factors, therapy-related factors, condition-related factors and health-system related factors (WHO, 2003).

Aims

This project aims to:

1. identify the current outcomes of those with vaginismus who have accessed psychosexual treatment within the service via an Audit
2. identify the barriers to adhering to psychosexual treatment
3. identify the facilitators to adhering to psychological/psychosexual treatment

4. identify the treatment preferences of women with vaginismus, and what makes some treatments more preferable than others
5. provide recommendations on improving psychological treatment adherence and psychological provision, based on findings.

Service role

- The external supervisor, Dr Eike Adams, is the lead Clinical Psychologist in the service and supported project design and recruitment.
- Staff assisted with patient recruitment and participated in staff consultation (phase A) and staff interviews (phase C).

Method

Participants

Patient eligibility criteria

Patients were included if they met the following criteria:

- 18 years or older
- on the waitlist for vaginismus psychosexual therapy ('waitlist' group)
- currently in psychosexual therapy or up to 6-months post-therapy for vaginismus ('treatment' group)
- capacity to provide consent and fluent in English

Staff eligibility criteria

Staff were included if they met the following criteria:

- deliver psychosexual therapy to patients with vaginismus in the Oxfordshire PTS
- have done so for 3> months

Recruitment

Staff within the service facilitated all patient recruitment. Service users were offered information leaflets during routine appointments, and a poster was placed within the service facility. An email was also sent by one staff member to all individuals with vaginismus on their waitlist and in treatment. All materials included a QR code, link to the survey or interview opt-in, and researcher contact details (Louise Nolan; louise.nolan@hmc.ox.ac.uk). Public and Patient Involvement (PPI) included two individuals with lived experience of mental and/or psychosexual health difficulties who were asked to be involved via the Oxford Pelvic Pain Service (via Dr Emma Evans) and People's Experience Group. The trainee held

a one-to-one meeting with each individual and asked for input on study objectives, interview questions, consent and debrief forms, to ensure they are acceptable and understandable.

Design

This project involved three phases, which are detailed below.

Phase A – Audit and Consultation

The first stage involved an audit of existing data gathered from the Individual or Couple's Evaluation Sheet, a pre- and post-therapy outcome measure (see Appendix F), and staff consultation. This elicits information regarding confidence, self-esteem, knowledge of sexual problem and helpfulness of therapy. Following the audit, consultation took place with two staff involved in delivering psychosexual therapy, to identify specific issues with psychosexual therapy adherence, which informed the patient survey and interview questions.

Phase B – Patient Survey

A patient survey (see Appendix G) was initially developed from existing literature and staff consultation. This was further refined through feedback from PPI, which recommended improved clarity on meaning of barriers and facilitators, minimising survey length and expanding gender and sexuality response options. The patient survey, on Microsoft Forms, elicited views on treatment preferences, barriers and facilitators, as well as collecting demographic information. Due to the sensitive nature of psychosexual difficulties, to encourage participation and enhance psychological safety, the survey was completely anonymised. The survey link was sent via email from August to October 2024.

Phase C – Patient and Staff Interviews

The final stage involved semi-structured interviews with patients and staff (see Appendix H for interview schedules). The questions were developed based on existing literature, consultation with staff (Phase A), and methodological considerations (e.g., thematic analysis). Questions were refined following consultation with PPI, who recommended more accessible wording (e.g., 'engagement' versus 'adherence'), clarity on the research purpose and advance guidance on interview questions. Several measures were taken to maximise recruitment, such as an optional phone call or email contact with the researcher, recruitment via email opt-in and staff members, and extending length of recruitment window by eight months. Despite this, there was considerable difficulty in recruiting patients for interviews. Two patients were recruited via survey opt-in. As such, interviews were extended to staff. Interviews were approximately 30 minutes in duration and held online using Microsoft Teams, after which they were recorded and transcribed.

Data analysis and management

Audit and Patient Survey

Descriptive statistics were used to report quantitative aspects of the audit and survey; this was tabulated and described. Selected qualitative data from patient surveys was used to illustrate corresponding quantitative results.

Interviews

Patient Interviews

Given the small sample (n=2), full thematic analysis was not appropriate, and a 'light-touch' thematic approach was used, guided by the three key aims of the project: understanding barriers, facilitators and preferences. Each transcript was read twice, and

content relating to the project aims was highlighted, responses were then mapped against these aims and thematised, allowing for a descriptive summary with illustrative quotes.

Staff interviews

Due to the relatively limited research exploring treatment barriers, facilitators and preferences in vaginismus, inductive thematic analysis was utilised (Braun & Clarke, 2006). This followed Braun & Clarke's six phase approach: data familiarisation, initial codes, searching for themes, reviewing themes, defining themes and writing up findings. This approach allows for identification of themes from the data itself rather than pre-existing theories or frameworks. As such, this well-established analytical technique was suitable for its ability to generate new and potentially unanticipated insights. Notably, whilst theme generation was inductive, the pre-defined categories of barriers, facilitators and preferences were utilised. Data analysis began after the completion of all interviews.

Data management strategy

The information from the survey and interview transcription underwent anonymisation to ensure that no individual could be identified. The collection and handling of all data followed the OUH Information Governance policy. This project did not require ethical approval; OUH NHS Trust approval is detailed in Appendix I. Interviews were recorded on a password-protected laptop and stored securely on the Oxford Health OneDrive of the Trainee. The data will be retained for five years and then disposed of.

Results

Audit

The audit involved identifying pre-and post-therapy outcome measures collected from individuals or couples discharged from the service between November and December 2023. This time period was selected based on the availability of complete outcome measures. Overall, 18 pre-therapy measures and 7 post-therapy measures were completed. When restricted to those completing both pre- and post-therapy measures, data were available for only two couples and no individuals. All data is presented below. For couples, this is presented alongside comparisons with non-completers (i.e., those not completing either pre- or post-therapy measures). For individuals, available data is reported but should be interpreted with caution given the absence of any matched pre- and post-therapy measures (i.e., data represents between-group rather within-person comparisons).

Across groups, helpfulness of therapy was rated high (overall mean=9.7/10) indicating current treatment is perceived to be highly effective. For couples therapy outcomes, cautious interpretation is required given the extremely small sample size. Across all items, scores demonstrated either a modest improvement or remained high at post-therapy (see Table 1). The helpfulness of therapy rating of 9.5 provides useful context that these observed improvements, albeit modest, were likely noticed and valued. At pre-therapy, compared to completers, the median rating for non-completers was lower on all items. At post-therapy, the median ratings for completers and non-completers were broadly similar on all items. Given the small sample size of completers, cautious interpretation is required. See tables 2 and 3. For individual therapy, the median and range of 6 pre-therapy and 2 post-therapy measures are detailed below (Table 4). As no individuals completed both, the data represents different

people and therefore cannot be interpreted as change over time.

Table 1. *Couples therapy outcomes (n=2)*

Item	**Pre-therapy Median (Range)**	**Post-therapy Median (Range)**
Sexual relationship rating	4.25 (2–6.5)	6 (5–7)
General relationship rating	10 (10–10)	10 (10–10)
Understanding of the problem	8.5 (7–10)	9 (8–10)
Therapy helpfulness	–	9.5 (9–10)

Table 2. *Pre-therapy comparisons – completers versus pre-data only (couples)*

Item	**Completers Median (Range)** (*n* = 2)	**Non-completers Median (Range)** (*n* = 10)
Sexual relationship rating	4.25 (2–6.5)	3 (1–8.5)
General relationship rating	10 (10–10)	6.5 (5–10)
Understanding of the problem	8.5 (7–10)	4.5 (1–9)

Table 3. *Post-therapy comparisons – completers versus post-data only (couples)*

Item	**Completers Median (Range)** (*n* = 2)	**Non-completers Median (Range)** (*n* = 3)
Sexual relationship rating	6 (5–7)	7 (7–8)
General relationship rating	10 (10–10)	10 (7–10)
Understanding of the problem	9 (8–10)	8 (8–10)
Therapy helpfulness	9.5 (9–10)	10 (9–10)

Table 4. *Individual therapy outcomes*

Item	**Pre-therapy Median (Range)** (*n* = 6)	**Post-therapy Median (Range)** (*n* = 2)
Confidence in making relationships	2.5 (1–7.5)	5 (5–5)
Confidence and self-esteem	9.25 (5–10)	5 (5–5)
Understanding of the problem	5.5 (2–9)	7.5 (7–8)
Therapy helpfulness	–	10 (10–10)

Note. No individuals completed both pre- and post-therapy measures

Patient Survey

The patient survey was completed by 17 patients, 10 in treatment and seven on the waitlist. All survey responses were collected between August and October 2024. Most respondents were aged 25 to 34 (59%; range: 18-44), and all identified as women and heterosexual. Full demographic information is reported in Table 3 (Appendix J).

The treatment group were asked how difficult or easy it was to stick to all aspects of their treatment, on a scale of 1 (very easy) to 5 (very difficult), and they rated this as moderately difficult (Mean score=3.1; Range= 2-4). A descriptive summary of findings regarding barriers and facilitators is described below, with corresponding tables. A detailed outline of corresponding qualitative survey responses can be found in Table 4.1 to 4.3 in Appendix K.

Barriers

For the treatment group, the highest rated barriers were not knowing how much therapy could help (Median score=3) and time constraints (Median=3). The most endorsed barriers included time constraints (50%), not knowing how therapy could help (30%) and stigma (30%). In the waitlist group, the highest rated barrier was not knowing how much therapy could help (Median=4). The most endorsed barriers were time constraints (57%), not knowing how much therapy could help (43%) stigma (43%) and emotional distress during sessions (43%). Regarding time constraints, respondents noted that '*life is bus*y' and that it's '*hard to fit in training between sessions'*. Regarding not knowing how therapy can help respondents noted '*therapy…didn't make sense in how it could help*' and '*fear in potential progression*'. Overall, the waitlist group endorsed more barriers (8 versus 9) and endorsed barriers more strongly (average endorsement: 20% versus 35%) than the treatment group. See Table 5.

Table 5 Descriptive statistics for barrier ratings

Barrier	Treatment Median (Range)	Treatment % Endorsement	Waitlist Median (Range)	Waitlist % Endorsement
Not knowing how much therapy could help	3 (1–4)	30%	4 (1–4)	43%
Not understanding ideas discussed	1 (1–2)	0	2 (1–3)	0
Time constraints	3 (3–5)	50%	3.5 (3–5)	57%
Financial constraints	1 (1–4)	10%	2 (1–3)	0
Stigma associated with therapy	1 (1–5)	30%	3 (1–4)	43%
Emotional distress during sessions	2 (1–3)	0%	3.5 (1–5)	43%
Mental health difficulties	1 (1–4)	10%	2 (1–5)	29%
Therapy being delivered online	1 (1-4)	10%	3 (2–5)	29%

Therapy being delivered in person	1 (1-5)	10%	3 (1–5)	14%
Therapy causing symptoms or distress to worsen	1 (1-2)	0	2 (1–4)	29%
Having to do between-session tasks	N/A	N/A	2 (1–4)	29%
Not understanding how to do between-session tasks	1 (1-4)	10%	N/A	N/A

Note. % endorsing = % of participants who rated the item as a barrier (4 or 5 on Likert scale). Likert scale 1–5, with 1=Not a barrier and 5=Significant barrier. N/A (Not Applicable) indicates where an item was only administered to one group due to its applicability (i.e., 'having to do between sessions tasks' was not considered applicable to the treatment group, as this is a core component of the treatment rather than a barrier. Similarly, 'not understanding how to do between session tasks' is not applicable to the waitlist group, who have not yet commenced treatment).

Facilitators

For the treatment group, facilitators were generally rated highly, with the exception of therapy being in person (Median=1). The most endorsed facilitators included having a supportive therapist (100%), understanding how to do between-session tasks (100%) and understanding therapy value (90%). In the waitlist group, facilitators were also generally rated highly. the most endorsed facilitators included having a supportive therapist (86%) understanding psychological ideas (86%) and understanding how to do between-session tasks (86%). Regarding a supportive relationship, respondents noted *'[a] trusting relationship is the most crucial aspect'* and '*helped to keep me on track'*. Regarding understanding how to do between-session tasks, respondents said, *'talking to a practitioner who could correct what I was doing wrong…was very helpful'* and '*more emphasis on this earlier would have*

helped'. Whilst both groups endorsed the same number of facilitators, the treatment group endorsed facilitators more strongly than the waitlist group (average endorsement: 75% versus 64%). See Table 6.

Table 6 Descriptive statistics for facilitator ratings

Facilitator	Treatment Median (Range)	Treatment % Endorsement	Waitlist Median (Range)	Waitlist % Endorsement
Supportive therapist/ healthcare professional	5 (4–5)	100%	5 (1–5)	86%
Support from partner/family /friends	5 (1–5)	60%	5 (1–5)	43%
Understanding therapy value/benefits	5 (3–5)	90%	5 (1–5)	71%
Having coping strategies	4 (1–5)	70%	5 (1–5)	71%
Therapy being in person	1 (1–5)	40%	3 (1–5)	43%
Therapy being online	4.5 (1–5)	60%	3 (1–4)	29%
Understanding psychological ideas	4.5 (1–5)	80%	5 (1–5)	86%
Understanding how to do between-session tasks	5 (4–5)	100%	5 (1–5)	86%

Note. *% endorsing = % of participants who rated the item as a facilitator (4 or 5 on Likert scale). Likert scale 1–5, with 1=Not a facilitator and 5=Significant facilitator)*

Preferences

Across groups, the most endorsed treatment type was individual psychosexual therapy. The second most commonly endorsed was self-help resources, however, respondents noted it potentially being *'harder to hold [myself] accountable in doing the exercises'* and their preference for *'the opportunity to discuss progress with a professional alongside – at least initially until confident'*. Couples therapy was also frequently endorsed, whilst some

qualitative responses corroborated this (e.g., *'hugely beneficial'*) others indicated discomfort with involving another person either at all (e.g., '*my embarrassment/shame around vaginismus would prevent me wanting others involved in the therapy'*) or initially ('*I would want to start with a few sessions by myself'*). Group-based psychosexual therapy was the least endorsed across groups, with respondents noting it feeling *'too intimate'* or *'too private'* but did value the idea of '*[feeling] like you're not alone in it'.* Whilst both groups endorsed the same number of treatment options, the waitlist group endorsed treatment options more strongly on average than the treatment group (average endorsement: 64% versus 50%; see Table 7).

Table 7 Descriptive statistics for treatment preferences

Treatment	Treatment Median (Range)	Treatment % Endorsement	Waitlist Median (Range)	Waitlist % Endorsement
Self-help resources	4 (2–5)	60%	5 (3–5)	71%
Individual psychosexual therapy	5 (3–5)	70%	5 (4–5)	100%
Couple's psychosexual therapy	5 (1–5)	50%	4 (2–5)	71%
Group based psychosexual therapy	3 (1–4)	20%	2 (1–5)	14%

Note. *% endorsing = % of participants who indicated 4 or 5 on Likert scale. Likert scale 1–5, with 1=Not Likely and 5=Very Likely)*

Patient suggestions

Patient suggestions included peer support (e.g., *'a buddy system'*), physical examinations (e.g., '*assist in mentally envisaging that there is a cavity…as opposed to feeling like there is no space')* and check-ins whilst on the waitlist (e.g., '*it's hard to then be left to wait for over 6 months by yourself… a very short check-in once in a while… would potentially be useful*').

Patient interviews

Both participants were first identified as having vaginismus during routine smear tests and were referred to the PTS via their GP. One had recently completed therapy; the other had completed six of eight sessions. A descriptive summary is presented below, and a detailed outline of themes and illustrative quotes is available in Table 8 (Appendix L).

Barriers

A key barrier reported by both patients was low motivation between sessions, occurring when progress felt slow (e.g., '*I didn't feel like I was making much progress…. That felt frustrating'*) and following noticeable progress ('*I feel as though I'm improving... so I'm becoming a bit more lax*'). One described not understanding how to do the therapy exercises until an in-person session, which led to avoidance ('*the leaflet didn't really work… I didn't know what I am supposed to do…so I was avoiding and procrastinating"*'). Motivation was also influenced by their initial reason for seeking treatment ('*in my case it wasn't really life changing or life threatening*'). One patient described feelings of guilt around missed homework tasks ('*it's not because you're a bad student*') and anticipation about their therapist's response *('feeling guilty right before the session'*), whilst another described that non-adherence to tasks were met with a supportive response ('*it's always a positive experience'*). Both reported practical barriers including work schedules, time constraints, travel and transport ('*it's not a quick thing*') and limited flexibility in rescheduling appointments.

Facilitators

Several facilitators were highlighted including supportive therapeutic relationships, use of humour (‘*we always have a laugh’*), the strong psychoeducational component *(‘comforting to know it’s a thing…it made it a lot less scary’*), sense of accountability from therapist or partner (‘*I've got a session next week… I need to make sure that I do [exercises]’*), service flexibility for in-person or online, contact with their therapist between sessions, and practical strategies such as setting phone reminders for homework tasks.

Preferences

Regarding treatment preferences, both patients valued the option of individual or couples therapy and felt these were well suited to their needs (‘*I think that the one to one is most valuable*’). The concept of group therapy was less valued, whilst one considered that this could theoretically be helpful in addition to individual sessions, both described concerns such as discomfort (‘*I don’t think I would be feeling comfortable’*), privacy (‘*Oxford is a very small town*’), and societal stigma *(‘[sexual issues] are difficult to talk about in society’*).

Patient suggestions

Suggestions for service improvement included increasing transparency regarding the treatment journey and direction (*‘where are we going?*’), shared access to notes and direct communication with their therapist (‘*we don’t have direct communication…it was all done through the coordinator’*). In addition, the requirement for an in-person session to avoid mis-understanding exercises (‘*requiring everyone to go and do at least one, the first session in person’*) and more service flexibility in session scheduling.

Staff interviews

Five semi-structured interviews with staff (all deliver psychosexual therapy: two gynaecologists, one clinical psychologist, one psychosexual therapist and one trainee clinical psychologist) were thematically analysed using reflexive thematic analysis (Braun & Clarke, 2006). Initial coding was inductive, with codes grouped under a priori categories of barriers, facilitators, and treatment preferences. Coding and theme development were done using NVivo (15) software. Themes were generated across the three domains (barriers, facilitators, preferences) capturing the patterning of meaning across the dataset (Braun & Clarke, 2006). Analysis is summarised in Table 9.1 to 9.3, with full details of themes and subthemes presented in Appendix M.

Table 9.1 Barriers to adherence in psychosexual therapy: summary with illustrative quotes

Theme	Sub-theme	Description	Illustrative Quote/s
The practical or the personal?	*The practical*	A variety of obvious practical factors such as time and work were identified as barriers to adherence	*"So it's things like time, jobs, kids, you know, all the other sort of life stuff gets in the way"* (Staff 5).
	What's behind it?	Staff suspected that practical reasons for non-adherence might mask avoidance of between-session tasks.	*"Are you cancelling because you're avoiding because you don't want to report back?"* (Staff 4).
	The personal	Less obvious factors as such cultural background, psychological (e.g., body image) issues and being single, might influence adherence.	*"We don't ask enough questions… about sexual taboos in their culture"* (Staff 1). "*they [single patients] … say, well, it wouldn't translate into real world scenarios*" (Staff 1)
The ripple of limited resources	*Unintended consequences*	Limited resources translate to long waitlists and limited session numbers which may create pressure for patients	"*we have very little time…to help people make changes…it can feel a bit more pressured*" (Staff 3).

	This way is not the only way	A behaviourally focused approach does not suit everyone and training gaps limit flexibility to use alternative approaches.	*"People's needs are varied and that doesn't work for everyone"* (Staff 3) "*there's just not the time to do [training on alternative approaches], but… there is the expertise in the team*" (Staff 3)

Table 9.2 Facilitators to adherence in psychosexual therapy: summary with illustrative quotes

Theme	Sub-theme	Description	Illustrative Quote/s
Elusive ingredients for adherence	*The 'right' ingredients*	A combination of factors, often at the patient-level, such as prior positive sexual experiences, reason for therapy, supportive partners, and psychological readiness, facilitated motivation for adherence.	"*there's something about sort of being in the right space at the right time*" (Staff 5) *"It can really help if people had positive sex before"* (Staff 5)
	The exception not the rule	Adherence without additional support is less common, with avoidance largely expected	"*My experience is not the majority with vaginismus [that adhere to treatment without additional support]*" (Staff 4).
The current approach works	*A good therapeutic offer*	Staff described significant strengths of the current service approach including, use of formulation, humour in the therapeutic relationship, normalisation and service flexibility.	*"doing what I would call a formulation... it stops it being nearly so scary"* (Staff 4). "*we completely normalise this… that's quite helpful for patients*" (Staff 1)
	It's hard but it's helpful	Recognition that the behavioural focus is challenging but practical, measurable and ultimately largely beneficial	"*it can be taught, it can be practised, it can be changed, by physical things…it makes it*

			more approachable" (Staff 5).

Table 9.3 Treatment Preferences: summary with illustrative quotes

Theme	Sub-theme	Description	Illustrative Quote
Group therapy – to do or not to do?	*Helpful to who?*	Divergent staff views about group helpfulness to patients and the service. Groups could be theoretically beneficial by improving efficiency and addressing common issues, but this could be undermined by patient apprehensions and additional service-level resource demands of a group	*"those presentations where you feel like they all need exactly the same*" (staff 5) *"People are reluctant enough to talk about their sex life to the sex therapist"* (Staff 4). "*if you actually calculated… those people could have all had a one to one appointment for an hour*" (staff 4)
	Meeting the need to feel 'normal'	A key benefit of a group would be addressing feelings of isolation and shame; however, this need could be met with other approaches such as peer support.	*"It's very beneficial to address issues like shame when you've got a lot of other people who are in the same boat* (Staff 5). "*I think peer support can be massively helpful*" (staff 4)
New approaches: who, where, what, when, why?	*Defining the role of group-based support*	A variety of purposes for groups were suggested, such as offering psychoeducation and/or psychological content, suited to clients with highly similar presentations.	"*some factors are common in a lot of patients with vaginismus and so certain things like psychoeducation…could be delivered quite effectively in the group setting*" (Staff 2).
	Groups as an addition not replacement	Offering groups in addition to individual/couple's therapy, was considered important.	*"It would be a sort of mixed delivery model"* (Staff 2).

Implementation challenges	Staff noted the additional demands of new approaches (e.g., groups), such as careful participant selection and logistical planning	"*You'd have to be very careful who you chose"* (Staff 4). "*I don't know how that would happen logistically in terms of confidentiality and everything*" (Staff 2)

Recommendations

Drawing on findings, several recommendations were proposed to the Oxfordshire Psychosexual Therapy Service. These recommendations include a mandatory in-person session for introducing pelvic floor exercises, expanding staff training using in-house knowledge, developing a structured 'blueprint' of the therapy journey, signposting to peer support or buddy systems, improving pathways for outcome data collection, and implementing 'check-ins' for those on the waitlist. Further information is reported in Table 10.

Table 10. Recommendations based on the study findings.

Recommendations
1. **Mandatory in-person session for introducing pelvic floor exercises** Pelvic floor exercises and dilator training were noted as key challenges for patients to adhere to, and patient feedback highlighted difficulties in understanding the correct techniques, when not demonstrated in person. Therefore, an actional step within the service would be to address this by introducing a mandatory in-person single session to introduce exercises. This would require no additional resource from the service and

although an in-person session can present additional barriers for some patients (e.g., time, work commitments), a single session requirement minimises this.

2. **Utilisation of in-house knowledge to expand staff training**

   Introduction of a regular (e.g., every two months) 'education slot' embedded into existing staff meetings, to allow for in-house training and expansion of skills (e.g., training in mindfulness, or wider reflective discussions). This recommendation comes in light of the particular challenge of the behavioural approach for some clients, whereby an alternative, evidence-based approach may prevent disengagement. For example, Mindfulness-Based Cognitive Therapy (Omidvar et al., 2021).

3. **Develop a 'blueprint' of the therapy journey**

   Lack of awareness of how therapy could help, and motivational demands on patients were considered key barriers. Therefore, an actional step would be to implement an accessible structured therapy blueprint or exemplar treatment journey, which can also be used to track progress. This might be particularly appropriate in this group, given the highly similar presentations. In feedback to the team, it was noted that this would be administered on a case-by-case basis, where helpful, and with the caveat that everyone's journey will be different.

4. **Signposting to peer support or buddy systems**

   Given the importance of normalisation and peer-support in vaginismus, combined with reluctance to implement a group, it is recommended that clinicians routinely signpost to peer support or buddy systems, for example, through The Vaginismus Network. Resource limitations within the service prevent the development of an in-

house buddy system, and as such, signposting to existing external support is a feasible alternative.

5. **Improve pathways for outcome data collection and research recruitment**

   Both the audit and project recruitment demonstrated challenges in collecting data from this group, which may reflect service-level limitations or be a challenge unique to patients with vaginismus. Lack of pathways for outcome data collection represents a considerable obstacle to evaluating the impact of changes such as implementing alternative support options or the current project recommendations (Russell et al., 2011). There are several potential strategies to address this including embedding outcome measure completion into therapy (e.g., at first/last session) or implementing a follow-up protocol for all discharged patients, to confirm completion of post-therapy measures. The service could also create an 'opt-in' system for research participation at time of assessment, which could streamline future recruitment efforts.

6. **Introduce 'check-ins' for those on the waitlist**

   The limited resources and resultant waitlist were commonly cited as particularly challenging for this group. Whilst resource-constraints limit means to reduce the waitlist, the service may be able to reduce the impact of the waitlist on patient motivation by introducing brief and structured check-ins (e.g., telephone call or email correspondence) at regular intervals. This recommendation is informed by the importance of psychological readiness and reliance on patient motivation for treatment success, which a long period of no-contact might undermine. Although this requires minimal additional resource, feedback from the service indicated that there is currently no capacity for implementing this. Nevertheless, this recommendation was retained to

highlight the gap between evidenced clinical need and existing funding within this service.

Presentation of results to the service

The Trainee joined a Multidisciplinary Team meeting to feedback the findings and recommendations. The team largely agreed with results, and a key discussion point was the feasibility of recommendations, given the limited staff hours. As such, recommendations were adjusted, where necessary, with consideration for resource limitations.

Discussion

The aim of this project was to identify barriers and facilitators to treatment adherence, as well as treatment preferences, in patients with vaginismus in the Oxfordshire Psychosexual Therapy Service. A mixed-methods approach was utilised and six recommendations for service improvement were developed. Findings and recommendations are discussed below.

Summary of main findings

1. What are the current outcomes of those with vaginismus who have accessed psychosexual treatment within the service?

The audit of pre- and post-treatment outcomes was significantly limited by the lack of available data, with complete data available for just two couples. This suggests a modest improvement across all domains and high satisfaction ratings; however, cautious interpretation is required. Comparisons between completers versus non-completers (couples) were separated to reflect both pre-therapy non-completers and post-therapy measure non-completers. Interestingly, prior to therapy, the non-completers rated all items lower, suggesting that with the most difficulties at baseline were less likely to complete post-therapy measures. At post-therapy, there were minimal differences which may reflect that therapy was similarly helpful for both groups, however, given the survivorship bias, this would be expected. Again, these are speculative interpretations held tentatively as a result of the limited data. For individual therapy data, meaningful interpretations on the pre-post therapy data could not be drawn, given no matched data were available. Considered in isolation, the two post-therapy median ratings were relatively low especially regarding confidence in making relationships and self-esteem,

when compared to couples data. However, cautious interpretation is required given the very small sample size of two and their limited meaningfulness in absence of pre-therapy score comparisons.

If outcome measure completion is considered indicative of patient-level factors, it may be that higher completion rates in couples reflects benefits of being in a couple such as additional accountability, which likely has broader benefits beyond measures for adherence. However, the wide-spread and seemingly random missing pre- and post-therapy data, suggests service-level factors likely contribute. Indeed, the poor data collection likely results from the absence of any pathways for outcome data collection. As such, a recommendation for implementing such a pathway was made and endorsed by the team. Given the lack of wider literature in vaginismus and related disorders, this is important (McEvoy et al., 2021).

2. What are the barriers to adhering with psychosexual treatment?

The survey data revealed similar barriers in both the waitlist and treatment groups, with time constraints, not knowing how much therapy could help, and stigma being most frequently endorsed. Interestingly, those on the waitlist endorsed more barriers and endorsed them more strongly than the treatment group, potentially demonstrating an overestimation of anticipated challenges of adhering to therapy. Patient interviews mostly echoed these findings, with practical barriers (e.g., time, work, schedules) frequently cited. Interviews further revealed patient's views that use of dilators was a key challenge for adherence, fitting with concerns raised by staff during consultation. Patients also cited motivation for exercises as a key barrier, which was impacted by their progress, lack of progress and not knowing how to do exercises. This pointed to a possible vicious cycle, whereby non-adherence creates guilt and anxiety, which given the importance of

relaxation for dilator use, creates an additional barrier to adherence (Padoa & Rosenbaum, 2016).

Staff similarly pointed to practical barriers (i.e., time, work demands) and noted more personal ones (e.g., cultural taboos, relationship status), describing how commonly cited practical reasons for non-adherence may be masking avoidance. Patients and staff both highlighted barriers linked to the service's limited resources, such as lack of flexibility in therapeutic approach and appointment scheduling, and its potential consequence of additional pressure, which as previously mentioned is the antithesis of the relaxation required for dilator training.

These findings led to the recommendation for a 'therapy blueprint' that would increase transparency of the therapy journey with the aim of increasing motivation and adherence. Improved data collection pathways with feedback from service users will be essential to evaluate its effectiveness.

3. **What are the facilitators to adhering with psychosexual treatment?**

Across both patient groups, the survey revealed that having a supportive therapist and understanding how to do between session tasks were key facilitators. Interestingly, the waitlist group were less likely to endorse facilitators, again potentially indicating an overestimation of the anticipated challenge of therapy adherence. Patient interviews revealed several facilitators, mostly at the service-level for example, therapeutic relationships, use of humour in sessions, use of psychoeducation, and service flexibility. Interestingly, staff perspectives emphasised patient-level facilitators, such as psychological readiness and prior positive sexual experiences. As such, there may be differing perspectives on where

'responsibility' for adherence lies. However, the lack of representation of service user views, especially in interviews, reduces confidence in such comparisons. The recommended pathway for data collection, such as an 'opt in' system for research would allow for sufficient data in future research.

4. What are the treatment preferences of women with vaginismus, and what makes certain treatments more appealing?

Across patient groups, individual therapy, self-help resources and couples therapy were all largely endorsed and are notably all currently offered in the service. The least popular option was group-based therapy, and subsequent interview data corroborated this, citing concerns around discomfort, privacy and social stigma. Interestingly, the treatment group were less likely to endorse all the currently available treatment options. This finding may reflect treatment falling short of expectations or needs having already been met (i.e. this treatment is no longer required). However, even with the corresponding qualitative data, the reasons for this remain unclear. Patient suggestions included introduction of a buddy or peer support system, an opportunity for physical examinations and contact from the service whilst on the waitlist.

Staff interviews largely corroborated these findings revealing that current approaches were largely valued. Concerns over the helpfulness, purpose, additional demands and logistics of group-based approaches were frequently raised, although their theoretical benefit, particularly for normalisation, was noted. Staff suggestions also supported the introduction of a peer support system. Given the overwhelming endorsement of peer support, it was initially recommended that an in-house peer support system was set up. However, given the service's limited capacity, this was scaled down for feasibility. The recommendation to signpost to

external support has the potential advantage of increased anonymity, however, one disadvantage is the service having no oversight of this or processes for offering additional support if issues arise. Nevertheless, this represents an appropriate recommendation, and feedback can be sought from the service to understand potential challenges.

Summary

Overall, between-session dilator training was considered the most challenging aspect of psychosexual therapy. The barriers and facilitators to adherence mapped onto all five of the WHO multidimensional adherence model domains including, patient-related factors (e.g., motivation, avoidance, body image issues, shame), social/economic factors (e.g., time constraints, work and life demands, stigma), therapy-related factors (behavioural focus, challenges in doing dilator training, jump to penis-in-vagina sex), condition-related factors (e.g., duration of vaginismus, avoidance expected) and health-system related factors (e.g., resource limitations leading to long waitlists, limited flexibility and the resultant pressure on patients) (WHO, 2003). Across patients and staff groups, there were considerable reservations around group-based treatments reflecting the need for careful consideration around its implementation.

Limitations

Despite the novel and interesting findings of this project, there are several important limitations to address, Firstly, sample sizes were small for audit data (n=2 completed measures), patient surveys (n=17), patient interviews (n=2) and staff surveys (n=5). Whilst this represents all psychosexual therapy staff, and a considerable portion of the vaginismus population within the service, only 10 patients had first-hand experience of therapy which limits the generalisability of findings within the service. Given the richness of qualitative

survey responses, full thematic analysis of this data could have been conducted, which may have provided unique insights. However, it was considered that this may have lacked depth, given data was not collected through interactive and exploratory methods such as semi-structured interviews. Moreover, no information was obtained on whether survey participants attended individual or couple's therapy, which would have helped contextualise the findings.

The addition of staff interviews as a result of low patient recruitment is a notable but unavoidable limitation, given it represents a divergence from the original proposal. Further, it is acknowledged that use of staff voices to gauge information about barriers and facilitators to patient adherence raises questions about its utility and generalisability. Nevertheless, all measures were taken to ensure transparency, and staff interviews provided important and unique insights. Given therapist allegiance is a well-established factor in treatment success, the views of staff are highly relevant (McLeod, 2009).

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Theory Driven Research Project (TDRP)

Obsessive Compulsive Disorder across the Menstrual Cycle: A Prospective Within-Subjects Design

Louise Nolan (louise.nolan@hmc.ox.ac.uk)

Student Number: 1579886

Internal Supervisor:

Dr Fiona Challacombe

External Supervisor:

Dr Graham Thew

August 2025

Word Count: 6547

Proposed Journal: This report is intended to be published in the Journal of Clinical Psychology (see Appendix E for Author Guidelines). This was selected given the relevance of menstrual cycle related symptom changes to clinical psychology.

Abstract

Background: Research has identified that some women with OCD experience a worsening of symptoms in the week preceding menstruation, known as premenstrual exacerbation (PME). However, these symptom changes are poorly understood, and it remains unclear whether some OCD dimensions, such as contamination, are more vulnerable to such exacerbations. The aim of this study was therefore to address this gap by prospectively measuring several dimensions of OCD alongside theoretically relevant mood factors across the menstrual cycle. **Method**: This online study utilised a prospective within-subjects design. Participants completed the Dimensional Obsessive-Compulsive Scale (DOCS: contamination, harm, unwanted thoughts, symmetry) alongside measures of pathogen disgust sensitivity (PDS), anxiety and depression at three time points across one MC including T1: early-follicular (days 4-7), T2: mid-luteal (days 19-22) and T3: premenstrual phase (days 24-27). **Results**: Contrary to expectations, across the whole sample ($N = 61$) OCD symptom severity, anxiety and depression significantly *improved* from T1 to T3. DOCS-Contamination scores remained relatively stable, and DOCS-Harm demonstrated the most change. PDS did not change significantly across the cycle, however, within-person variations in PDS were significantly associated with concurrent changes in DOCS-Contamination scores. Exploratory analyses identified that 23% of the sample experienced clinically meaningful symptom change (≥30%) across the cycle. **Conclusion:** OCD symptoms demonstrated significant premenstrual improvement rather than exacerbation and there appears to be a complex and heterogenous relationship between hormonal fluctuations and OCD symptom changes. The implications for clinical practice and future research are considered.

Introduction

Obsessive–compulsive disorder (OCD) is a chronic disorder characterised by obsessions and compulsions causing considerable distress and functional impairment (American Psychiatric Association., 2013). Whilst epidemiological data suggests a roughly equal prevalence between sexes, women demonstrate a later onset and an increased risk of developing contamination concerns as well as certain comorbidities such as eating disorders (Fawcett et al., 2020; Torresan et al., 2013). These sex differences suggest that reproductive hormones may play a role in OCD development and symptomology. Indeed, a breadth of research has identified that OCD onset and/or exacerbation can occur around reproductive events such as pregnancy and menstruation (Mathes et al., 2019).

Obsessive Compulsive Disorder across the Menstrual Cycle

The menstrual cycle (MC) is one reproductive event where existing symptoms of OCD might be vulnerable to fluctuation corresponding with hormone changes. In four retrospective studies, 20-49.7% of female participants with OCD reported symptoms worsening in the 7 days leading up to menses (Labad et al., 2005; Williams & Koran 1997; Moreira et al., 2013; Gugliemli et al., 2014). Similarly, a study utilising prospective methodology found 49% of participants with OCD reported significant worsening of symptoms during the premenstrual phase (defined as 3 days before menstruation) compared with other phases (Vulink et al., 2006). This pattern of symptom changes suggests OCD may be vulnerable to Premenstrual exacerbation (PME), a worsening of symptoms during the premenstrual phase, which typically includes the days preceding and during menses with a return to baseline severity thereafter (Green & Graham, 2022). This phase is characterised by

a sharp decline in the reproductive hormones, oestradiol and progesterone, and sensitivity to this hormonal decline is thought to underpin symptom exacerbations (Schmidt et al., 2017).

Whilst preliminary research into PME of OCD appears promising in establishing a link between the MC and OCD symptomology, it is lagging compared to other disorders such as Psychosis and Eating Disorders, where PME is well-established across multiple studies using gold standard prospective methodology (Nolan & Hughes, 2022; Reilly et al., 2020). The existing research into PME of OCD also lacks sufficient methodological rigor due to small sample sizes and the utilisation of mostly retrospective methodology. Prior research has demonstrated little concordance between retrospective and prospective estimates of PME, such that retrospective studies tend to overestimate PME prevalence and are subject to recall bias (Schmalenberger et al., 2021). The sole prospective study included MC lengths of 21-to-35-days, whilst defining the 'mid-cycle' phase as days 12-15. This considerably undermines day-to-phase correspondence and limits conclusions about specific phases (Vulink et al., 2006).

There remains little understanding of whether some OCD dimensions are more vulnerable to PME than others. One study found that women experiencing PME were more likely to have sexual/religious obsessions, whereas another study identified no such differences (Moreira et al., 2013; Vulink et al., 2006). Research suggests that contamination-concerns are more common in women and may emerge or worsen during or after pregnancy, a time of hormonal fluctuation (Forray et al., 2010; Starcevic et al., 2020). Much of this research is based on retrospective methodology, and such findings may also reflect psychosocial factors unique to this event (e.g., fear of harming the child by contamination; Challacombe & Wroe, 2013). Nevertheless, various factors directly relevant to contamination

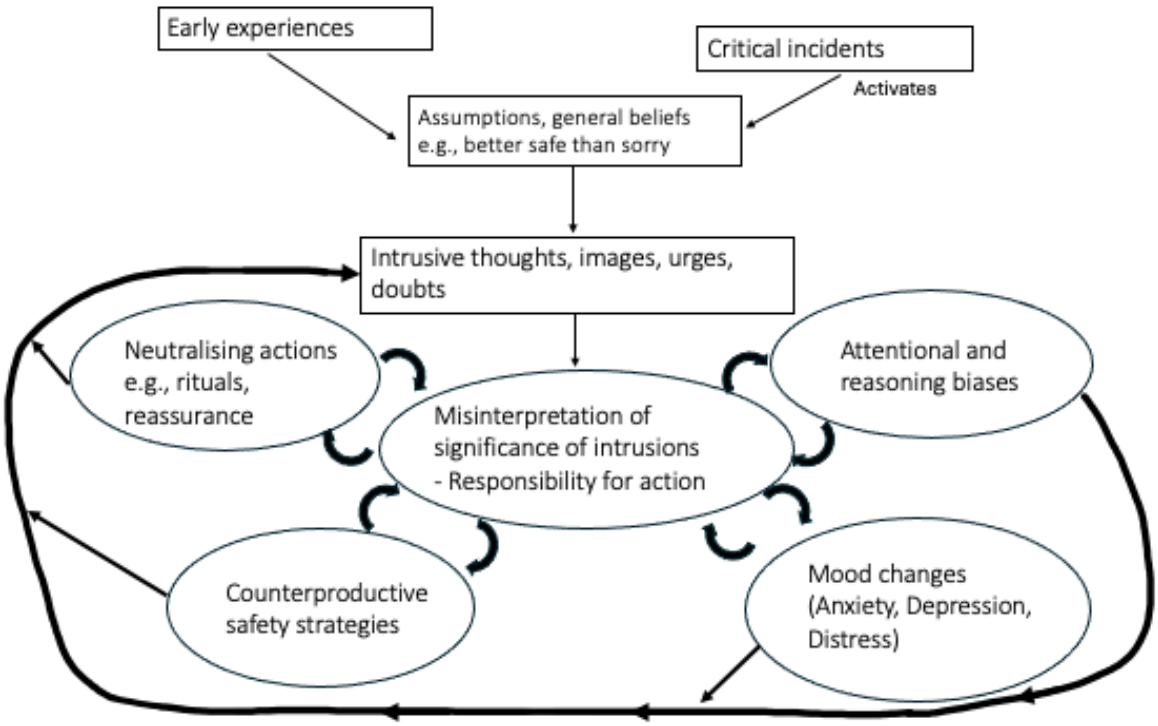
concerns, such as disgust sensitivity, disgust regulation and perceived vulnerability to disease, have been demonstrated to change at times of hormonal fluctuation (Sorokowska et al., 2024; Milkowska et al., 2021; Olatunju et al., 2020). It is therefore logical to consider that this dimension may be particular vulnerable to PME.

Cognitive Behavioural Model of OCD (Salkovskis, 1985)

Overall, little progress has been made on developing a theoretical understanding of these symptom changes using an established psychological model relevant to OCD. The cognitive model of OCD (Salkovskis, 1985) may provide a theoretical framework from which to understand PME of OCD. This model poses that OCD begins with 'normal' intrusive thoughts which are experienced by most people and it's the *interpretation* of the content and occurrence of intrusive thoughts that is central to OCD. These intrusions are often egodystonic, or inconsistent with an individual's belief system. Intrusions are interpreted as having important implications and indicating the individual may be responsible for harm to oneself or others (Salkovskis et al., 1999). Such appraisals can lead to neutralising behaviours ('compulsions') in an attempt to prevent the feared outcome and reduce distress. Whilst neutralising behaviours such as rituals may temporarily reduce distress, they prevent people learning how accurate this appraisal is, which serves to maintain OCD. Such appraisals also lead to counterproductive safety-seeking strategies, selective attention and increased negative mood (e.g., anxiety, distress). Although not central to the model, Salkovskis (1985) also described how pre-existing mood disturbance (anxiety and depression) can widen the range of stimuli that trigger intrusions, lower the threshold for responsibility or threat appraisals, and increase the activity level of pre-existing dysfunctional schemata. Likewise, if an intrusive thought is appraised as indicating responsibility and/or threat, this will result in subsequent mood disturbance. As such, the impact of appraisals on

mood is bidirectional, and may become part of a 'mood-appraisal spiral' (Teasdale, 1983; Rachman, 1983). Later work developed this theory into an integrated schematic model describing the origins and maintenance of OCD, which is visually depicted below (Salkovskis et al., 1998; Figure 1).

Figure 1. Cognitive Behavioural Model of Obsessive-Compulsive Disorder (Salkovskis et al., 1998)



Understanding Premenstrual Exacerbation of OCD

Changes in mood and anxiety across the MC are extremely common, with up to 80% of women of reproductive age experiencing Premenstrual Syndrome (PMS; Yonkers et al., 2008). In one retrospective clinical interview study, a significant association was found between premenstrual mood symptoms (e.g., anxiety, irritability, mood lability) and premenstrual worsening of OCD (Labad et al., 2005). If considered within this cognitive behavioural framework, these common premenstrual mood changes may drive increased

negative appraisals and subsequent exacerbation of OCD symptom severity. Whilst this model provides a useful framework from which to understand PME of OCD, research prospectively examining how anxiety, mood and OCD symptoms interact across the MC is lacking.

Disgust

A particular mood factor that is not specified in this model and may be relevant to understanding PME of OCD is disgust. Until recently, disgust has been understudied in the field of psychology and psychiatry (Krusemark & Li, 2011). Research suggests that disgust can contribute to the development and maintenance of OCD, particularly contamination related concerns (Ludvik, Boschen, & Neumann, 2015). Moreover, disgust has been demonstrated to fluctuate across the MC, for example, Żelaźniewicz et al. (2016) found that in a non-clinical sample, disgust levels were highest in the mid-luteal phase and positively correlated with progesterone levels. Given that contamination concerns may be most vulnerable to PME, disgust could be an important additional factor to inform our theoretical understanding of PME of OCD.

Prior research suggests that disgust alone is not sufficient to drive OCD, and, consistent with the cognitive model outlined above, it is the interaction with negative appraisals that is central to understanding its influence. For example, a study by Cisler et al. (2009) demonstrated that disgust propensity interacted with obsessional beliefs to potentiate contamination fears. Disgust may influence appraisals by leading to an overestimation of threat, anxiety and attentional biases towards disgust-relevant stimuli. Given that disgust may operate similarly to broader mood disturbances, it is important to identify its role over and above anxiety and depression to understand its unique contribution in OCD, (Davey, 2003).

Pathogen Disgust Sensitivity and Contamination Concerns

There are various aspects of disgust described within the literature, such as disgust propensity and disgust sensitivity (Nicholson & Barnes-Holmes, 2012). Disgust propensity describes how easily one is disgusted whereas disgust sensitivity (DS) is how negative the experience of disgust is perceived to be (Van Overveld et al., 2006; Fergus & Valentiner, 2009). By comparison, DS has been relatively overlooked, and their distinction is important given these constructs may uniquely contribute to the development and maintenance of OCD and potentially require different treatment approaches (Nicholson & Barnes-Holmes, 2012; Bhikram et al., 2017).

Three domains of DS have been outlined: *pathogen DS*, *moral DS* and *sexual DS* (Tybur et al., 2009). Pathogen Disgust Sensitivity (PDS) describes sensitivity to disgust in response to stimuli associated with potential disease transmission. Much of the literature has focused specifically on its role in the development and maintenance of contamination concerns (Bhikram et al., 2017; Olatunji et al., 2015). For example, PDS is demonstrated to predict feelings of physical contamination and one study found that PDS was a mediating factor between gender and contamination fears (Poli et al., 2019; Olatunji et al., 2005). Research has also demonstrated that PDS changes across the MC. A recent study utilising a within-subjects design in a non-clinical sample and found that the premenstrual phase was associated with a significant increase in PDS, and this corresponded with an increased score on the Contamination Obsessions & Washing compulsions subscale of the Padua Inventory (Miłkowska et al., 2021). As such, PDS may be an aspect of disgust that is particularly relevant to PME of OCD, especially contamination concerns.

Whilst PDS has been associated with OCD symptoms, there is a lack longitudinal data within clinical samples examining how PDS influences OCD symptoms (Knowles, Jessup & Olatunji, 2019). Further, no research has examined the association between within-person changes in PDS and severity of contamination concerns across the MC in a clinical sample, with consideration for broader mood factors.

Rationale for research

In summary, evidence suggests OCD symptom severity may worsen during the premenstrual phase, and this is associated with premenstrual mood changes in retrospective studies (e.g., anxiety; Labad et al., 1985). The Salkovskis (1985) cognitive model of OCD provides a theoretical framework from which to understand such changes, suggesting premenstrual mood changes may influence maladaptive appraisals and subsequent symptom severity. Research on other reproductive events suggests that contamination concerns may be most vulnerable to PME. PDS, which may operate similarly to mood by influencing negative appraisals, may therefore be an additional factor relevant to understanding PME of OCD. However, its influence over and above anxiety and depression has not yet been prospectively examined in clinical samples. Therefore, the current study addresses these gaps by prospectively tracking within-person changes in all OCD dimensions, PDS, mood and anxiety across the MC. The aims are to clarify the unique contribution of PDS in OCD, especially contamination concerns, and progress theoretical understanding of PME of OCD symptoms.

Hypotheses

1a. OCD symptoms (total) will be significantly worse in the premenstrual phase (T3; days 24-27) compared to the early follicular phase (T1; days 4-7)

1b. OCD symptoms of contamination (DOCS subscale) will vary significantly more across the cycle, compared with other symptom dimensions

2. Anxiety, mood and PDS scores will be significantly worse in the premenstrual phase (T3) compared to the early follicular phase (T1)

3. Within-person changes in PDS from T1 to T3 will be significantly positively associated with within-person changes in contamination dimension from T1 to T3

4. Exploratory analysis: changes in PDS from T1-T2 will predict a worsening in OCD from T1 to T3, for the contamination dimension but not other dimensions, after controlling for anxiety and depression.

Method

Design

This study employed a prospective, within-subjects design measuring OCD symptoms, PDS, depression and anxiety at three phases across one MC: the early-follicular phase (Timepoint 1; day 4 to 7 after menses onset), mid-luteal phase (Timepoint 2; day 19 to 22) and premenstrual phase (Timepoint 3; day 24 to 27). See Appendix O for further information on the definition and selection of MC phases. Data collection took place between October 2024 and April 2025. Ethical approval was obtained from the University of Oxford Central University Research Ethics Committee (CUREC Approval Reference: R94465/RE002; see Appendix P). This study was developed with input from a Public and Patient Involvement (PPI) group (see Appendix Q).

Recruitment

Participants were recruited through charities (e.g., OCD-UK), and social media (e.g., Instagram). Interested individuals completed an online screening survey via Qualtrics which required informed consent for initiation. The survey used logic throughout to exclude ineligible individuals and all eligible individuals provided email addresses. Participants were not blinded to the study's purpose and attempts to mitigate demand characteristics involved noting on recruitment materials that people with MCs can experience *positive, negative, or no effects* (Schmalenberger et al., 2021).

Sample

A G*Power a priori analysis was conducted based on previous research identifying moderate effect sizes when examining symptoms across the MC (Cohen's ds = 0.4–0.6;

Nillni et al., 2015). To achieve a 95% chance of detecting a moderate effect size (f = 0.25) in a repeated-measures ANOVA, a sample size of 43 would be required for a three-timepoint comparison (T1, T2, T3) and 54 would be required for a two-timepoint comparison (T1 vs. T3).

Participants were included if they satisfied the following criteria:

- women and people assigned female at birth (AFAB)
- aged 18+ years
- between menarche and menopause
- currently experiencing OCD with a total score of ≥18 on the Dimensional Obsessive-Compulsive Scale (DOCS). This is suggested for classifying OCD from other anxiety disorders (Abramowitz et al., 2010)
- report a MC length between 25-31 days (initially set as 26-30 days but expanded to increase power; see Appendix O).

Exclusion criteria included:

- being pregnant, breastfeeding or trying to conceive,
- having irregular MCs/dysmenorrhea in preceding 3 months (self-report)
- hormonal medications or implants (e.g., contraceptive pill; within past 3 months), as this removes exposure variable of interest
- hormonal disorders (e.g., Poly-Cystic Ovarian Syndrome).

Procedure

Following screening, participants received the same surveys throughout the study. First, participants were emailed a MC start date survey (MCSS), ascertaining cycle day 1.

This was sent daily for 8 days, starting 2 days before their estimated MC start date, provided at screening. Following confirmation of menses start date, the main surveys measuring OCD, PDS, anxiety and depression were sent via email on day 4, day 19 and day 24 of the cycle. Each survey link expired after 4 days. Finally, participants were emailed a second MCSS to ascertain the start date of their next MC. This was sent daily for 8 days, starting on cycle day 28. Further information about measures is detailed in Table 1.

Table 1 *Measures*

Domain	Measure
Screening for inclusion	***Screening Survey*** The initial screening survey ascertained demographics (e.g., age, gender identity, ethnicity, education), reproductive status (pregnant, trying to conceive, hormonal contraceptives, naturally cycling, perimenopause, menopause), OCD onset (age, perinatal onset y/n), current medications (psychotropic and otherwise), psychological treatment status (currently in treatment, not in treatment) mental health comorbidities (e.g., depression, anxiety, addiction), physical health (e.g., hypothyroidism, hormonal issues), MC (e.g., length of MCs, length of menses, age at menarche). Participants were asked 'do you have a regular MC?' (yes, no, don't know) and the estimated start date of their next MC was ascertained. Participants were also asked to identify their verification method (e.g., using an app such as Clue or Flo, using own calendar). Items pertaining to exclusion criteria will be presented first, to ensure no unnecessary information was obtained. See Appendix P for Screening Survey and the corresponding Participant Information Sheet.
Obsessive Compulsive Disorder – dimension and symptom severity	***The Dimensional Obsessive-Compulsive Scale*** *(DOCS;* Abramowitz et al., 2010) DOCS is a 20-item measure assessing the severity of OCD across four symptom domains: contamination/washing, responsibility/checking, harm obsessions and unacceptable thoughts. Each item is measured using a 5-point Likert scale ranging from 0 to 4. This provides an overall score and subscale (dimension) scores with higher scores indicating more severe symptoms. A maximum total

score is 80, and maximum score for each subscale in 20. A total cut-off score of 18 is suggested in classifying OCD from other anxiety disorders (López-Solà et al., 2014). For the current study, the wording of items was adapted to indicate 'past few days' rather than 'over the past month'. This scale demonstrated good internal consistency in the current sample for the DOCS total (Cronbach's α = .86) and all subscales DOCS-contamination (Cronbach's α = .94), DOCS-Harm (Cronbach's α = .88), DOCS-Unacceptable Thoughts (Cronbach's α = .92), DOCS-Symmetry (Cronbach's α = .94) when calculated at Time 1 (baseline).

Pathogen Disgust Sensitivity

Three Domain Disgust Scale (TDDS; by Tybur, Lieberman, and Griskevicius, 2009). TDDS measures disgust sensitivity across three domains: pathogen disgust, sexual disgust, and moral disgust. It consists of 21 items (7-items per domain) rated on a 7-point Likert scale, with higher scores indicating higher levels of disgust sensitivity in each domain. Only the Pathogen Disgust subscale items were administered. This scale demonstrated marginal internal consistency (Cronbach's α =.66) in the current sample when calculated at Time 1 (baseline).

Anxiety

The Generalised Anxiety Disorder Assessment (GAD-7; Spitzer et al., 2006) GAD-7 is a seven-item instrument that is used to measure the severity of generalised anxiety. Each item is measured on a 4-point Likert scale. For the current study, the wording of items will be adapted to indicate 'past few days' rather than 'past two weeks'. This scale demonstrated good internal consistency (Cronbach's α =.80) in the current sample when calculated at Time 1 (baseline).

Depression

Patient Health Questionnaire-8 **(**PHQ-8; Kroenke et al., 2003)

PHQ-8 enquires about the frequency of depressed mood and anhedonia using a 4-point Likert scale. Higher scores indicate more severe symptoms. For the current study, the wording of items will be adapted to indicate 'past few days' rather than 'past two weeks'. This scale demonstrated good internal consistency (Cronbach's α =.85) in the current sample when calculated at Time 1 (baseline).

Data analysis

All statistical analyses were completed using IBM SPSS (version 29). Descriptive statistics were generated for all demographic, clinical and MC characteristics. The normality of continuous variables was assessed using the Shapiro-Wilk test and visual inspection of histograms. Where assumptions were violated the Mann-Whitney U test was applied. For categorical variables, chi-squared analysis or Fisher's exact test was used. For all within-subject comparisons, the assumption of sphericity was assessed with Mauchley's test of sphericity. To assess within-person changes in OCD (all dimensions), PDS, anxiety and depression, a repeated measures ANOVA utilising total scores at T1 and T3 was applied (N = 61). Sensitivity analyses were conducted for all main hypotheses using a repeated measures ANOVA across T1, T2 and T3 (n = 53). To compare the variability of OCD dimensions across the cycle, a 2(timepoint) x 4 (dimensions) repeated measures ANOVA was conducted. Pairwise comparisons were computed, with Bonferroni corrections applied. Significance was determined at an alpha level of .05.

Deviation from planned analyses

The study originally aimed to examine group differences in total OCD scores across the MC based on a two-group design, OCD-contamination versus OCD-other, assigned based on those scoring highest on DOCS-contamination or another dimension. However, due to low power in the OCD-contamination group (n = 10 for all timepoints), the analysis was restructured to examine within-person changes across all dimensions. Comparisons between timepoint 1 to timepoint 3 were prioritised to maximise power. To reflect this new analysis plan, hypotheses were therefore restructured; these are directionally identical to original hypotheses with any differences reflecting this new analytical strategy.

Results

Sample characteristics

605 individuals initiated the initial screening survey. A total 221 participants were eligible, 171 of which completed the first MC start date survey. Eight added incorrect dates, leaving 163 participants. Of these, 142 were expected to have completed all required surveys by the time of data analysis. Of these, 66 participants did not complete the minimum number of timepoints and 15 were excluded due to verified MC lengths outside the inclusion range. This left a final sample of 61 participants, 53 completed all surveys (T1, T2, T3) and eight completed all except the T2 survey (T1 and T3).

Potential differences between participants who completed all study timepoints (n = 61) and those who did not (n = 81), were analysed and revealed no significant differences between groups on any variable (see Appendix R).

Demographics, Clinical and Menstrual Cycle Characteristics

Demographic data was available for all participants (N = 61) and detailed in Table 2.

Table 2

Overview of baseline demographic, clinical and menstrual cycle characteristics (N = 61)

Domain	Characteristic	Percentage (%)
Demographics		
	Women	91.8%
	Age 25-34	47.5%
	Cohabiting relationship or married	44.3%
	Heterosexual	57.4%
	White British, Irish or Other	88.5%
	Postgraduate degree	36.1%

	Employed (full-time, part-time or self-employed)	68.8%
	Annual income £24,001-£55,000	49.2%
OCD		
	Mean DOCS score	30.67 (SD = 9.14)
	Mean age of OCD onset	**12.36 years** (*SD* = 5.62, range = 4–30)
	Onset around pregnancy	1.6%
	Onset around menarche (first period)	23%
Menstrual Cycle		
	Mean cycle length	27.69 days (SD = 1.73)
	Self-reported Premenstrual Syndrome	82%
	Self-reported Premenstrual Dysphoric Disorder	31.1%
Co**morbidity**	Self-reported co-morbidity (e.g., Post-Traumatic Stress Disorder, Depression, Generalised Anxiety Disorder)	82%

Note. The table reports the most frequently reported categorical variables, and full demographic data is available in Appendix R.

Symptom Patterns Across the Cycle

Means and standard deviations of scores of all measures are detailed in Table 3 for main analyses (*N*=61) and Table 4 for sensitivity analyses (*n*=53)

Table 3

Mean scores on measures across MC phases (N = 61)

Measure	T1 Mean (SD)	T3 Mean (SD)
DOCS (OCD)	28.44 (10.19)	25.90 (10.21)
GAD-7 (Anxiety)	14.38 (4.14)	12.23 (5.30)
PHQ-9 (Depression)	12.87 (5.60)	11.39 (5.94)
TDDS-Pathogen	30.00 (5.91)	28.84 (6.10)

Note. T1 = Early follicular phase; T3 = Premenstrual phase.

Table 4

Mean scores on measures across all MC phases, relevant to sensitivity analyses (n = 53)

Measure	T1 Mean (SD) ***n*** **= 53**	T2 Mean (SD) ***n*** **= 53**	T3 Mean (SD) ***n*** **= 53**
DOCS (OCD)	28.81 (10.48) 1.44	26.83 (9.43)	26.98 (10.32) 1.42
GAD-7 (Anxiety)	14.45 (4.36) 0.60	11.49 (4.64)	12.64 (5.02) 0.69
PHQ-9 (Depression)	13.13 (5.74) 0.79	10.89 (5.96)	11.79 (5.78) 0.79
TDDS-Pathogen	29.83 (6.05) 0.83	28.36 (6.14)	28.64 (6.18) 0.85

Note. Values are reported as follows: mean (standard deviation) standard error.

Hypothesis 1a

We hypothesised that OCD severity would be significantly worse at T3 than T1**,** as measured by the DOCS total score. A repeated-measures ANOVA was conducted and

revealed a significant main effect of time**,** $F(1, 60) = 8.22$, $p = .006$**,** with a moderate effect size**,** *partial* $\eta^2 = .120$**.** Mean DOCS total scores decreased from T1 **(***M* = 28.44, *SD* = 10.19) to T3 (*M* = 25.90, *SD* = 10.21). As such, hypothesis 1a was not supported.

A sensitivity analysis using the restricted sample (*n* = 53) across T1, T2, and T3 found no significant main effect of time, $F(2, 104) = 2.71$, $p = .071$, partial $\eta^2 = .049$. Mean scores declined from T1 (*M* = 28.81, *SD* = 10.48) to T2 (*M* = 26.83, *SD* = 9.43) and remained stable at T3 (*M* = 26.98, *SD* = 10.32). A significant linear trend, $F(1, 52) = 4.32$, $p = .043$, partial $\eta^2 = .077$, indicated an overall decline in OCD symptoms across the cycle. The non-significant main effect of time likely reflects the relatively small change between T2 to T3, following the initial reduction from T1 to T2. The significant linear trend corroborates findings in the main analysis, demonstrating the robustness of the effect of symptom improvement, rather than worsening, across the cycle. Similarly to main analysis, sensitivity analysis shows hypothesis 1a was not supported.

Hypothesis 1b

We hypothesised that the DOCS contamination dimension would show greater symptom exacerbation, from the early-follicular phase (T1) to premenstrual phase (T3) compared to all other symptom dimensions. A 2 (Time: T1 vs T3) x 4 (symptom dimension: contamination, harm, unacceptable thoughts, symmetry) repeated-measures ANOVA showed a significant Time x Symptom interaction, $F(3, 180) = 3.86$, $p = .010$, *partial* $\eta^2 = .060$**,** suggesting that the degree of symptom change differed by symptom type. Contrary to expectations, follow-up simple effect comparisons with Bonferroni corrections revealed a significant reduction in DOCS-Harm (Mean reduction=1.34, $p = 0.004$) and DOC-unacceptable thoughts (Mean reduction = 1.20, $p = 0.003$) whereas no significant change was

identified in DOCS-contamination (Mean reduction = 0.20, $p = 0.587$) or DOCS-symmetry (Mean increase = 0.20, $p = 0.617$). As such, hypothesis 1b was not supported.

Table 5

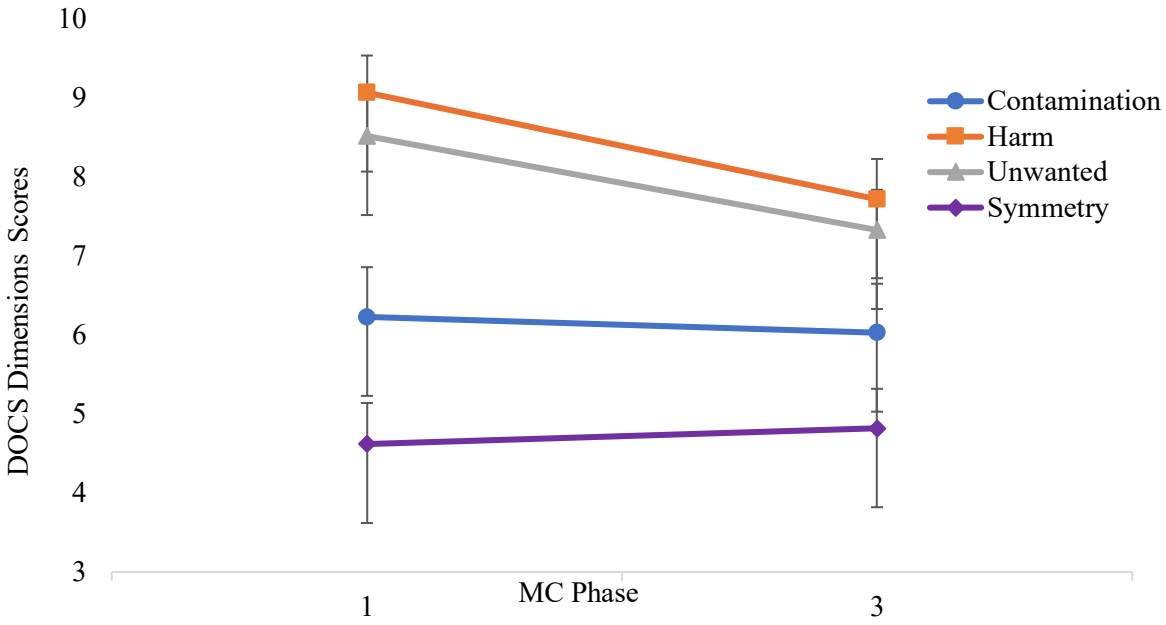
Mean scores, change scores and change score comparisons for all DOCS dimensions, for T1 to T3 (N = 61)

Measure	T1 Mean (SD)	T3 Mean (SD)	Change Mean (SD)
Contamination	6.23 (4.91)	6.03 (4.84)	-0.20 (2.81)
Harm	9.07 (3.70)	7.73 (3.98)	-1.34 (3.55)
Unwanted Thoughts	8.52 (4.35)	7.33 (3.97)	-1.20 (3.00)
Symmetry	4.62 (4.07)	4.82 (3.87)	+0.20 (3.06)

Note. T1 = Early follicular phase; T3 = Premenstrual phase. Change Mean = change in contamination score minus change in the comparison subscale.

Figure 2

Mean scores across OCD dimensions at Time 1 and Time 3



Note. Error bars represent ±1 SE.

A sensitivity analysis across all timepoints (n = 53) was conducted using a 3(timepoint) x 4 (dimension) repeated-measures ANOVA, showing no significant time x symptom interaction $F(6, 312) = 1.45$, $p = .196$, partial $\eta^2 = .027$. The main effect of time was not significant ($p = .071$, *partial* $\eta^2 = .049$), although the linear trend was significant, $F(1, 52) = 4.32$, $p = .043$, *partial* $\eta^2 = .077$. The main effect of dimension was significant (GG), $F(2.50, 129.90) = 13.64$, $p < .001$, partial $\eta^2 = .208$, with simple-effects revealing only the DOCS-Harm changed significantly across time, Pillai's trace = .120, $F(2, 51) = 3.46$, $p = .039$. Similarly to the main analysis, sensitivity analysis shows hypothesis 1b was not supported.

Hypothesis 2

It was hypothesised that PDS, anxiety and depression scores would be significantly higher in the premenstrual phase (T3) compared to the early-to-mid-follicular phase (T1).

For PDS, a repeated-measures ANOVA showed no significant main effect of time, $F(1, 60) = 3.86$, $p = .054$, partial $\eta^2 = .060$. A sensitivity analysis across all timepoints ($n = 53$) also revealed no significant main effect of time, $F(2, 104) = 2.83$, $p = .064$, partial $\eta^2 = .052$.

For anxiety, a repeated measures ANOVA revealed a significant main effect of time, with a moderate effect size, $F(1, 60) = 9.77$, $p = .003$ partial $\eta^2 = .140$. Mean GAD-7 scores decreased from Time 1 ($M = 14.38$, $SD = 4.14$) to Time 3 ($M = 12.23$, $SD = 5.30$), indicating a significant reduction in anxiety. A sensitivity analysis across all timepoints ($n = 53$) also revealed a significant main effect of time, $F(1.75, 94.11) = 10.46$, $p < .001$, partial $\eta^2 = .167$, with scores decreasing from Time 1 ($M = 14.45$, $SD = 4.36$) to T2 ($M = 11.49$, $SD = 4.64$) followed by a slight increase at T3 ($M = 12.64$, $SD = 5.02$).

For depression, a repeated measures ANOVA showed a significant main effect of time with a moderate effect size, $F(1, 60) = 6.07$, $p = .017$, partial $\eta^2 = .092$. Mean PHQ-8 scores decreased from Time 1 ($M = 12.87$, $SD = 5.60$) to Time 3 ($M = 11.39$, $SD = 5.94$), indicating a significant reduction in depression. A sensitivity analysis ($n = 53$) similarly showed a significant main effect of time, $F(2, 104) = 6.97$, $p = .001$, partial $\eta^2 = .118$. Depression scores decreased from Time 1 ($M = 13.13$, $SD = 5.74$) to Time 2 ($M = 10.89$, $SD = 5.96$) before increasing slightly at Time 3 ($M = 11.79$, $SD = 5.78$). Therefore, hypothesis 2 was not supported.

Hypothesis 3

Hypothesis 3 proposed that between T1 to T3, changes in PDS would be significantly positively associated with changes in DOCS-contamination scores. As expected, DOCS contamination change score was significantly correlated with the PDS change score (r = .32, p = .012). As such, hypothesis 3 was supported.

Hypothesis 4

For the exploratory analysis, we predicted that changes in PDS from TI to T2 would predict premenstrual exacerbation of OCD symptoms from T1 to T3, for the DOCS contamination dimension only, even after controlling for mood and anxiety. However, as OCD symptoms *improved* from T1 to T3, and PDS remained stable across the cycle, this hypothesis could not be meaningfully tested. As an alternative, we examined whether changes in DOCS (total score) from T1 to T3 was correlated with concurrent changes in PDS, anxiety and depression, as well as assessing the inter-relationship between these variables. Change scores were calculated by subtracting scores at T1 from T3. OCD symptom change was significantly correlated with changes in anxiety (r = .33, p = .010) and depression (r = .29, p = .024), but not with PDS (r = .22, p = .094). Anxiety changes were strongly correlated with depression changes (r = .55, p < .001) but not changes in PDS (r = .17, p = .201). Depression changes were significantly associated with changes in PDS (r = .29, p = .022). To control for family-wise error rate, the Holm-Bonferroni method was applied (Holm, 1979), after which only the association between anxiety and depression (adjusted threshold 0.05/6=0.083) and DOCS and anxiety (adjusted threshold 0.10/5=0.010) remained significant.

Exploratory and sensitivity analyses

Exploratory analysis – individual variability (planned)

To capture individual variability in MC-related symptom change, participants were categorised as hormone-sensitive based on the percentage change in OCD symptoms from the early-follicular (T1) to the premenstrual phase (T3) with a change of ≥30% considered clinically meaningful (Eisenlohr-Moul et al., 2018). Demographics and clinical characteristics were compared between the hormone-sensitive and non-hormone sensitive groups. Across the full sample, 8.2% (n = 5) showed premenstrual exacerbation (PME), 14.8% (n = 9) showed premenstrual improvement, with 77.0% (n = 47) showing no meaningful change. See Figures 3 and 4 for an illustration of individual trends. Participants were categorised as hormone-sensitive (n=14), or non-hormone-sensitive (n=47) and demographic characteristics were compared. The hormone-sensitive group had a significantly earlier onset age of OCD (M = 9.21 years vs. M = 13.39 years; U = 187.00, Z = -2.445, p = .014) and were more likely to be within the 25-34 age group (Fisher-Freeman-Halton Exact Test, p = .023). No significant differences were identified on any other variables. See Table 6 in Appendix U for further details.

Figure 3

Premenstrual Exacerbation Group – individual OCD symptom scores across the cycle (n = 5)

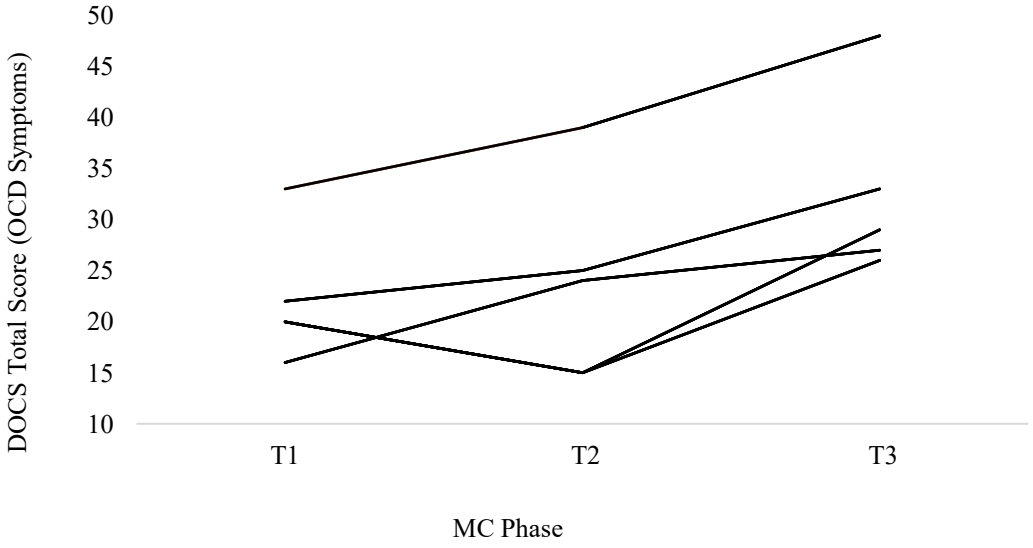
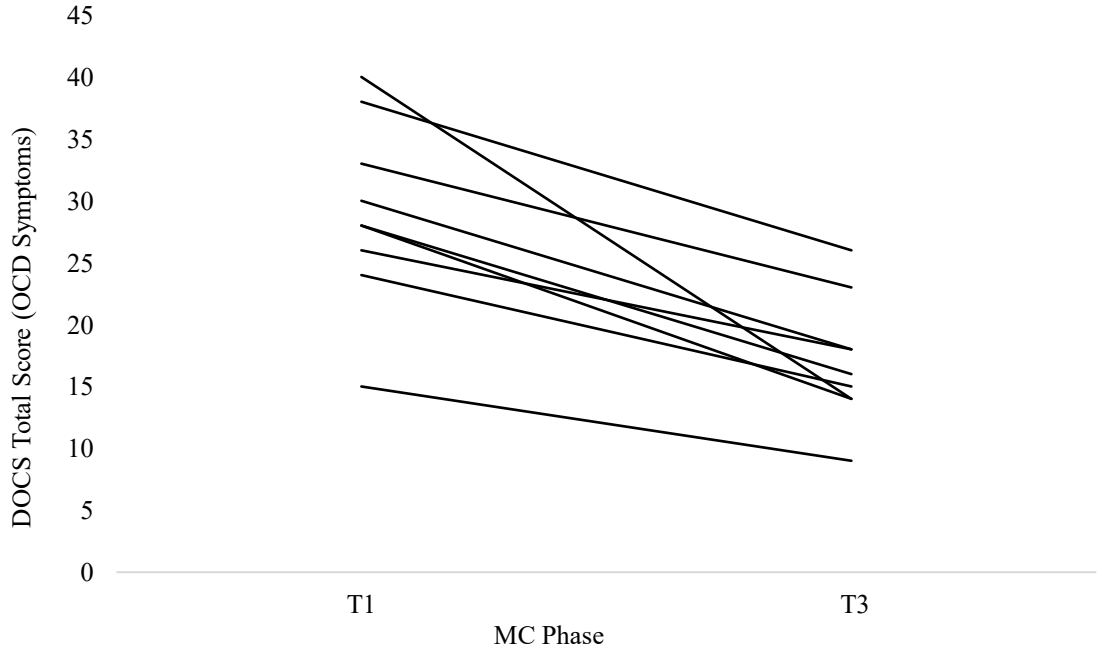


Figure 4

Premenstrual Improvement Group – individual OCD symptom scores across the cycle (n = 9)



Sensitivity analyses – menstrual cycle length (post hoc)

To confirm if widening inclusion of cycle lengths (from 26-30 days to 25-31 days) considerably influenced results, post hoc sensitivity analyses were conducted. All main analyses in hypothesis 1 to 3 were repeated on a subsample with cycle lengths of 26-30 days. Results were mostly consistent with main findings, however, while total DOCS score and depression followed similar trends, these effects didn't reach significance in this restricted sample (Appendix T).

Exploratory analysis – Treatment effect

Analyses were planned to identify potential confounding of the 'treatment effect', however, very few participants had recently commenced treatment (<5%). As such, sensitivity analyses were not conducted. No significant differences were found in recent treatment commencement rates between hormone-sensitive and non-hormone-sensitive groups (see Table 6 in Appendix U).

Discussion

This study aimed to examine the longitudinal pattern of OCD symptoms, particularly contamination concerns, across the MC and to understand the role of PDS and other mood factors in any changes. The cognitive model of OCD (Salkovskis, 1985) was utilised as a framework from which to understand symptom changes. A prospective within-subjects design was employed measuring OCD severity, PDS, anxiety and depression at three timepoints across one MC.

OCD across the Menstrual Cycle

Contrary to expectations, OCD severity reduced significantly from T1 to T3, demonstrating premenstrual improvement rather than the expected premenstrual exacerbation. This largely diverges from prior research which reports an exacerbation of OCD symptoms in the premenstrual phase (Vulink et al., 2006; Labad et al., 2005; Gugliemli et al., 2014, Williams & Koran, 1997, Moreira et al., 2013). One possible explanation is that the use of more rigorous methodology in this study, employing a prospective within-subjects design and restricting MC lengths, may provide a more accurate representation of OCD symptoms across the cycle than prior studies. Alternatively, as T1 largely includes menstruation (bleeding), findings may reflect an exacerbation of symptoms in response to navigating this, for example, contact with blood, sanitary products, public sanitary bins, pain, fatigue, and the cultural taboo menstruation still represents in many cultures (e.g., Thapa & Aro, 2021). Further research is required to examine these speculative explanations and to consider how MC-related factors beyond hormones influence appraisals and symptoms.

Whilst the observed reduction in DOCS scores was statistically significant, a 2.5-point change may not reflect clinically meaningful improvement. No threshold for clinical

meaningfulness has been established to guide interpretation, however, prior OCD trials have reported post-treatment reductions of around 10-points (Enander et al., 2012). Nevertheless, within MC research, minimal differences are unsurprising when based on group-level averages of change which can obscure more profound individual variability. This is because the MC is fundamentally a within-person process and individuals have different starting points (e.g., baseline DOCS scores) and patterns of symptom change (improvement vs. exacerbation) across the cycle (see Schmalenberger et al., 2021). Indeed, when individual patterns of fluctuation were examined, applying a 30% change threshold, 23% of the sample experienced clinically meaningful changes, both exacerbation and improvement, across the cycle. This reflects a limitation of the current group-level analytical approach and recommendations for future research to include a more complex and person-centred analytical strategy are outlined in the limitations section below.

It was hypothesised that the DOCS-contamination dimension would demonstrate the most fluctuation across the cycle. Contrary to this, the DOCS-harm dimension showed significantly more change than DOCS-contamination, which remained relatively stable. Current results provide no evidence that contamination concerns are particularly sensitive to menstrual-cycle related changes. This suggests that vulnerability to onset or exacerbation of contamination concerns observed at other reproductive events such as pregnancy, may reflect psychosocial factors such as increased responsibility, rather than being primarily explained by hormonal fluctuations (Hudak & Wisner, 2012). This novel finding that DOCS-harm may be most vulnerable to menstrual-cycle related hormonal fluctuations contrasts with prior research suggesting that women experiencing PME were more likely to have sexual/religious obsessions. This may be explained by the observed premenstrual improvement in DOCS-harm rather than exacerbation observed in sexual/religious obsessions. Such inconsistencies

within a sparse literature point to the need for further research and the importance of looking beyond overall OCD symptoms.

Anxiety, Depression and Pathogen Disgust Sensitivity

Similarly to OCD, it was hypothesised that anxiety, depression and PDS would worsen at T3 compared to T1. This hypothesis was not supported, and the observed pattern of findings paints a mixed picture. Surprisingly, PDS did not change significantly across the cycle on either the main or sensitivity analyses. The lack of change in PDS alongside significant changes in OCD suggests this may not be a significant driver in overall OCD symptom changes. Exploratory analyses supported this interpretation, demonstrating no significant association between changes in PDS and overall DOCS scores. This finding is contrasted by previous research suggesting the premenstrual phase was associated with a significant increase in PDS (Milkowska et al., 2021). Notably, this research utilised a non-clinical sample and failure to replicate in the current study suggests that this may not extend to a clinical OCD sample, for example, there may be a ceiling effect, whereby PDS is relatively high in this group. However, no validated PDS severity thresholds are available and Miłkowska et al., (2021) reported mean Likert scale scores limiting comparisons with the mean total scores used in this study.

By contrast, both anxiety and depression changed significantly across the cycle but surprisingly, a reduction in scores was observed, demonstrating premenstrual improvement. Sensitivity analyses revealed the largest reduction in both scores occurred from T1 to T2 with a slight increase from T2 to T3. The *improvement* in anxiety and depression is puzzling and contrasts with a considerable body of research suggesting this phase is associated with a worsening of emotional symptoms (e.g., Nolan & Hughes, 2022). Interestingly, exploratory

analyses revealed a significant positive association between changes in anxiety and depression and changes in overall OCD symptoms. This association is in line with the cognitive model of OCD which describes the bidirectional influence of mood on appraisals, impacting subsequent OCD severity (Salkovskis et al., 1985).

The Association between PDS and Contamination Concerns

As expected, changes in DOCS-contamination were significantly correlated with changes in PDS across the MC. This suggests that individuals who experienced changes in PDS experienced concurrent changes in contamination concerns, and vice versa. This finding can be understood within the cognitive behavioural framework of OCD suggesting that similarly to anxiety and depression, PDS may influence appraisals of threat and responsibility subsequently increasing the severity of contamination concerns (Salkovskis, 1985). Given that PDS was not associated with overall OCD symptom changes in exploratory analyses, it suggests that unlike anxiety and depression, its influence is specific to contamination concerns. Notably, the strength of appraisals of threat or responsibility related to contamination fears were not explicitly assessed here, and future research could look into the specific influence of PDS. This finding is consistent with previous studies suggesting changes in PDS corresponded with changes in Contamination Obsessions & Washing compulsions scores across the cycle (Milkowska et al. 2021). As hypothesis 4 could not be meaningfully tested, it remains unclear whether changes in PDS predict changes in DOCS-contamination over and above changes in anxiety and mood.

For exploratory analyses, individuals were categorised as ‘hormone sensitive’ (HS) if they experienced ≥30% change in scores across the cycle. This revealed that 23% were HS, with 8.2% experiencing PME and 14.8% experiencing premenstrual improvement. The

considerably lower proportion of individuals meeting criteria for PME, compared to prior research (9% versus 20-49%) could be explained by the current study's use of prospective methodology, which is less prone to recall bias, and the stricter definition of PME (e.g., ≥30% change score versus a 3-point change on the Y-BOCS in Vulink et al., 2006). Further, in an attempt to understand differences between HS and non-HS individuals, comparisons on demographic and clinical characteristics were made. The HS group had a significantly earlier onset age of OCD and a greater proportion of individuals aged 25-34. This suggests that longer chronicity of OCD may be associated with HS and potentially reflects that the increased psychosocial stress associated with this age group is a vulnerability factor for HS (Bencker et al., 2024). However, given the exploratory nature of this analysis, findings should be interpreted with caution and future research utilising larger samples is warranted.

Strengths and limitations

The current study has several strengths. Firstly, this is the first study utilising gold-standard prospective methodology to examine OCD symptoms across the MC alongside theoretically relevant factors, in a clinical sample. Further, the collection of MC start-dates combined with restriction of cycle lengths to 25-31 days increases confidence in day-to-phase correspondence, relative to prior research

There are several important limitations to address. Firstly, the relative improvement at T3 for OCD, anxiety and depression suggests this timepoint may have invertedly captured the mid-luteal phase, where hormone levels remain elevated, rather than the perimenstrual phase, when hormones sharply withdraw. The mid-late luteal phase has been associated with symptom improvement in some studies (Owens et al., 2023). Lack of hormonal assays prevents verification of this, however, our sensitivity analysis conducted on shorter cycles,

where T3 is more likely to correspond with the premenstrual phase showed a similar pattern of improvement across all variables. This suggests that findings are unlikely to be explained by phase misclassification. Further, lack of daily measurements alongside observations across just one cycle preclude definitive conclusions on the role of specific hormonal events (Schmalenberger et al., 2021). Nevertheless, the current approach had ecological application, reflecting measurements that could reasonably be administered in clinical practice. Moreover, the potential influence of the 'initial elevation bias' cannot be ruled out, and elevated scores at T1 may simply reflect this being the first timepoint (Shrout et al., 2018). Importantly, whilst the sample size was sufficient for the revised within-person analyses, the small number of participants meeting criteria for the 'OCD contamination group' prevented the originally planned between-group comparisons. This reflects a deviation from the initial proposal, however, changes were documented and reported transparently. Finally, sampling bias may have influenced findings, for example, recruitment was largely online (e.g., via Instagram) and materials clearly reported this as menstrual cycle research. The high proportion of participants reporting PMDD (31%) suggests that individuals with a pre-existing interest may have been more likely to take part. As such, it remains unclear whether results are generalisable to wider clinical OCD populations.

Implications

Clinical Practice

These findings have several implications for clinical practice. Firstly, clinicians working with women of reproductive age should be aware that OCD symptom severity can fluctuate considerably across the MC. Given that symptom improvement rather than exacerbation was observed, and that some dimensions such as harm concerns may be more

vulnerable to change, clinicians could encourage the use of symptom diaries and/or cycle-tracking apps such as Clue or Flo, to understand individual patterns of symptom change. incorporate hormone-sensitivity into psychological formulations. The clinical meaningfulness of the MC related changes at a group-level was unclear and likely minimal, however, services may still benefit from identifying hormone-sensitive individuals for whom the MC does influence symptoms. Hormone-sensitivity could be incorporated into psychological formulations and may be important for planning around subsequent reproductive events (e.g., pregnancy), although prospective exploration of this is lacking. These findings also have implications for interpretation of routine outcome measures (e.g., a worsening of symptoms may be misattributed to treatment failure or a relapse).

Research

Findings also generate several recommendations for future research. Firstly, the observed distinction between the minimal group-level improvement across the cycle and more profound individual variability demonstrates the importance of appropriate analytical strategies in MC research. Analysis should account for the MC having heterogeneous influences on symptoms and consider this a within-person process, by employing more rigorous analytical methods such as Multilevel Modelling (Schmalenberger et al., 2021). Treatment trials within OCD research could consider the MC as a prognostic variable, given it is associated with a significant change in symptoms. Indeed, the magnitude of symptom change identified in this study reflects a moderate effect size (η^2_p = .120), which is akin to effect sizes of treatment outcomes observed in Cognitive Behavioural Therapy with Exposure and Response Prevention (e.g., g = 0.74; Reid et al., 2021). Additional research with larger sample sizes, daily (or more frequent) symptom measures across multiple MCs and confirmation of ovulation via hormonal assays is required to further elucidate the influence of

the MC on OCD symptoms. Research should continue utilising existing cognitive behavioural frameworks to develop a theoretical understanding of symptom changes which could inform treatment efforts. Given the central role of appraisals in OCD severity, future research should further explore psychological experiences of the MC; qualitative methods may provide valuable insights into changes in appraisals across the cycle. More broadly, future research should consider psychological, social and cognitive factors in addition to hormonal explanations.

Conclusions

This study found that, contrary to expectations, OCD symptoms, anxiety and depression improved significantly in the premenstrual phase. Furthermore, when specific dimensions were analysed, contamination concerns remained relatively stable and harm-related concerns demonstrated the most change. PDS did not change significantly across the cycle, however, within-person variations in PDS were significantly associated with contamination concerns. This association was not observed with overall OCD symptoms suggesting PDS is unlikely to be a major driver in overall OCD symptomology, beyond contamination concerns. Notably, 23% of the sample experienced clinically meaningful changes of OCD across the cycle (14% improvement, 13% worsening). Despite findings being mixed and unexpected, they highlight the potential role of hormonal fluctuations in OCD symptomology. Implications include awareness of the MC in clinical practice and recommendations for further research to more explicitly examine the role of appraisals in MC-related symptom changes.

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Executive Summary

Background

Researchers have identified that mental health disorders, including obsessive compulsive disorder (OCD), can worsen at certain points of the menstrual cycle. Some women with OCD may notice their symptoms (e.g., intrusive thoughts, anxiety) are worse in the week before their period starts, this is known as ‘premenstrual exacerbation’ or PME. During this phase, key hormones such as oestradiol and progesterone are low, which has been associated with a worsening in symptoms of emotional disorders. Currently, there is limited good quality research on PME of OCD, and little is known about how mood and other factors of interest influence such exacerbations. Here, we used the cognitive model of OCD (Salkovskis et al., 1985) in an attempt to understand these changes. One potential factor of interest is "disgust sensitivity," or how negative the feeling of disgust is, which has been overlooked in OCD research. A specific type of disgust sensitivity, Pathogen Disgust Sensitivity (PSD; disgust sensitivity towards germs or infection) has been shown to change throughout the menstrual cycle and is associated with specific OCD-related concerns such as contamination.

Therefore, this research aimed to examine:

- how OCD symptoms, PDS, anxiety and mood change across the menstrual cycle in women with OCD
- whether contamination concerns are more to change across the menstrual cycle than other OCD dimensions
- the influence of PDS, mood, and anxiety on OCD symptom changes across the menstrual cycle

Method

This study was conducted online, and participants were recruited through social media (e.g., Instagram) and OCD-related charities (e.g., OCD UK). Before taking part, potential participants completed a screening survey, at which point they provided informed consent.

A 'prospective' design was used, meaning that measurements were taken in 'real time' across the cycle, rather than relying on memory of symptom changes. Participants completed Measures of OCD, PDS, anxiety and mood at three points in their menstrual cycle:

- Timepoint 1 (days 4 to 7 after bleeding onset; early-follicular phase)
- Timepoint 2 (days 19 to 22 after bleeding onset; mid-luteal phase)
- Timepoint 3 (days 24 to 27 after bleeding onset; premenstrual phase)

In addition, all participants were asked to confirm the first day of two consecutive menstrual cycles, allowing us to calculate their menstrual cycle length (e.g., 28 days). All surveys were administered by email.

Results

A total 61 people participated, with 53 completing all three timepoints. The majority were white (88.5%), aged 25-34 (47.5%), identified as women (91.8%) and heterosexual (57.4%).

Contrary to predictions, OCD, anxiety and depression scores were significantly lower at timepoint 3 (premenstrual phase) compared to timepoint 1 (early follicular phase). By contrast, PDS scores did **not** change significantly across the menstrual cycle. Contamination concerns group were **not** more likely change across the cycle, and harm concerns demonstrated the most change between timepoint 1 and 3. Interestingly, individual variability in PDS across the cycle was associated with changes in contamination concerns. In total, 23% of the sample experienced clinically meaningful (≥30%) fluctuation in OCD symptoms across the cycle, 8.2% experienced premenstrual worsening and 14.8% experienced premenstrual improvement.

Discussion

The unexpected finding that OCD, anxiety and mood symptoms improved during the premenstrual phase is puzzling. This could reflect low levels of key hormones such as oestradiol, and/or that this phase corresponds with menstrual bleeding. It may be that the additional 'burden' of menstruation (e.g., fatigue, pain) or more specific concerns such as contact with blood, sanitary bins or cultural taboos, explains the exacerbation in OCD. Much more high-quality research is needed, using large samples to examine OCD symptoms in 'real time' across the menstrual cycle.

Implications

The findings that OCD symptom severity changes significantly across the menstrual cycle is an important consideration for treatment trials. Care should be taken to determine if improvements in symptoms are due to the treatment or merely reflect changes naturally occurring across the cycle. These findings also suggest that clinicians working with women of reproductive age should be aware that OCD symptom severity can fluctuate considerably across the MC. Clinicians could encourage the use of symptom diaries and/or cycle-tracking apps such as Clue or Flo and consider incorporating symptom fluctuations into treatment.

Conclusion

This study demonstrates that OCD symptoms change improved during the premenstrual phase, which is contrary to expectations. Considerable differences in patterns of symptom change were observed between people (e.g., improvement or worsening). Findings highlight the potential role of hormonal fluctuations in OCD symptoms, and further research is required to further elucidate the role of mood changes and PDS. Implications include awareness of the MC in clinical practice and acknowledgement of the MC in treatment trials.

Connecting Narrative

A common thread across my projects is the focus on women's mental health. When starting clinical training, I had a prior interest in how the menstrual cycle influenced mental health, for example, Premenstrual Syndrome (PMS). This interest was formed and nurtured during my Masters, during which time I completed and published a systematic review on this the topic of Premenstrual Exacerbation (PME). I became aware of how psychology and psychiatry has long overlooked the role of hormones in mental health, and this fuelled my decision for the three projects I chose for this Doctorate of Clinical Psychology thesis.

Theoretically Driven Research Project

I knew from my previous systemic review that there was a huge lack in research exploring obsessive compulsive disorder (OCD) across the menstrual cycle. I am eternally grateful I was supported to do a project that fit so perfectly with my interests. Nevertheless, this project has was a huge challenge in many ways. Firstly, finding supervisors who were interested in and saw the value in this area was challenging. Secondly, trying to fit the area of PME with the course requirement for a theory-driven project was something I initially considered an obstacle; however, this ultimately benefited the project and its clinical utility. Thirdly, the logistics of collecting bookend menstrual cycle start dates, sending surveys at specific points in the menstrual cycle, along with reminders, was arduous and time-consuming. Next, the statistical analysis approach to this project is notably not to the gold-standard, which expects multi-level modelling using nested data: nevertheless, the method does adequately reflect the within- and between-subject factors required.

By contrast, recruitment was much more successful than I anticipated, and the project received lots of interest. I think this speaks to how overlooked this area has been until now. I

was also lucky enough to be invited to talk at the OCD-UK conference and the International OCD Foundation conference. This was my first experience of original menstrual cycle research, and I have learnt a huge amount; I am now viscerally aware of the difficulties in developing and executing high quality menstrual cycle research. Whilst there are excellent best-practice guidelines to draw on, these were notably not directly applicable to the type of research that is feasible with the limited resources, both financial and time, that the DClinPsych offers. The unexpected results were initially puzzling but ultimately tell us that far more research is required and importantly that OCD does seem to be influenced by the menstrual cycle.

Systematic Review of the Literature

The lack of research into Premenstrual Disorders extends to understanding their aetiological and maintenance factors. I had come across a few studies pointing to a potential role of trauma, and this was an area I felt required more thorough consideration. Upon scoping the literature, I was surprised at how many studies had explored the association between trauma and PMDs; this wasn't a niche finding in one or two studies. The number of studies was part of the reason for considering PTSD as a potential confounding variable – it was sufficiently saturated to ask whether all this research demonstrated an association between PMDs and PTSD, trauma alone, or both? Owing to the vagueness of my initial research question in 'understanding the association between trauma and PMDs', my review required untangling the various ways research had approached answering this question. It was a time-consuming process and but turned out to be highly satisfying.

A stand-out period during my review was when a similar paper exploring this topic was published. Given I was already far along in the process of data extraction, I felt extreme

dread and anxiety, before bringing myself to read the paper. Thankfully, this was sufficiently different to mine, and I was able to continue with my review. This left me with an understanding of the speed at which research in this field is developing, which is in equal parts intimidating and encouraging. I hope my review sheds further light on this area and encourages more high-quality research which sufficiently considers potential cofounding variables in the elucidation of aetiological factors in PMDs.

Service Improvement Project

Understanding therapeutic experiences of women with vaginismus in an under-researched area. This is despite the immense obstacles, societal and personal, to identifying vaginismus, and seeking treatment. It was therefore unsurprising that the psychosexual therapy service was unsure of how to respond to issues with treatment adherence in vaginismus. This project felt really important but was the most challenging of all. Recruitment was difficult, and whilst this was not a total surprise, given the shame and stigma that surrounds vaginismus, I had not fully anticipated other barriers to recruitment. There were multiple bureaucratic obstacles and lots of 'red tape', partly because of the project being located within a sexual health service. This was compounded by my supervisor going on maternity leave. Despite this, I took all possible measures to enhance patient recruitment, such as creating and re-creating posters, letters, emails, at multiple stages, and keeping the recruitment window open. Recruitment for interviews was slow and the decision to extend this to staff was taken. Initially, I felt disappointed. However, I ultimately found the process extremely valuable and given that much of the recommendations rely on staff willingness, their input was highly applicable. I also wondered about the appropriateness of including my original research supervisor as an interview participant. Discussion with my

internal supervisor allowed me to conclude that this was appropriate, as their maternity leave minimised recent involvement in the project.

Conclusion

My aim is for women's mental health, particularly relating to the menstrual cycle and menopause, to be viewed as fundamental to care and wellbeing. Beyond hormones, consideration for gendered aspects of mental health is important – with differing societal pressures placed on men, women and gender non-confirming individuals. All clinicians and researchers should have a baseline knowledge of women's health, rather than the topic being viewed as a 'niche' interest.

Acknowledgments

Firstly, I want to say a huge thank you to my family – mum, dad, Josie, Jack and little Finn – for their unconditional support and love throughout this journey, and for always keeping me humble. To my beautiful friends from the DClin past and present, who made the course infinitely more bearable and fun – I have no doubt this experience has bonded us for life. To my lovely friends from my pre-DClin life, thank you for your support, even if none of my complaining made sense to you, and for reminding me there is more to life than the DClin.

To all the people participating in my research, I am endlessly thankful, I did my best to make your investment of time and energy worth it. I want to thank Dr Katja Schmalenberger, at the University of Illinois Chicago, for all the support with developing my research. I would also like to thank OCD-UK for your brilliant help in recruiting for this project, it made a huge difference.

To my supervisors, Dr Fiona Challacombe, Dr Susannah Jenner, Dr Graham Thew, Dr Eike Adams and my course tutor, Dr Laura Fisk, for your belief and support throughout these projects. Your willingness and enthusiasm to support me through a research area in its relative infancy did not go unnoticed. A shout out to Missing Bean, for providing me with the coffee and sweet treats needed to sustain my three years in Oxford!

Thank you all for making this journey possible, I don't think little Louise ever thought she would be writing acknowledgements for her doctoral thesis at the University of Oxford.

Appendix A: SRL – Search Terms

Medline search terms (n = 151)

Premenstrual disorder* OR premenstrual syndrome OR PMS OR Premenstrual Dysphoric Disorder OR PMDD OR Premenstrual Tension OR menstrual symptoms OR premenstrual symptoms

AND

Adverse childhood experience* OR childhood maltreatment OR abuse OR childhood trauma OR sexual abuse OR neglect OR trauma OR trauma event* OR traumatic event* OR violence exposure OR physical abuse

Embase search terms (n = 328)

Premenstrual syndrome OR PMS OR Premenstrual Dysphoric Disorder OR PMDD OR Premenstrual Tension OR PMT OR menstrual symptoms OR premenstrual symptoms

AND

Adverse childhood experience* OR child maltreatment or maltreatment OR abuse OR childhood trauma OR sexual abuse OR physical abuse OR emotional abuse OR neglect OR trauma or trauma event* OR traumatic event* OR violence exposure

PsycINFO search terms (n= 103)

Premenstrual syndrome OR PMS OR Premenstrual Dysphoric Disorder OR PMDD OR Menstrual Disorders OR Premenstrual Tension OR PMT OR menstrual symptoms OR premenstrual symptoms

AND

Trauma OR Complex trauma OR emotional trauma OR birth trauma OR childhood adversity OR child abuse OR sexual abuse OR physical abuse OR emotional abuse

CINAHL search terms (n= 240)

Premenstrual syndrome OR PMS OR Premenstrual Dysphoric Disorder OR PMDD OR Menstrual Disorders OR Premenstrual Tension OR PMT OR menstrual symptoms OR premenstrual symptoms

AND

Trauma OR Complex trauma OR emotional trauma OR birth trauma OR childhood adversity OR child abuse OR sexual abuse OR physical abuse OR emotional abuse

Appendix B: SRL – Risk of Bias Scoring

Risk of Bias Scoring

For the CASP, a score of 1 was used to reflect 'can't tell' and where a condition was 'partially met'. This reflects the multitude of methodological considerations specific to menstrual cycle and trauma research. For example, for the item '*Were the measures accurately measured to reduce bias?'* if a validated tool was used alongside a prospective measure of premenstrual symptomology, but another important measurement bias was not considered (e.g., mood at the time of recalling traumatic events), a score of 1 was awarded. This reflects that this condition was partially met.

Appendix C: SRL – Categorisation of Premenstrual Disorders

Categorisation of Premenstrual Disorders

Studies will be categorised according to the following criteria:

- PMDD – requires classification of participants according to diagnostic criteria e.g., DSM-5, which requires at least five specific symptoms, emotional and physical, occurring in the week before menstruation and causing significant distress or impairment (APA, 2013). Retrospective assessment is acceptable if aforementioned criteria is satisfied, whilst this is not the gold-standard, this criteria has been used in similar reviews (e.g., Grewal et al., 2024).
- PMS – requires classification of participants according to diagnostic thresholds e.g., ACOG, which defines PMS as the presence of cyclic physical and/or mood-related symptoms occurring in the luteal phase, resolving with menstruation, and causing some level of distress or interference, but not meeting the full criteria for PMDD (ACOG, 2023).

Appendix D: SRL – Appendix D – Interpretability of Results

Three factors were considered to influence to the interpretability of findings and each is detailed below:

- PTSD – categorised as yes, no, partially controlled. A study was rated 'yes' if PTSD or all psychiatric disorders (self-report or verified via diagnostic interview) were excluded or statistically controlled for. A study was rated 'partially controlled' if PTSD was only excluded from some groups or if psychiatric disorders were excluded but PTSD symptoms were separately measured (note, this is not akin to a diagnosis of PTSD). If a study did not consider PTSD, this would be considered 'no'.

- Hormonal contraceptive use – categorised as 'yes' or 'no'. The fundamental consequence of HC is the suppression of ovulation preventing a physiological menstrual cycle. This means if the sample includes individuals taking HC, symptoms cannot be interpreted as related to the hormonal fluctuations associated with the luteal phase of the menstrual cycle. Studies will be categorised as 'no' if HC if individuals taking HC are included, or if HC is not mentioned. Studies will be categorised as 'yes' if individuals taking HC are excluded. Studies incorporating statistical control for HC-use does not overcome this problem and therefore will still be categorised as 'no'.

- Measurement of premenstrual symptomology – retrospective or prospective. It is well-established that due to recall bias, retrospective symptom assessment can overestimate the prevalence and severity of premenstrual symptomology (Henz et al., 2018). The importance of accurate measurement is further justified given the overlap of premenstrual symptomology with common mental health disorder symptoms (e.g.,

anxiety, depression). Therefore, assessment that prospectively measures the onset of new symptoms in 'real time' from the follicular to the luteal phase reflects the gold-standard.

Studies examining PMS will be considered 'high interpretability' if controlling for HC and PTSD (i.e., a rating of 'yes' for both). For PMDD, studies will be considered 'high interpretability' if controlling for all three factors (i.e., a rating of 'yes' for all). This increased focus on prospective methodology in PMDD reflects the common methods used amongst studies in each disorder and the stricter criteria prospective required for PMDD diagnoses.

Appendix E: SRL/TDRP – Author Guidelines

Author Guidelines

Sections

1. Submission and Peer Review Process
2. Article Types
3. After Acceptance
4. In Session Author Guidelines

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Appendix F: SIP – Pre- and Post-Therapy Measures

Therapy Outcome Measures

The measures below were developed within the service and are not standardised or validated measures of vaginismus treatment.

Psychosexual Therapy: If you currently are single evaluation sheet
AT INITIAL ASSESSMENT

Please circle the appropriate number.

My sexual problem affects my confidence in making relationships……..									
1	2	3	4	5	6	7	8	9	10
Very much									Not at all

My confidence and self-esteem is……..									
1	2	3	4	5	6	7	8	9	10
Low									High

My understanding of my sexual problem is……..									
1	2	3	4	5	6	7	8	9	10
Poor									Good

Please tell us what you hope to achieve from therapy in your own words…….

Psychosexual Therapy: If you currently have a partner evaluation sheet
AT INITIAL ASSESSMENT

Please circle the appropriate number.

My sexual relationship now is……..									
1	2	3	4	5	6	7	8	9	10
Not at all as I want it to be									Very much as I want it to be

My general relationship now is……..									
1	2	3	4	5	6	7	8	9	10
Not at all as I want it to be									Very much as I want it to be

My understanding of my sexual problem is……..									
1	2	3	4	5	6	7	8	9	10
Poor									Good

Please tell us what you hope to achieve from therapy in your own words…….

Psychosexual Therapy – Individual's Evaluation Sheet

AT END OF THERAPY

Please circle the appropriate number.

My sexual problem affects my confidence in making relationships……..									
1	2	3	4	5	6	7	8	9	10
Very much									Not at all

My confidence and self-esteem is……..									
1	2	3	4	5	6	7	8	9	10
Low									High

My understanding of my sexual problem is……..									
1	2	3	4	5	6	7	8	9	10
Poor									Good

This course of psychosexual therapy was……..									
1	2	3	4	5	6	7	8	9	10
Very unhelpful									Extremely helpful

Psychosexual Therapy – Couple's Evaluation Sheet

AT END OF THERAPY

Please circle the appropriate number.

My sexual relationship now is……									
1	2	3	4	5	6	7	8	9	10
Not at all as I want it to be									Very much as I want it to be

My general relationship now is ……..									
1	2	3	4	5	6	7	8	9	10
Not at all as I want it to be									Very much as I want it to be

My understanding of my sexual problem is……..									
1	2	3	4	5	6	7	8	9	10
Poor									Good

This course of psychosexual therapy was……..									
1	2	3	4	5	6	7	8	9	10
Very unhelpful									Extremely helpful

Appendix G: SIP – Patient Survey

The participant information sheet, consent form, and all questions are outlined in the links below. Only a full copy of the treatment group survey is added below, this because it is largely the same for the waitlist, except where changes are otherwise specified in this report (e.g., survey question '*not understanding how to do between session tasks'* not applicable in the waitlist group).

- Link to treatment group survey: **https://forms.office.com/e/RBYdutFRAM**
- Link to waitlist group survey: **https://forms.office.com/e/Ji6Y8tJ7ZM**

Patient Survey – treatment group

Vaginismus Service Improvement Survey (Treatment)

Participant Information section

We would like to invite you to take part in this service improvement project. Before you decide whether or not to take part, it is important to understand why this project is being done and what your participation will involve. Please read the following information carefully.

What is the study about?

You have been invited to take part in this study as we understand that you experience vaginismus, a condition characterised by involuntary vaginal muscle spasms and are either in treatment, or on the waitlist for treatment, at the Psychosexual Therapy Service. We aim to explore your experience of treatment or being on the waitlist within the service. In particular, we want to find out more about your treatment preferences and the factors that make it easier or more difficult to fully engage with treatment.

What is the purpose of the study?

The purpose of this study is to improve psychological treatment provision for people with vaginismus within the Oxfordshire Psychosexual Therapy Service. The knowledge we gain from you, as someone with first-hand experience of treatment or waiting for treatment, will allow us to make recommendations to improve the service. These recommendations may lead to changes or expansion of treatment within the service to improve the service's approach to treating people with vaginismus. This study has been approved by the Oxford University Hospital NHS Trust Psychological Medicine Clinical Governance Committee.

Who is conducting the study?

The project is being conducted by Louise Nolan, a Trainee Clinical Psychologist, as part of the Doctorate of Clinical Psychology Programme at the University of Oxford. This project will be supervised by Dr Susannah Jenner (Clinical Psychologist, University of Oxford), Dr Emma Evans (Clinical Psychologist, Pelvic Pain Service) and Dr Eike Adams (Clinical Psychologist, Oxfordshire Psychosexual Therapy Service).

Who will be asked to take part?

Anyone aged over 18 who is currently engaging with or waiting for psychological treatment for vaginismus within the Oxfordshire Psychosexual Therapy Service is welcome to take part.

What will happen if I take part?
Participation is voluntary. You may choose whether or not to be a part of it, and your decision will be respected without any consequences to your treatment. You will be asked to complete one short survey. This will ask about your preferences for treatment options and factors that might make it easier or more difficult to engage with psychological treatment.

Following completion of the survey, you will be invited to take part in an optional 30-minute one-to-one conversation with the researcher, Louise, to find out more information about your treatment preferences and factors that make it easier or more difficult to engage with treatment, and how you think treatment for vaginismus could be improved. This is entirely voluntary, and additional information will be provided. You will **not** be asked for any personally identifiable details, except for your email address if you choose to participate in the second part of the study - a one-to-one conversation with Louise.

Vaginismus Service Improvement Survey (Treatment)
Required
Participant Information section
What will happen to my information?
You will **not** be asked to provide any personally identifiable details in this survey. All survey responses provided will be anonymous, ensuring your privacy and protecting your identity. At the end of the survey, you may decide to share you email address - this is optional and will be kept strictly confidential within the research team.

What will happen to the results of the study?
The results of this project will be written in a report as part of the Doctorate of Clinical Psychology thesis and may be submitted for publication in a journal. The results will be presented to the Oxfordshire Psychosexual Therapy service. Due to the anonymity measures taken, you will not be identifiable from the results or report.

Contact Information:
If you have any questions about the study, please don't hesitate to reach out to me at: louise.nolan@hmc.ox.ac.uk

Thank you for helping us improve our services and support for individuals with vaginismus.

Sincerely,
Louise Nolan
Trainee Clinical Psychologist
University of Oxford
1.Please confirm you have read and understood the participant information sheet
Yes
No
I have some questions (email: Louise.Nolan@hmc.ox.ac.uk)

Vaginismus Service Improvement Survey (Treatment)
Required
Consent form
2.Please read the statements below and select those that apply:
Please select 4 options.

I confirm I have read the participant information sheet for the above study.
I have had the chance to consider the information, and have been given the opportunity to ask questions about the study and/or my involvement.
I understand that my participation is voluntary and that I am free to withdraw at any time whilst completing the survey without giving any reason, without my treatment being affected.
I agree to take part in the above study.

Vaginismus Service Improvement Survey (Treatment)
Required
Demographics / About You
Please tell us about yourself. It's helpful for us to know these details to identify whether there are similarities or differences between groups of people.
3.**How old are you?**
18 to 24
25 to 34
35 to 44
45 to 54
55 to 64
Over 65
4.**What best describes your gender?**
Woman
Man
Non-binary
Prefer to self describe
Prefer not to say
5.**What best describes your sexual orientation?**
Straight or heterosexual
Lesbian or gay
Bisexual
Asexual
Pansexual
Prefer not to say
6.**How long have you been experiencing vaginismus?**
Less than 1 year
1 to 3 years
3 to 5 years
5 to 10 years
More than 10 years
7.**Do you have Primary vaginismus (i.e., you have always experienced vaginismus) or Secondary vaginismus (i.e., there was a time you did not experience vaginismus)?**
Primary Vaginismus (you have always experienced vaginismus)
Secondary Vaginismus (there was a time you did not experience vaginismus)
8.**How many psychological therapy sessions have you had within the Psychosexual Therapy Service?**
1
2
3
4
5
6
7

8
9
10
11
12

9.**Are you currently accessing other support for vaginismus?**
Yes (please specify in the text box below)
No
10.**If you answered yes to the question above, please specify the type of support you are currently receiving**

11.**How difficult or easy have you found it to stick to all aspects of your psychological treatment?**
1 (very easy)
2
3 (neither easy or difficult)
4
5 (very difficult)

Vaginismus Service Improvement Survey (Treatment)
Psychological Treatment 'Adherence' in Vaginismus
We want to hear your experience about what makes it easier or harder for you to take part in or persevere with treatment for your vaginismus. Importantly, we recognise partaking in treatment can be hard for a variety of reasons, we have a non-judgemental and non-blaming stance towards patient experiences.

What is 'treatment adherence' (i.e., taking part) in your treatment?
Treatment adherence refers to the extent to which someone is able to engage with their treatment (e.g., attending therapy sessions, completing between-session tasks). High adherence would mean engaging with the treatment for the most part (e.g., attending most sessions), low adherence would mean not engaging with the treatment much (e.g., only attending a few sessions).

We recognise that many factors can influence how much you feel able to persevere with treatment. We call these "barriers" and "facilitators" and have defined these below.

Barriers/obstacles to adherence are things that make it *harder* for you to persevere with psychological treatment (e.g., lack of time, not knowing if the therapy will be effective).

Facilitators to adherence are things that make it *easier* for you to persevere to psychological treatment (e.g., support from loved ones or online/face to face treatment options).

Barriers to Treatment Adherence
Please rate each of the following examples based on the extent to which they have been barriers/obstacles to your adherence to psychological treatment for vaginismus, using a scale from 1 (Not a Barrier) to 5 (Significant Barrier).
12.**Not knowing how much the therapy could help**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)

13.Optional: please explain your answer to the above
14.**Not understanding ideas discussed within the session (e.g., psychological concepts)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
15.Optional: please explain your answer to the above
16.**Time Constraints (i.e., finding time to attend sessions and do between session tasks)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
17.Optional: please explain your answer to the above
18.**Financial Constraints (e.g., affording time off work to attend sessions or affording transportation to sessions)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
19.Optional: please explain your answer to the above
20.**Stigma associated with attending psychological therapy**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
21.Optional: please explain your answer to the above
22.**Emotional distress related to therapy sessions (e.g., discussing matters related to vaginismus)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
23.Optional: please explain your answer to the above
24.**Mental health difficulties (e.g., anxiety, depression).**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
25.Optional: please explain your answer to the above
26.**Therapy being delivered online (e.g., via Microsoft teams)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)

27.Optional: please explain your answer to the above
28.**Therapy being delivered in person (e.g., within the Churchill Hospital clinic)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
29.Optional: please explain your answer to the above
30.**Therapy causing symptoms or distress to become worse**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
31.Optional: please explain your answer to the above
32.**Not understanding how to do the between-session tasks (e.g., trainers/dilators or pelvic floor exercises)**
1 (Not a Barrier)
2
3
4
5 (Significant Barrier)
33.Optional: please explain your answer to the above
34.**Are there any other factors that meant it was difficult for you to engage with or take part in the psychological support being offered?**

Facilitators of Treatment Adherence
Please rate the following factors based on the extent to which they have facilitated/helped your adherence to psychological treatment for vaginismus, using a scale from 1 (Not a Facilitator) to 5 (Significant Facilitator).
35.**Supportive relationship with your therapist or healthcare professional**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
36.Optional: please explain your answer to the above
37.**Support from your partner, family, or friends**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
38.Optional: please explain your answer to the above
39.**Understanding or experiencing the value and benefits of psychological treatment**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)

40.Optional: please explain your answer to the above
41.**Having coping strategies for managing emotional difficulties that may come up during therapy**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
42.Optional: please explain your answer to the above
43.**Therapy being delivered in person (e.g., within the Churchill Hospital clinic)**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
44.Optional: please explain your answer to the above
45.**Therapy being delivered online (e.g., via Microsoft teams)**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
46.Optional: please explain your answer to the above
47.**Understanding the psychological ideas discussed within sessions**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
48.Optional: please explain your answer to the above
49.**Understanding how to do the between-session tasks (e.g., using trainers/dilators, pelvic floor exercises)**
1 (Not a Facilitator)
2
3
4
5 (Significant Facilitator)
50.Optional: please explain your answer to the above
51.**Any other factors that helped you to engage with or take part in the support being offered?**
52.**Additional Comments:**

Please share any additional thoughts or comments regarding your experiences.

Treatment Preferences

A variety of possible treatment options are available to manage vaginismus. To explore your opinions about these treatments, a number of these options have been presented below. **Please note that the options below are <u>not</u> all currently available within the Oxfordshire Psychosexual Therapy service.**

Please read the descriptions of each treatment option and rate how likely you are to engage with

each of these on a scale from 1 (not likely) to 5 (very likely).

53.**Self-Help Resources**
Description: Self-help resources, such as books and educational materials, provide information and exercises to help you manage vaginismus on your own.

1 (Not Likely)
2
3
4
5 (Very Likely)
54.Optional: please explain your answer to the above
55.**Individual Psychosexual therapy**
Description: psychosexual therapy involves talking to a health professional (e.g. a sex therapist or psychologist) who specialises in vaginismus. It involves discussing thoughts, feelings, behaviours and how your body works, to help you understand and manage vaginismus. It involves doing physical tasks at home, such as pelvic floor exercises and using trainers/dilators, which can be done individually or as a couple. Sessions can take place in person or online.
1 (Not Likely)
2
3
4
5 (Very Likely)
56.Optional: please explain your answer to the above
57.**Couples' Psychosexual therapy**
Description: Couples' Psychosexual Therapy is similar to individual therapy but involves both people in the relationship. In addition to individual therapy, this would cover discussions around sex and the relationship. Physical tasks done in-between sessions such as using trainers/dilators can be done individually and as a couple. Sessions can take place in person or online. For those in a relationship, couples therapy is often recommended for the best outcomes. NB: if you are not currently in a relationship, please indicate how likely you would be to engage if you were.
1 (Not Likely)
2
3
4
5 (Very Likely)
58.Optional: please explain your answer to the above
59.**Group-based psychosexual therapy**
Description: this group would be attended by a small number of people who also experience vaginismus and is facilitated by a trained therapist. The group covers the same concepts and techniques learnt in individual therapy. Typically, all group members are invited, but not pressured, to share their experiences, thoughts and feelings. This can take place in person or online. (Please note: this is not currently available in this service).
1 (Not Likely)
2
3
4
5 (Very Likely)
60.Optional: please explain your answer to the above

61.**Are there any other treatments or interventions that have not been mentioned that you would find helpful?**
62.**Do you have any other comments on your treatment preferences for vaginismus?**

Would you be happy to share more of your views with the research team?
If you would be happy for the lead researcher (Louise Nolan) to contact you to ask more about your treatment experiences and treatment preferences in vaginismus, please provide your email address. You may be invited to take part in a short conversation with Louise Nolan to get more information about your experience of treatment for vaginismus. Note: all your responses will be kept confidential, and you can change your mind at any time.
63.Email address (please provide if you would like to be contacted to take part in a conversation with the researcher)

Appendix H: SIP – Interview Schedules

Patient interviews

1) Could you tell me about your journey to being referred to the psychology service for vaginismus.
2) What motivated you to start therapy?
3) How has your experience of psychological support been?
4) Have there been any difficult aspects of psychological support or therapy?

   Prompt: If yes, what were they?
5) Have there been any valuable/helpful aspects of psychological support or therapy?

   Prompt: If yes, what?
6) Have there been any factors that have made engaging with therapy more difficult?

   Prompt: why was that so difficult?
7) Have there been any factors that have made engaging with therapy feel easier?

   Prompt: why was that so helpful?
8) The Oxfordshire psychosexual therapy service currently offers individual/1:1 or couples therapy. Did you feel this was right for you?

   a) If yes, could you explain why?

   Prompt: do you think other forms of psychological treatment (e.g., groups) would be helpful for you and why?
9) Is there anything the service could do differently to improve your experience of psychological support?

   Prompt: Is there anything else you would like to share about your experiences with vaginismus treatment

Staff interviews

1. What do you think motivates patients to begin psychosexual therapy for vaginismus?
2. From your perspective, how would you describe patients' experiences of psychological support for vaginismus?
3. Which aspects of psychological support or therapy are particularly difficult for patients?
4. Which aspects of psychological support or therapy do you feel are most valuable or helpful for patients?
5. What factors have you noticed that make it more difficult for patients to engage with therapy?

   Prompt: Why do you think these aspects are especially challenging?
6. What factors have you noticed make it easier for patients to engage with therapy?

   Prompt: Why do you think these aspects help?
7. The Oxfordshire Psychosexual Therapy Service currently offers individual/1:1 and couples therapy. From your perspective, do you think this format is appropriate for most patients?

   a) *If yes, could you explain why?*

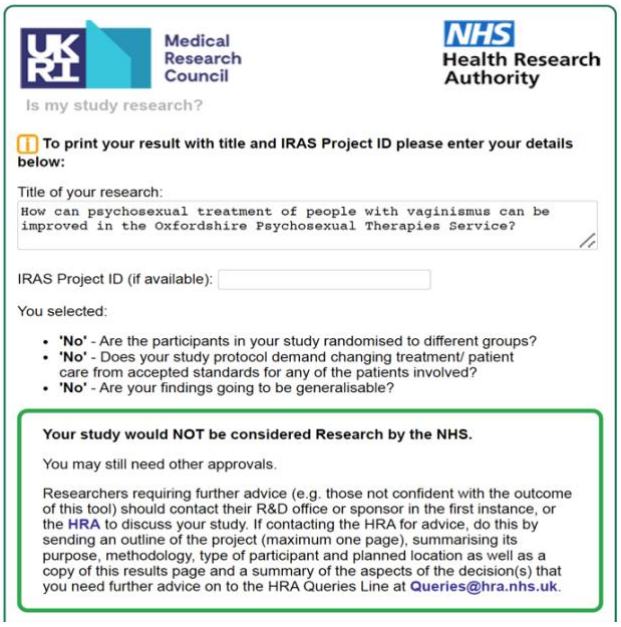
   Prompt: do you think alternative formats (e.g., groups) might be more beneficial in some people? Why?
8. Is there anything you think the service could do differently to improve the psychological support provided to patients with vaginismus?

   Prompt: Are there any suggestions or changes you've thought about based on your work with patients?

   Prompt: Is there anything else you'd like to share about your experience supporting patients with vaginismus?

Appendix I: SIP – Project Approval

Confirmation of Project Classification



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

How can psychosexual treatment of people with vaginismus can be improved in the Oxfordshire Psychosexual Therapies Service?

IRAS Project ID (if available):

You selected:

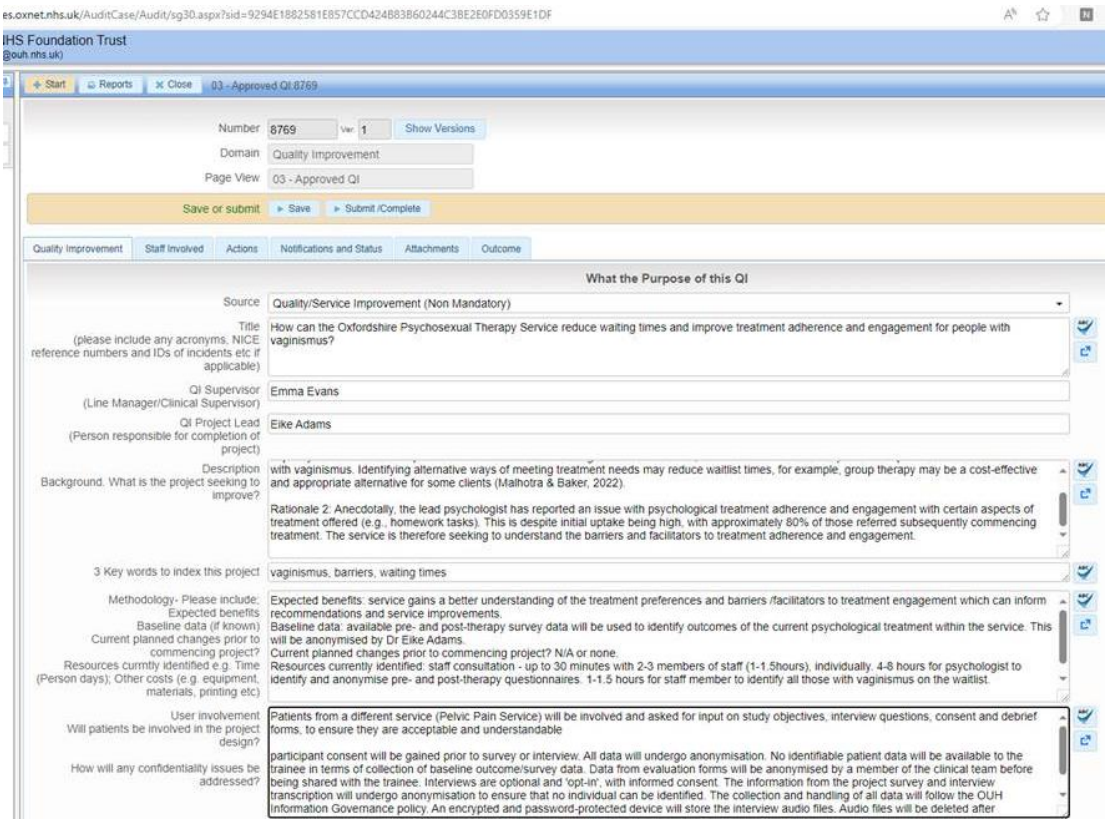
- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

Trust Approval and Registration of Project (Ulysses)



es.oxnet.nhs.uk/AuditCase/Audit/sg30.aspx?sid=9294E1882581E857CCD424B83B60244C3BE2E0FD0359E1DF

IHS Foundation Trust

@ouh.nhs.uk)

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Number 8769 Ver 1 Show Versions

Domain Quality Improvement

Page View 03 - Approved QI

Save or submit: Save | Submit /Complete

Quality Improvement | Staff Involved | Actions | Notifications and Status | Attachments | Outcome

What the Purpose of this QI

Source: Quality/Service Improvement (Non Mandatory)

Title (please include any acronyms, NICE reference numbers and IDs of incidents etc if applicable): How can the Oxfordshire Psychosexual Therapy Service reduce waiting times and improve treatment adherence and engagement for people with vaginismus?

QI Supervisor (Line Manager/Clinical Supervisor): Emma Evans

QI Project Lead (Person responsible for completion of project): Eike Adams

Description Background. What is the project seeking to improve?: with vaginismus. Identifying alternative ways of meeting treatment needs may reduce waitlist times, for example, group therapy may be a cost-effective and appropriate alternative for some clients (Malhotra & Baker, 2022).

Rationale 2: Anecdotally, the lead psychologist has reported an issue with psychological treatment adherence and engagement with certain aspects of treatment offered (e.g., homework tasks). This is despite initial uptake being high, with approximately 80% of those referred subsequently commencing treatment. The service is therefore seeking to understand the barriers and facilitators to treatment adherence and engagement.

3 Key words to index this project: vaginismus, barriers, waiting times

Methodology- Please include: Expected benefits Baseline data (if known) Current planned changes prior to commencing project? Resources currntly identified e.g. Time (Person days); Other costs (e.g. equipment, materials, printing etc): Expected benefits: service gains a better understanding of the treatment preferences and barriers /facilitators to treatment engagement which can inform recommendations and service improvements.
Baseline data: available pre- and post-therapy survey data will be used to identify outcomes of the current psychological treatment within the service. This will be anonymised by Dr Eike Adams.
Current planned changes prior to commencing project? N/A or none.
Resources currently identified: staff consultation - up to 30 minutes with 2-3 members of staff (1-1.5hours), individually. 4-8 hours for psychologist to identify and anonymise pre- and post-therapy questionnaires. 1-1.5 hours for staff member to identify all those with vaginismus on the waitlist.

User involvement Will patients be involved in the project design?: Patients from a different service (Pelvic Pain Service) will be involved and asked for input on study objectives, interview questions, consent and debrief forms, to ensure they are acceptable and understandable

How will any confidentiality issues be addressed?: participant consent will be gained prior to survey or interview. All data will undergo anonymisation. No identifiable patient data will be available to the trainee in terms of collection of baseline outcome/survey data. Data from evaluation forms will be anonymised by a member of the clinical team before being shared with the trainee. Interviews are optional and 'opt-in', with informed consent. The information from the project survey and interview transcription will undergo anonymisation to ensure that no individual can be identified. The collection and handling of all data will follow the OUH Information Governance policy. An encrypted and password-protected device will store the interview audio files. Audio files will be deleted after

Appendix J: SIP – Demographic Data

Demographic data was not reported in the main results or used as a basis for comparison. This largely reflects the small sample sizes, which limit meaningful comparisons. Nevertheless, collection of demographic data was important for providing important context in the interpretation of findings and can inform the generalisability of findings to wider groups.

Table 3

Demographic details of survey participants

	Treatment (*n* = 10)	**Waitlist** (*n* = 7)
Age		
18-24	4 (40%)	2 (29%)
25-34	5 (50%)	5 (71%)
35-44	1 (10%)	0
45-54	0	0
55-64	0	0
65+	0	0
Gender		
Women	10 (100%)	6 (86%)
Man	0	0
Non-binary	0	0
Prefer to self-describe	0	0
Prefer not to say	0	1 (14%)
Gender		
Heterosexual	9 (90%)	6 (86%)
Lesbian or gay	0	0
Bisexual	0	0
Asexual	0	0
Pansexual	0	0
Demisexual	1 (10%)	0
Prefer not to say	0	1 (14%)
Other	0	0

Vaginismus Type		
Primary	4 (40%)	7 (100%)
Secondary	6 (60%)	0
Duration of Vaginismus		
< 1 year	1 (10%)	0
1-3 years	1 (10%)	1 (14%)
3-5 years	2 (30%)	1 (14%)
5-10 years	5 (40%)	5 (71%)
>10 years	1 (10%)	0
Accessing other support		
Yes	0	1 (14%)
No	10 (100%)	6 (86%)
Sessions of psychotherapy		
1	1 (10%)	-
2	1 (10%)	-
3	0	-
4	2 (20%)	-
5	0	-
6	1 (10%)	-
7	0	-
8	0	-
9	0	-
10	2 (20%)	-
11	1 (10%)	-
12	1 (10%)	-
12+	1 (10%)	-

Note. - = *Not Applicable*

Appendix K: SIP – Patient Survey Qualitative Responses

Given this data was not analysed using established methods of qualitative analysis (e.g., thematic analysis), the full detail of responses is presented below, allowing for the reader to draw their own interpretations.

Table 4.1
Patient Survey Quotes (Barriers)

Barrier	Quotes – Treatment group	Quotes – Waitlist group
Not knowing how much therapy could help	*"Because it feels a very physical thing- I think the idea of therapy to me didn't make sense in how it could help"* *"Therapy has a stigma but you also associate it with mental health more than sexual."* *"I wasn't sure whether or not it was worth me continuing the therapy after a few sessions because once I understood my condition I didn't think more sessions would be very useful"* *"This is a complex question. I have confidence in the therapy/the therapist but have experienced fear in the unknown, and fear in potential 'progression'."* *"I've had vaginismus for as long as I can remember, so sometimes it feels hard to believe I'll get anywhere because the therapy requires lots of repetition over a long period of time."*	*"I learn about my condition, mental health and what steps I can take to overcome it"* *"Assumption that by needing therapy it would making the issue bigger/more prevalent in my mind and believing therapy would not work"*
Not understanding ideas discussed	*"I understood all the ideas discussed"*	*"The assessment session was very clear but don't know what therapy would include so can't be sure."*
Time constraints	*"Hard to always fit in training between sessions due to working late at night/ early mornings. Being too tired to want to do the exercises"* *"Just depends on the availability at the time"* *"I often complete my tasks before bed. As I do shift work and have to do sleeping nights I*	*"Balancing work/life commitments and availability of sessions/resources reducing options for planning"* *"I wouldn't feel comfortable trying to get time off for therapy during the working day which limits options"*

	find it more challenging to complete tasks then" *"There is travel time associated with the sessions"* *'Practicing use of trainers/other tasks between sessions is a big commitment. I have had several periods of time where I've not felt able to give it the time and space needed alongside other aspects of life (work, family, relationships, etc.)."* *"Obviously, life is busy and finding the time and privacy to do exercises can be hard. I have ADHD so remembering to do my exercises is also hard."*	
Financial constraints	*"I'm very lucky, I'm a student and this is not a barrier to me."* *"I feel fortunate to have accessed this support through the NHS. Financial barriers would've been much more significant if having to pay for private therapy."* *"I am lucky with my shift work that I can work around appointments"*	*"Flexible work from home days makes this more accessible"* *"I wouldn't be able to take time off for this or change my contract; transport not an issue"*
Stigma associated with therapy	*"Hard to explain to an employer to have time for a session"* *"For me, I would say the stigma is more attached to vaginismus than with therapy specifically. Very few people are aware of this aspect of my life. I have given vague reasons to employers in order to attend appointments (e.g. medical appointment)"* *"It is hard to talk about something which is very personal and intimate, but I feel this can be overcome through practice."*	*"As an unmarried woman, who is not planning on reproducing anytime soon, it feels strange to be asking for help for something that is just for my comfort, pleasure and confidence (even though the point is for it to not be painful)"* *"There is particular stigma associated with sexual psychological therapy."* *"if there isn't a suitable slot outside of work, wouldn't feel comfortable asking - would likely need a note for HR"* *Stigma, keeping it hidden from family*
Emotional distress during sessions	*"I felt less confident at the start of the session but the psychosexual therapist was great in enabling me to feel relaxed even over a video call."* *"Less of a barrier as treatment continues"* *"At the beginning of my sessions, this was much more significant (4 or 5). I now feel that*	*"Embarrassing to talk about, difficult recalling events that may have contributed to the condition"* *"The person I spoke to previously seemed very understanding, I would likely struggle to articulate but don't think it would stop me trying"*

	any emotional distress triggered by therapy is more short-term, and I am able to process it more effectively."	
Mental health difficulties	*"Whilst I experience anxiety and depression I find they have no affect on my sessions"* *"I don't have a diagnosis of anxiety or depression. I can experience anxiety related to vaginismus, and this treatment/therapy."*	*"mental health has not been a barrier to attending appointments previously; potentially may impact adherence to self-directed activities"*
Therapy being delivered online	*"If anything it being online made it very accessible to me and made it very easy to attend sessions due to me being in between university"* *"I live at home with family and wouldn't feel comfortable talking about vaginismus where they could hear"* *"Would prefer to talk about personal health matters in person rather than on video call but not always easy to get transport to the clinic/hospital"* *"All my sessions have been delivered online."* *"Finding a private place to do the therapy over video call. Sometimes is difficult living in your family home and not wanting to go to a public space"*	*"Prefer face to face but don't think it's a hindrance"* *"I do not have access to a physically private space for this."* *"If an option could be useful depending on when the session was. In a shared house so if they were in, this would majorly impact my ability to fully participate"*
Therapy being delivered in person	*"Finding the time to get there."* *"Much prefer in person. Only downside is it's about an hour from my house"*	*"Face to face more effective than online"* *"It is important to me that therapy is in person rather than online for physical privacy reasons. But it takes time to get to and from the hospital"* *"finding time to get across to the Churchill; also slight fear of meeting someone I'd know whilst walking through the hospital"*
Therapy causing symptoms or distress to worsen	*"I have felt accepting that therapy has been likely to trigger distress at times."*	*"This has occurred with trauma therapy."* *"I don't foresee it but can't be sure as I have no idea what to expect from the therapy"*
Not understanding how to/having to do the between-session tasks	*"Sometimes not knowing if you are doing tasks correctly can be off putting because you don't want to do it wrong"* *"This was a problem, as I had been doing some exercises on my own but having no improvement. A meeting with a practitioner who explained and walked me through how to*	*"Understand it is part of the process and would be taken slowly"* *"Dilators have caused pain in the past."* *"I don't foresee it but can't be sure as I have no idea what to expect"*

	do the exercises properly was very helpful." "It was explained very well by my psychotherapist and didn't experience any problems"	
Other	*"I have struggled with feeling alone with vaginismus and therapy. Although I have valued the support of my therapist, I have felt misunderstood by the few friends and family I have confided in"* *"Low sex drive. Fear of dilators when not in state of arousal."*	*Lack of availability of help, not enough societal awareness of this condition and how many people it affects and long wait lists* *How long I remain in the area - unsure if I will need to move for work in the new year so just depends on how long I am on the waitlist for.* *I had a session with a psychosexual therapist who said there may not be much they can help me with as I didn't have a partner. Not being able to have sex has never been a positive thing in any relationship I've had and so I worry that this will be a never-ending loop of not being able to have sex and not having a partner. I was hoping that I could still have therapy despite not being in a relationship.*

Table 4.2 **Patient Survey Quotes (Facilitators)**

Facilitator	Quotes – Treatment group	Quotes – Waitlist group
Supportive relationship with therapist or healthcare professional	*"Sessions with my therapist have helped to keep me 'on track or to explore barriers when things have been more challenging."* *"Having a supportive professional who will hold you to account by checking to see if you are doing your exercises or how you are feeling is extremely helpful"*	*"I feel like trusting relationship is the most crucial aspect of this process"*
Support from partner, family, or friends	*"My partner is supportive, and it can help to talk things through after therapy sessions."* *"I told both my mum as well as my partner who was very supportive in the treatment"* *"I generally don't talk about it"* *"I have kept to myself"* *"my partner is supportive, and it can help to talk things through after therapy sessions."*	*"Support has been mixed"* *"I am not going to be sharing this process with anyone"*

Understanding or experiencing the value and benefits of psychological treatment	*"Experiencing the positive changes, I've achieved have been a main motivating factor for me to continue."* *"It can feel hard to believe that the treatment is going to work, and things will get better, especially as it is a psychological based problem. When progress is naturally slow it can demotivate you to keep up your exercise schedule."*	*"this could be useful but I haven't looked into this"*
Having coping strategies for managing emotional difficulties	*"These have definitely developed since starting therapy"*	*"could be useful but I haven't considered"*
Therapy being delivered in person	*"I find it much easier to discuss in person"* *"At least initially this was significant"*	*"I imagine in person would be better for forming the supportive relationship"*
Therapy being delivered online	*"All my sessions were virtual. This made therapy easier to access around work."* *"After having established a rapport, this made sessions more accessible time-wise"* *"I think it is important to offer online therapy because not everyone is able to attend appointments in person"*	*"this could be helpful if the times work out with when I am home alone (e.g. during the working day when housemates are out)"*
Understanding the psychological ideas discussed within sessions	–	*"Having some theory to understand would probably make the issue seem less personal and more medical"*
Understanding how to do the between-session tasks	*"More emphasis could have been placed on this early in the treatment as it has been very helpful."* *"I had been trying to do exercises on my own but had little improvement. Talking to a practitioner who could correct what I was doing wrong and give me alternative exercises was very helpful."*	*"Not an issue with sufficient guidance/instructions"* *"The clearer the explanation, the better"* *"Being able to do the between-session tasks correctly is likely to help"*

Table 4.3

Patient Survey Quotes (Treatment Preferences)

Treatment	Quotes – Treatment group	Quotes – Waitlist group
Self-help resources	*Feels more overwhelming, and harder to hold myself accountable in doing the exercises* *Currently, I feel more able to access self-help materials. However, at the start of my treatment I don't feel I would've been able to, at all.*	*It can be intimidating to engage with this by myself.* *Audio books / trade books would be easier to engage with* *More likely if there is also the opportunity to discuss progress with a professional alongside - a least initially until confident;*
Individual psychosexual therapy	*Personally, the relationship with my therapist and the guidance provided has been such an integral part of my journey.*	*I think a lot of my issues come from inside my own thinking. Being able to adjust the way I think about sex (not panicking, no pressure etc.) would be helpful for me* *Being told how therapy can improve the issue;*
Couple's psychosexual therapy	*Not currently in a relationship but would be open to it if I was. I think I would want to start with a few sessions by myself* *Although I think there would be benefits to having joint therapy with a partner, this is not something I can see myself doing. I think my embarrassment/shame around vaginismus would prevent me wanting others involved in the therapy* *I am in a relationship, but couples therapy was not possible due to our individual circumstances. I feel it could be hugely beneficial and it may be something we pursue privately (if finances allow).*	*If I was in a relationship, yes I would* *Not in relationship but don't envisage wanting to share that space initially;*
Group based psychosexual therapy	*I think this would be helpful just to feel like you're not alone in it and to listen to people's experiences and what helped them- although I think it could also be negative as you'd then compare yourself to others in your treatment which might make you feel worse about it all.* *Unsure on this. It would be good to meet others with shared experiences but also may feel to private to discuss in groups*	*Feels too intimate a topic to discuss with strangers* *Awkward* *It would be nice to share similar experiences but I'd be worried I would take on / remember other people's experiences and overthink my own* *More likely if it were online and anonymous*

	I might attend this in person, but would not want to join group therapy online *I feel I would've benefited from peer support. However, I feel this would be difficult to manage with confidentiality.* *I don't know if I would or wouldn't engage with this. The idea of having other people who are going through the same thing could be motivating. Especially if there was the chance to meet people who have completed treatment and have overcome Vaginismus, this would give reassurance that though progress is slow it does get you somewhere eventually.*	
Other	*I wonder if there could be any other avenues to be explored for peer support, e.g. a buddy system?*	*Examinations to understand the curvature/positioning of the vaginal canal to assist in mentally envisaging that there is a cavity (as opposed to feeling like there is no "space") and be able to better use trainers as will understand which angles to insert at*

Appendix L: SIP – Patient Interview Responses

Table 8
Summary of Patient Interviews

Theme	Description	Example Quotes
Barrier: Motivation levels	Patients described the requirement for self-motivation, particularly between sessions, this was influenced by multiple factors such as perceived progress, and initial reasons for treatment.	*"It definitely requires a lot of self-motivation"* *"I feel as though I'm improving... becoming a bit more lax"* *"in my case it wasn't really life changing"*
Barrier: Therapist response to non-adherence	Patients reported divergent experiences of anticipated therapist response, with one patient describing feeling shame and guilt and another noting a positive experience	*"You feel guilty... not doing those breathing exercises"* *"It's always a positive experience"*
Barrier: Misunderstanding of therapy exercises	Initial difficulty in understanding instructions initially led to avoidance and procrastination.	*"The leaflet didn't really work… I didn't know what I am supposed to do"*
Barrier: Practical challenges	Patients reported common how practical factors including work shift patterns, time constraints, travel difficulties, general life stressors made attendance and adherence difficult.	*"[Attending an appointment] it's not a quick thing"* *"Life happens"*
Barrier: Resource limitations and flexibility	One patient described rigidity around appointment rescheduling which lead to additional pressure.	*"I felt bound to those timings"* *"I could lose my spot"*
Barrier: Transparency of the treatment journey	One patient described feeling unclear on the trajectory of treatment, and how lack of access to therapy notes influenced this.	*"There is no central place where all those things live"* *"Where are we going?"*
Facilitator: Service flexibility	Both patients described valuing the flexibility to have sessions in-person or online, with each having their own pros and cons.	"In-person was very valuable" "Good to have the online option"
Facilitator: Therapeutic relationship	Patients described the importance of a positive therapeutic relationship, use of humour for engagement	*"We would have a bit of a laugh"* *"It's never scary"*

Facilitator: Psychoeducation component	The psychoeducation component of therapy was perceived to be helpful in helped normalising vaginismus	*"The diagrams made it all make sense"* *"Being told it wasn't just me made it easier"*
Facilitator: Accountability and reminders	Patients reported valuing the accountability provided by their therapist or partner, and how setting reminders helped with adherence.	*"I've got a session next week – I need to make sure I do [exercises]"*
Preferences: Current treatment options are valued	1:1 or couples therapy was considered largely appropriate and helpful by both patients.	*"I think the one-to-one is most valuable"*
Preferences: Group therapy	Groups were considered unsuitable by both patients due to stigma, privacy concerns, and discomfort. However, their theoretical benefits were noted.	*"Oxford is a very small town"* *"I wouldn't feel comfortable sharing"*

Appendix M: SIP – Thematic Analysis of Staff Interviews

Barriers

Theme 1: The practical or the person?

Subtheme: the practical

Staff described a variety of practical barriers that were obvious ("*So it's things like time, jobs, kids, you know, all the other sort of life stuff gets in the way*"). These were frequently cited by patients, in particular as reasons for non-adherence to between session dilator training tasks ("*it's that engaging in the regime of exercises is what they find difficult*").

Subtheme: what's behind it?

A common hunch was that these frequently cited reasons for non-adherence were actually masking avoidance of the task ("*the question is always asked that are you cancelling because you're avoiding because you don't want to report back and so you haven't done anything?"*).

Subtheme: the personal

Beyond the obvious practical barriers and reasons for avoiding tasks (e.g., fear of pain) more subtle influences were noted as a barriers to adherence, such as cultural background *("we don't ask enough questions… about sexual taboos in their cultural, cultural understanding of sexual taboos"*), being single creating an unclear endpoint, compounding the common challenge of jump from dilator to PIV sex *("they…say, well, it wouldn't translate into real world scenarios"*).

Theme 2: The ripple of limited resources

Subtheme: Unintended consequences

Staff described how the long waitlist and limited number of sessions, may both implicitly and explicitly have the unintended consequence of additional pressure ("*I sometimes wonder how much are they doing this for them or how much is there a worry that they'll be disappointing*

the therapist" "we have very little time…to help people make changes. And I think with that means, it can feel a bit more pressured"). Such factors, although common in the NHS, may be particularly problematic to adherence in this group ("*they have to wait a really long time…between 9 and 10 months…that's a really long time to wait for anything like this,*").

Subtheme: This way is not the only way

Staff noted the behaviourally focused therapeutic approach (i.e., use of dilators) does not suit everyone ("[*we] have been trained is a very…behavioural approach, and you know, people are varied, people's needs are varied and that doesn't work for everyone"*), might be too simplistic ("*I think someone should rewrite a manual and focus a bit more on the cognitive aspect"*) and staff are aware of but not trained in other approaches *("it would really benefit us to have more training in different approaches so we could be more flexible with the approach"*) due to lack of training opportunities *("unfortunately there's just not the time to do this, but and because there is the, there is the expertise in the team"*).

Facilitators

Theme 3: Elusive ingredients for adherence

Subtheme: the 'right' ingredients

Staff described the key facilitators that contributed to motivation for engagement, often within the patient themselves including prior positive sexual experiences *("it can really help if people had had positive sex before"*), having a supportive partner *("if they have a supportive partner, that helps"*), reason for therapy ("*wanting children, and that provides a really strong motivation"*), psychological factors *("it helps if people have a good sense of their body image"*) and the combination of these (*"there's something about sort of being in the right space at the right time, having the resources, having being in a good space psychologically having time from work"*).

Subtheme: the exception not the rule

Avoidance and non-adherence, particularly to behavioural aspects was largely expected *("I don't really see that as a block, certainly not for the first six weeks because… that is literally part of what sensate focus is set up to solve"*) and individuals who had the ingredients needed to adhere and engage with no additional support, were less common *("that absolutely can work for some people… my experience is not the majority with vaginismus"*).

Theme 4: The current approach works

Subtheme: A good therapeutic offer

Staff described how despite the challenges, there are significant strengths to their current approach that they feel help engagement. These include, psychoeducation, self-help resources ("*they get a lot of resources, you know, a lot of information"*) use of humour in the therapeutic relationship *("there's a lot of potential for, using a bit of humour"*), formulation ("*someone spending a long dedicated time taking the history and doing what I would call a formulation... it stops it being nearly so scary*"), normalisation ("*we completely normalise this idea of just using a word like sex… that's quite helpful for patients"*), use of 'roadmaps' ("*regular stopping and reassessing where we're at in the in the treatment, are we progressing?"*), free, service flexibility (e.g., for face to face or online "*the…change of offering video has made a huge difference"*).

Subtheme: Hard but helpful

There was shared recognition of the behavioural focus as challenging, but practical achievable and tangible *("on the surface, both for the clinician and for the patient, that feels really nice because… it's obvious what we need to do" "that can be learned, it can be taught, it can be practised, it can be changed, by physical things. It makes, I think it makes it more*

approachable") and success is measurable ("*where people really struggle with bits of it and then when it does work, they realise that it's actually, yeah, very helpful"*).

Preferences

Theme 5: Group Therapy – to do or not to do?

Subtheme: Helpful to who?

Divergent opinions were expressed regarding the perceived helpfulness of groups to patients and the service, in particular due to the highly similar presentations in vaginismus *("those presentations where you feel like they all need exactly the same"*). For patients, some felt I would be appropriate *("the explanation about pelvic floor exercises and also some of the psychological aspects which I think lend themselves to group work"*), but many noted that patient's reluctance to engage ("*people are reluctant enough to talk about their sex life to the sex therapist… they just don't really want to do it in front of other people as well"*) would undermine theoretical benefit ("*if they actually got there? I imagine they would get a lot out of it, but I think they would really struggle to go"*). For the service, some noted its potential utility in improving efficiency *("[a group would make] the delivery of at least some aspects of the therapy more efficient."*) whilst others questioned whether this translates in reality and noted the additional resource demands of a group (*"if you actually calculated… you had four man hours of clinical psychologist per one hour of group. If only four people were turning up, those people could have all had a one to one appointment for an hour."*).

Subtheme: Meeting the need to feel 'normal'

Staff noted how many patients often feel alone ("*it's rarely that anybody's spoken to anyone else, so they feel really isolated…people feel that they're the only one"*) and a key benefit raised for group therapy was the 'normalising' element ("*it's very beneficial to address issues like shame when you've got a lot of other people who are in the same boat*"). Notably others'

mentioned alternative options, such as stand-alone peer support, could equally meet this need ("*I think peer support can be massively helpful*"; *"an element of treatment is definitely that peer support element, or finding out that you're not the only one with the problem and that you're not alone"*).

Theme 6: New approaches – who, where, what, when, why?

Subtheme: Defining the role of group-based support

When considering the implementation of a group, a variety of purposes and functions were suggested such as psychoeducation *("some factors are common in a lot of patients with vaginismus and so certain things like psychoeducation about anatomy and the sexual response… could be delivered quite effectively in the group setting"*) and psychological components of therapy (*"some of the psychological aspects which I think lend themselves to group"),* delivering groups in addition to therapy *("it would be a sort of mixed delivery model…group delivery and then in addition have individual support…after the group's been delivered"*) with many staff describing how groups should not replace individual or couple's therapy ("*if you were to offer that as the only option, then maybe people would come, but then that feels really unfair"*). Another suggestion was a group for the sole purpose of peer support (*"there could be development of a peer group, that might want to meet in their own time").*

Subtheme: implementation challenges

A common talking point amongst the alternative approaches suggested (e.g., peer support, groups), was the associated logistical and practical challenges (e.g., regarding a peer support group *"I don't know how that would happen logistically in terms of confidentiality and everything"*). Staff described the need for careful selection of eligible participants *("you'd have to be very careful who you chose or who you thought it was appropriate for"*). Overall,

this suggests that the introduction of a group would require thoughtful decisions regarding its intended function and implementation.

Appendix N: SIP – Author Guidelines

Author guidelines for BMJ Sexual and Reproductive Health

Original research

We welcome original, robustly designed/conducted and well-described quantitative or qualitative research, as well as consensus statements and meta-analyses. Original research should include a structured abstract and key message points, both of which should reflect accurately the content and findings of the study, rather than the opinions of the authors. Research reviews that systematically synthesise evidence (e.g. Systematic reviews, Meta-analysis, Scoping reviews, Mixed methods reviews, etc) should be submitted as Systematic reviews. If the topic of your manuscript relates to research on sexual or reproductive health in a particular country, it is the journal's policy to require that at least one co-author is based in that country. Your manuscript may be rejected if you do not meet this requirement or adequately explain in your cover letter why it is not possible to include a local co-author. Following the lead of The BMJ and its patient partnership strategy, BMJ Sexual and Reproductive Health is encouraging active patient involvement in setting the research agenda. As such, we require authors of research articles to add a Patient and Public Involvement statement in the Methods section. Please see more details in the 'Reporting public involvement in research' section. The structured abstract should comprise no more than 250 words (additional to the words of the main body of the text) and should be structured under the headings: background/introduction, methods, results, and conclusions (or similar as appropriate). Please include the key messages of your article after your abstract using the following headings. This section should be no more than 3-5 sentences and should be distinct from the abstract; be succinct, specific and accurate.

- What is already known on this topic – summarise the state of scientific knowledge on this subject before you did your study and why this study needed to be done
- What this study adds – summarise what we now know as a result of this study that we did not know before
- How this study might affect research, practice or policy – summarise the implications of this study

This will be published as a summary box after the abstract in the final published article.

Introduction: The introduction should set the study in context by relating to a brief review of relevant knowledge of the subject. This should be followed by a concise statement of the study's aims and objectives. **Methods:** Please describe clearly the design, setting, participants, intervention, prespecified outcomes, sample size and statistical analysis for your study. Please provide sufficient information so that other researchers can repeat the study. For statistical analyses, please give sufficient details of the experimental design and analysis so that the reader can assess their adequacy and validity. **Patient and Public Involvement statement:** The journal actively encourages the involvement of patients in research. Please include a statement in the methods section of your manuscript under the sub-heading 'Patient and Public Involvement'. This should provide a brief response to the following questions:

- How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?
- How did you involve patients in the design of this study?
- Were patients involved in the recruitment to and conduct of the study?
- How will the results be disseminated to study participants?
- For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

Results: Please present your results in the form of text, tables and figures as appropriate. Data given in tables and figures should not be repeated in the text. Tables and figures should be cited in the text in numerical order. **Discussion:** The interpretation of results should be discussed, observations should be related to relevant studies, limitations of the study acknowledged and the implications of results for future research should be outlined. Results should not be repeated in this section. Word count: up to 2500 words **Illustrations/tables:** maximum of 4 tables or figures (additional supplementary online-only data permitted) **References:** maximum of 30 references NB. Whilst the journal does not publish short communications, authors are welcome to submit audit reports, pilot studies, preliminary reports of a clinical study, and follow-up reports from previously published papers. These should be written as concisely as possible (the suggested maximum word count is 1500 words, with a maximum of 2 tables or figures and 20 references), they should include a structured abstract and key message points and ideally should contain the same headings as for research articles.

Appendix O: TDRP – Menstrual Cycle Phases

Defining MC Phases

The early follicular, mid-luteal and premenstrual phases were chosen due to comparable studies identifying that emotional symptoms of other mental health disorders (e.g., borderline personality disorder) were lowest in the early-to-mid-follicular phase and highest in the mid-luteal and premenstrual phases, demonstrating these were ideal phases for comparison (Peters et al., 2020). The cycle phase definitions used in this study are guided by recent recommendations for studying the MC (see Schmalenberger et al., 2021). As neither daily measures nor hormonal measurements were feasible within this study, a forward-counting approach was taken. This defined the early follicular phase as days 4-7 after menses onset (with first day of bleeding considered day 1), the mid-luteal phase as days 19-22 (adjusted from recommendations given the breadth of cycle lengths included in this study) and the premenstrual phase as days 24-27.

According to Schmalenberger et al (2021) there is no 'true' baseline where the MC does not influence symptoms and timing of baseline measures should be determined based on methodology. Given that the current study will be recruiting purely online and no hormonal verification will occur, all participants will be instructed to begin testing at the same time in their cycle, to standardised timing of measurements. Bleeding onset is an easily identifiable menstrual event and was therefore used as an anchor point to guide the timing of data collection.

Expanding range of included cycle lengths

MC lengths were determined through the verified MC dates provided in MC start date survey 1 and 2, bookending T1-T3. The initial exclusion criterion of MC range of 26-30 days was initially specified but expanded to 25-31 days to increase power. Notably, this is also in line with recruitment materials (specifying 25-31 days) as it was expected that estimates would likely have an error of +/- 1 days. Importantly, the expansion of the cycle lengths does not compromise the cycle-to-phase correspondence, which is important for drawing conclusions on particular phases.

Challenges of cycle lengths and measurement timepoints

The forward counting method was most appropriate for this methodology (i.e., no daily measures and no hormonal assays to confirm ovulation), as was the selection of just three time-points, to reduce participant burden and attrition rate, and the selection of a 25-31 day cycle length for balancing power and day-to-cycle phase correspondence. However, as explained in the discussion, findings may be an artefact of methodology, particularly the fixed timepoints and cycle lengths. For example, T3 is sent on day 24, allowing 4 days for completion (24 to 27 inclusive) meaning that for a 25-day cycle, this could have been completed after the next menses start date and up to just one day before T1 of the next cycle.

Appendix P: TDRP – Ethical Approval and Participant Materials

CUREC Approval Letter

MEDICAL SCIENCES INTERDIVISIONAL RESEARCH ETHICS COMMITTEE
Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB
Tel: +44(0)1865 616575
ethics@medsci.ox.ac.uk

CONFIDENTIAL

Dr Fiona Challacombe & Louise Nolan
Oxford Institute for Clinical Psychology Training (OxICPT)
Isis Education Centre
Warneford Hospital
Oxford

17 September 2024

Dear Dr Challacombe and Louise,

Research Ethics Approval - CUREC 1

Ethics Approval Reference: R94465/RE001

Study title: Obsessive Compulsive Disorder across the Menstrual Cycle: A Prospective Within-Subjects Design

Short title: Obsessive Compulsive Symptoms across the Menstrual Cycle

The above application has been considered on behalf of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) in accordance with the University's procedures for ethical approval of all research involving human participants.

I am pleased to inform you that, on the basis of the information provided to the IDREC, the proposed research has been judged as meeting appropriate ethical standards, and approval has been granted from **17th September 2024** until **16th March 2026.**

Insurance-provided indemnity arrangements are in place for the duration of the approval stated above. It is your responsibility to ensure that you request an extension to the end date for indemnity to remain in place should you continue the research beyond the dates covered.

Amendments
Should there be any subsequent changes to the study, you should submit details to the MS IDREC for consideration and approval. Details of changes must be listed on an amendment form.

Yours Sincerely

DocuSigned by:
Leah Butts
9F14889D2BC549A...

Mrs Leah Butts
Research Ethics Administrator

for
Dr Helen Barnby-Porritt
Research Ethics Manager

CUREC Amendment Approval

R94465/RE002: OCD across the Menstrual Cycle: A Prospective Within-Subjects Design - Amendment Approval

From MSD Ethics <ethics@medsci.ox.ac.uk>
Date Wed 16/10/2024 12:50
To Louise Nolan <louise.nolan@hmc.ox.ac.uk>
Cc Fiona Challacombe <fiona.challacombe@psy.ox.ac.uk>

1 attachment (259 KB)
Oct_CUREC_2024.docx;

Dear Louise,

Thank you for submitting a request for an amendment to project R94465, which has been reviewed on behalf of the Medical Sciences Interdivisional Research Ethics Committee (IDREC).

I am pleased to inform you that your requests to:

- **add the use of unique ID codes for participants, that will be required in all surveys**
- **send the menstrual cycle confirmation survey 1 for 7 days, not 10 days (from 2 days before, to 5 days after estimated period start date)**
- **include the menstrual cycle length of 25-31 days (and not 25 to 35 days)**
- **make a change in the menstrual cycle days that correspond to timepoint 1 (this was day 8-12 and is now day 4-7, to correspond with early to mid-follicular phase)**
- **make a change in the menstrual cycle days that correspond to timepoint 1 (this was day 17-21 and is now day 19-22, to correspond with mid-luteal phase)**
- **add an additional item to the consent form, regarding emailing participants directly if they have not returned the menstrual confirmation survey 2**
- **revise the poster, to reflect 2 menstrual cycle confirmation surveys and addition of 'click on the link to take part'**
- **include a question in the screening survey regarding hormonal contraceptives**
- **remove a question from the Menstrual cycle confirmation survey 1 and 2, regarding if period started**
- **revise the email for menstrual cycle survey, to state it should only be completed if period has started**
- **revise the main surveys thank you email, to reflect when next survey should be expected**

have been judged as meeting appropriate ethical standards, on the basis of the information provided to the IDREC, and approval has been granted, under reference R94465/RE002.

Please note that this email is your sole approval. Please find attached your CUREC form, where I have made a couple of final revisions – please save and use this version.

Best wishes
Leah

UNIVERSITY OF OXFORD RESEARCH SERVICES
researchsupport.admin.ox.ac.uk

Mrs Leah Butts
Research Ethics Administrator, Medical Sciences
Research Services I Research Governance, Ethics & Assurance Team
University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB
T: 01865 616575 E: ethics@medsci.ox.ac.uk
Working days/hours (Tues-Fri)

Participant Information Sheet

Participant Information Sheet V1.2 6 Oct 2024

Oxford Institute of Clinical Psychology Training and Research

Dr Fiona Challacombe
fiona.challacombe@psy.ox.ac.uk

Obsessive Compulsive Symptoms across the Menstrual Cycle

Ethics Approval Reference: R94465/RE001

General Information

We are a group of Clinical and Trainee Psychologists at the University of Oxford. The aim of this research is to help increase understanding of how the menstrual cycle influences obsessive compulsive disorder (OCD) and obsessive-compulsive symptoms. You do **not** need a diagnosis of OCD to take part in this research.

Before you decide if you want to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information sheet and discuss it with others if you wish.

This study is being conducted by Louise Nolan and is being supervised by Dr Fiona Challacombe and Dr Graham Thew. If you have any questions, you can contact Louise Nolan on: louise.nolan@hmc.ox.ac.uk

What is the purpose of the study?

Many people who menstruate experience physical and emotional changes in the days leading up to their period. This is likely to be the case for people with an existing mental health difficulty, such as obsessive-compulsive disorder (OCD). OCD is a mental health condition where a person experiences unwanted thoughts (obsessions) and feels compelled to perform certain behaviours (compulsions) to alleviate the anxiety these thoughts cause. It can cause considerable distress and interfere with relationships, education and/or work. Research on other mental health difficulties such as anxiety or psychosis has shown that the menstrual cycle can have a positive, negative or no effect on symptoms. Women's health is an under-researched area in general and there is a lack of research on how the menstrual cycle influences OCD.

The purpose of this study is to better understand if and how OCD symptoms are influenced by the menstrual cycle. We aim to explore factors, including mood and sensitivity to disgust, that may help

explain how the menstrual cycle interacts with OCD symptoms and why this may be difficult for some individuals. We also hope to identify if particular symptoms of OCD are more likely than others to change across the menstrual cycle. Gaining a better understanding of the impact of the menstrual cycle on OCD could improve treatment for OCD and increase recognition of the role of the menstrual cycle in mental health disorders.

Who would we like to take part in the study?

You are able to take part in this study if you:

1. are aged 18 years and over
2. a menstrual cycle that usually lasts between 25 and 31 days
3. experience obsessive compulsive disorder symptoms (either self-report or diagnosis)
4. are not currently taking hormonal contraceptives (e.g., the contraceptive pill)
5. are not currently pregnant, breastfeeding or trying to conceive
6. do not have a diagnosis of any hormonal or menstrual health disorders (e.g., Polycystic Ovary Syndrome/PCOS).

You will be one of many other people who will be taking part. We are hoping to recruit many people to help represent a range of people from different backgrounds.

Do I have to take part?

No. Participation is voluntary. If you do decide to take part, you may withdraw at any point for any reason before submitting your answers by pressing the 'Exit' button or closing the browser. Some questions are optional and include a 'Prefer not to say' option.

What will taking part involve?

You will complete a screening survey to check if you are eligible to take part, this will take around 10-15 minutes to complete. You will be asked some one-off questions about your background (such as age, gender, ethnicity), your usual menstrual cycle, medication (such as antidepressants) and whether your OCD started around pregnancy or when you had your first period. Most of these questions will be multiple choice, where you will be asked to select one option from multiple possible options. You will be asked questions about when your last period started and when your next period is due. It would be ideal if you used an app such as Clue or Flo to track your cycle, as this is the best way to accurately measure the length of your menstrual cycle. You can download this prior to taking

part in the study.

If you are eligible, you will receive a unique ID code that you will need to provide each time you complete a survey. This code allows us to anonymously track your responses across your menstrual cycle. After completing the screening survey, you will receive an email with a link to a short survey asking you to confirm whether your period has started and when it started. This survey will be sent 5 days before your estimated start date and will continue until you confirm your period has started. If we do not receive a response, the reminders will stop after 10 days.

Following confirmation of your menstrual cycle start date, you will complete the same three surveys at different times in your menstrual cycle. The surveys will ask you questions about your OCD, feelings of disgust, anxiety, and mood. This survey will take **around 10 minutes** to complete. Following completion of these surveys, you will be asked again to confirm when your next period starts. You will receive a short daily survey via email daily for around the time when your next period is due.

What are the possible risks of taking part?

The survey will ask questions about sensitive topics such as your mental health, menstrual cycle and pregnancy (where applicable) which may raise concerns for you. As survey responses will be anonymised, we will not be able to discuss your survey responses with you. If you are concerned about your emotional distress or wellbeing, we would recommend you discuss this with your General Practitioner. You may also wish to contact the following:

Samaritans. To talk about anything that is upsetting you, you can contact Samaritans 24 hours a day, 365 days a year. You can call 116 123 (free from any phone)

International Association of Premenstrual Disorders. Offer peer support for people experiencing premenstrual disorders https://iapmd.org/peer-support

OCD UK. Offer a helpline on: 01332 588112 (Tuesday – Thursday 4pm-8pm) and further information can be found on their website https://www.ocduk.org/

OCD Action. Offer a helpline (Monday – Friday 9.30am-8pm), you can request a call via their

website https://ocdaction.org.uk/i-need-support/helpline/

Emergency services if you feel you are at immediate risk of harm, please call emergency services on **999.**

How will my data be used?

If you agree to take part in this study, after collecting your consent we will ask you to provide your email address to allow us to send you the study survey. Your email address will be kept strictly confidential within the research team, and all data will be stored in a password-protected electronic file on University of Oxford secure servers. Beyond this, you will not be asked to provide any personally identifiable details. Your IP address will not be stored.

All survey responses provided will be anonymised, ensuring your privacy and protecting your identity, and will be stored separately from your email address. The research team will take all reasonable measures to ensure that all data remains confidential. You can withdraw from the study at any time and have all data permanently deleted, up until the point of data analysis. All personal data will be destroyed following data analysis.

The anonymous responses may be used in academic publications in peer-reviewed journal, conference presentations and reports for external organisations such as OCD or women's health charities. Research data will be stored for three years after publication.

Who will have access to my data?

Data will be stored on Oxford University network files that are password-protected and accessible by the researchers: Louise Nolan (Trainee Clinical Psychologist, Oxford Institute of Clinical Psychology Training and Research) and her supervisors Dr Fiona Challacombe (Research Tutor and Clinical Psychologist, Oxford Institute of Clinical Psychology Training and Research) and Dr Graham Thew (Clinical Psychologist, Oxford Health NHS Foundation Trust).

In line with University of Oxford requirements, access will be granted to The Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) to survey responses and personal data (i.e., email address) for the purpose of monitoring and/or audit of the research. No other researchers/organisations will have access.

The results will be written up for a Doctorate of Clinical Psychology degree.

Who has reviewed this research?

This research has been reviewed by and received ethical approval from a subcommittee of the

University of Oxford Central University Research Ethics Committee [Ethics Approval Reference: R94465/RE001].

Who do I contact if I have a concern or I wish to complain?

If you have a concern about any aspect of this research, please speak to the project lead Louise Nolan (louise.nolan@hmc.ox.ac.uk) or their primary supervisor Dr Fiona Challacombe (Fiona.challacombe@hmc.ox.ac.uk) and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

Who should I contact if I have any questions?

If you have any questions or require more information about this study, please contact Louise Nolan using the following contact details: louise.nolan@hmc.ox.ac.uk

Screening survey

Screening survey administered via Qualtrics, red indicates exclusion criteria.

Obsessive Compulsive Symptoms across the Menstrual Cycle
Ethics Approval Reference: R4465/RE002

Initial screening survey

- **I am aged 18 years or over**
  Yes
  No

- **I can confirm I experience a menstrual cycle**
  Yes
  No

- **I can confirm that I have not taken hormonal contraceptives or other hormonal medication (e.g., Hormone Replacement Therapy) in the previous two months**
  Yes
  No

- **I can confirm that I experience Obsessive Compulsive Disorder (OCD) or OCD-like difficulties**
  Yes

No

- **I can confirm that I am not currently pregnant, breastfeeding or trying to conceive**
  Yes
  No

- **I can confirm that I have not been diagnosed with any hormonal or menstrual health disorders (e.g., Polycystic Ovary Syndrome/PCOS, hypothyroidism, hyperthyroidism, endometriosis)**
  Yes
  No

[LOGIC: If any responses in red are selected, send to thank you page 2**]**

Main screening survey

Demographics

1. What is your gender identity?
   - Woman
   - Man
   - Transwoman
   - Transman
   - Non-binary
   - Prefer to self-describe (please specify)
   - Prefer not to say

2. What is your age?
   - 18-24
   - 25-34
   - 35-44
   - 45-54
   - Over 55

3. What is your current marital status?

   - Single
   - In a relationship (not cohabiting)
   - In a relationship (cohabiting / married / civil partnership)
   - Divorced or separated
   - Widowed
   - Other (please specify)

4. What is your sexual orientation?

- Straight or heterosexual
- Lesbian or gay
- Bisexual
- Asexual
- Pansexual
- Other (please specify)
- Prefer not to say

5. Which of the following best describes your ethnicity?
   - White British
   - White Irish
   - White Other
   - Black/African/Caribbean/Black British
   - Arab
   - Asian/Asian British
   - Mixed or multiple ethnic groups
   - Other ethnic group
   - Prefer not to say

6. What is your highest level of education?
   - no qualifications
   - Apprenticeship
   - Secondary school or equivalent (for example, GCSEs)
   - A-levels/BTECs or equivalent
   - Undergraduate level degree
   - Postgraduate level degree
   - Other level of qualification (please specify)

7. What is your employment status?
   - Employed full time
   - Employed part time
   - Self-employed
   - Unemployed
   - Unable to work due to sickness or disability
   - Retired
   - Student

- Carer
- Other (please specify)

8. Which of the following represents your annual gross income (income from all sources before deductions for income tax and national insurance)?

- Less than £15,000
- £15,000-£24,000
- £24,000-£55,000
- £55,000-£90,000
- More than £90,000
- Prefer not to say

Health information

The following section is about your physical and mental health including reproductive issues.

1. How would you describe your current menstrual status?
o Experiencing a menstrual cycle and **not** going through perimenopause (also referred to as the menopause transition)
o Experiencing a menstrual cycle and going through perimenopause
o Menopause or post-menopause (no menstrual cycle for at least 12 consecutive months)

[**LOGIC**: End of survey if select any exclusion criteria including all except first option]

2. What age did you first develop OCD symptoms?
[dropdown box option of 1 to 60 presented]

3. Did your OCD develop around the time of pregnancy (i.e., during, soon before or soon after)?
Yes
No
Prefer not to say

4. Did your OCD develop around the time of your first period?
Yes
No
Prefer not to say

5. Do you take prescribed medication for OCD?
   Yes
   No

6. Did you start taking prescribed medication for OCD in the past 6 weeks?
   Yes
   No

7. Are you currently in psychological therapy for OCD?
   Yes
   No

8. Did you start psychological therapy for OCD in the past 6 weeks?
   Yes
   No

9. Do you experience other mental health difficulties?
   Yes – please specify
   No
   Prefer not to say

10. Do you take prescribed medication for other mental health difficulties?
    Yes
    No
    Prefer not to say

11. Did you start taking prescribed medication for other mental health conditions in the past 6 weeks?
    Yes
    No

12. Do you experience Premenstrual Syndrome (PMS; a set of physical, emotional and behavioural symptoms that occur in the luteal phase of the menstrual cycle)?
    Yes – I have been diagnosed
    Yes – I have not been diagnosed
    No

13. Do you experience Premenstrual Dysphoric Disorder (PMDD; a severe form of PMS characterised by significant mood changes, irritability, and other symptoms that considerably impacts daily life)?
    Yes – I have been diagnosed
    Yes – I have not been diagnosed
    No

14. If you have taken hormonal contraceptives (e.g., hormonal contraceptive pill) in the past, what was the main reason you stopped taking this?
    Emotional side effects (e.g. mood swings, anxiety)
    Physical side effects (e.g. weight gain, acne)

No particular reason
Not applicable (I have never taken hormonal contraceptives)

15. Do you track your menstrual cycle (e.g., using a diary or an app such as Clue or Flo)?
Yes (LOGIC: go to block A)

No (LOGIC: go to block B)

Block A (tracks menstrual cycle)

16. According to your diary or app, when is your next period due to start?
[dd/mm/yyyy]

17. In the past three months, has your menstrual cycle typically ranged between 25 and 31 days? (your period comes every 25 to 31 days). You can check your app or diary to confirm this.
Yes
No
Not sure

Block B (does not track menstrual cycle)

18. In the past three months, has your menstrual cycle typically ranged between 25 and 31 days? (your period comes every 25 to 31 days).
Yes
No
Not sure

[LOGIC: If 'no' is selected, send to thank you page 2]
[LOGIC: If 'not sure' is selected, send to thank you page 3]

19. Do you know approximately when your next period is due?
Yes
No

17. When is your next period start?
[dd/mm/yyyy]

Menstrual Cycle Confirmation Surveys

Menstrual cycle confirmation survey 1 was sent before main surveys, and menstrual cycle confirmation survey 2 was sent after main surveys.

Menstrual cycle confirmation 1

Before you start, please add your unique ID code here. This allows us to anonymously track your responses across the menstrual cycle

[TEXT BOX]

Please complete the below **only** if your next period has started (i.e., in the past few days)

On what date did your most recent period start? [DD/MM/YYYY]

Menstrual cycle confirmation 2

Before you start, please add your unique ID code here. This allows us to anonymously track your responses across the menstrual cycle

[TEXT BOX]

Please complete the below **only** if your next period has started (i.e., in the past few days)

On what date did your most recent period start? [DD/MM/YYYY]

Appendix Q: TDRP – Public and Patient Involvement

Public and Patient Involvement

Two female volunteers from the People's Experience Group at the Oxford Institute of Clinical Psychology Training and Research provided input on this project. Following an initial project proposal, feedback was sought on the study design (including number of measures), recruitment materials, the participant information sheet, survey questions and content. Overall, the project and its aims were considered highly relevant and necessary. Changes were made to improve the accessibility and length of the participant information sheet as well as questions on menstrual cycle characteristics.

Appendix R: TDRP – Demographic Data and Comparisons

Demographic comparisons – completers versus non-completers

To assess potential differences between participants who completed all study timepoints (n = 61) and those who did not (n = 81), a series of chi-square tests were conducted on categorical demographic variables. There were no significant differences between groups in terms of gender identity, $\chi^2(1, N = 142) = 0.63$, $p = .426$; age group, $\chi^2(2, N = 142) = 2.84$, $p = .242$; marital status, $\chi^2(2, N = 142) = 1.46$, $p = .482$; sexual orientation, $\chi^2(2, N = 142) = 0.45$, $p = .801$; ethnicity, $\chi^2(2, N = 142) = 3.91$, $p = .142$; education level, $\chi^2(2, N = 142) = 0.95$, $p = .623$; employment status, $\chi^2(2, N = 142) = 3.45$, $p = .178$; income group, $\chi^2(4, N = 142) = 3.42$, $p = .491$. Mann-Whitney U tests revealed no significant differences in age of OCD onset, $U = 2274.00$, $Z = –0.57$, $p = .568$ (mean ranks: 72.72 for completers, 68.78 for non-completers), or in baseline OCD symptom severity, $U = 2157.50$, $Z = –1.29$, $p = .197$ (mean ranks: 66.37 for completers, 75.36 for non-completers).

Full demographics of final sample (N = 61)

The final sample consisted of 61 participants, and demographic data were available for all. The majority identified as women (91.8%), with the remainder identifying as non-binary (6.6%) or transman (1.6%). Participants were primarily aged 25–34 (47.5%), followed by 18–24 (29.5%) and 35–44 (23.0%). In terms of marital status, 44.3% were in a cohabiting relationship or married, 19.7% were in a non-cohabiting relationship, 29.5% were single, and 6.6% reported another status (e.g., separated, divorced). The majority identified as heterosexual (57.4%), with others identifying as bisexual (18.0%), pansexual (8.2%), lesbian or gay (6.6%), asexual (1.6%), or other (4.9%); 3.3% preferred not to disclose. Most participants identified as White British (60.7%), with additional representation from White

Irish (6.6%), White Other (21.3%), and ethnic minority groups (11.5%) including Asian, Black, and mixed ethnic backgrounds. Regarding education, 36.1% held a postgraduate degree, 29.5% an undergraduate degree, 23.0% had A-levels/BTECs, and 4.9% completed secondary education; 6.6% selected "other". In terms of employment, 68.8% were employed (full- or part-time or self-employed), 14.8% were students, and 16.4% were either unemployed, unable to work due to disability, or selected "other". Finally, regarding annual income varied, almost half (49.2%) earned between £24,001 and £55,000, with 23.0% earning less than £15,000, 13.1% earning £15,000–£24,000, and 8.2% earning above £55,000; 6.6% preferred not to disclose their income.

Appendix S: TDRP – Supplementary Data on Subsamples

Given the various subgroups categories applied across the sample, the means, standard deviations and standard error across all subsamples is available below.

Full sample (*N* = 61)

Table S1
Values across the menstrual cycle for full sample (N = 61)

Measure	T1	T2 (*n* = 53)	T3
DOCS	28.44 (10.19) 1.30	26.83 (9.43) 1.29	25.90 (10.21) 1.31
GAD	14.38 (4.14) 0.53	11.49 (4.64) 0.64	12.23 (5.30) 0.68
PHQ-8	12.87 (5.60) 0.72	10.89 (5.96) 0.82	11.39 (5.94) 0.76
TDDS-PD	30.00 (5.91) 0.76	28.36 (6.14) 0.84	28.84 (6.10) 0.78

Note. Values are reported as follows: mean (standard deviation) standard error.

Subsample (completing all timepoints; *n* = 53)

Table S2
Values across the menstrual cycle for full subsample (n = 53)

Measure	T1	T2	T3
DOCS	28.81 (10.48) 1.44	26.83 (9.43) 1.29	26.98 (10.32) 1.42
GAD	14.45 (4.36) 0.60	11.49 (4.64) 0.64	12.64 (5.02) 0.69
PHQ-8	13.13 (5.74) 0.79	10.89 (5.96) 0.82	11.79 (5.78) 0.79
TDDS-PD	29.83 (6.05) 0.83	28.36 (6.14) 0.84	28.64 (6.18) 0.85

Note. Values are reported as follows: mean (standard deviation) standard error.

Sensitivity analyses (samples restricted to cycle lengths of 26-30 days)

Full sample (*N* = 50)

Table S3
Values across the menstrual cycle for the full subsample with restricted cycle lengths (n = 50)

Measure	T1	T3
DOCS	27.66 (10.29) 1.46	25.76 (10.25) 1.45
GAD	14.14 (4.21) 0.60	12.36 (5.30) 0.75
PHQ-8	12.80 (5.50) 0.78	11.58 (6.08) 0.86
TDDS-PD	30.06 (6.05) 0.85	29.52 (5.92) 0.84
Measure	**T1**	**T3**
DOCS	27.66 (10.29) 1.46	25.76 (10.25) 1.45
GAD	14.14 (4.21) 0.60	12.36 (5.30) 0.75
PHQ-8	12.80 (5.50) 0.78	11.58 (6.08) 0.86

TDDS-PD	30.06 (6.05) 0.85	29.52 (5.92) 0.84

Note. Values are reported as follows: mean (standard deviation) standard error.

Table S4

Values across the menstrual cycle for the subsample with restricted cycle lengths completing all timepoints (n = 43)

Measure	**T1**	**T2**	**T3**
DOCS	27.95 (10.59) 1.61	26.70 (9.64) 1.47	27.07 (10.29) 1.57
GAD	14.14 (4.46) 0.68	11.91 (4.70) 0.72	12.79 (4.92) 0.75
PHQ-8	13.12 (5.60) 0.85	11.07 (6.04) 0.92	12.05 (5.83) 0.89
TDDS-PD	29.81 (6.18) 0.94	29.09 (6.32) 0.96	29.40 (5.94) 0.91

Note. Values are reported as follows: mean (standard deviation) standard error. These were not used in any analyses within this paper

Appendix T: TDRP – Sensitivity Analyses

Sensitivity analysis

Hypothesis 1a

To confirm if widening inclusion on cycle lengths considerably influenced results, a sensitivity analysis was conducted by repeating a repeated-measures ANOVA on all those with cycle lengths between 26 and 30 days (n=50) at T1 and T3. A repeated-measures ANOVA similarly revealed a trend-level reduction in OCD symptoms from T1 (M = 27.66, SD = 10.29) to T3 (M = 25.76, SD = 10.25), F(1, 49) = 3.48, p = .068, η^2_p = .066, although this effect did not reach statistical significance.

Hypothesis 1b

Sensitivity analysis on the restricted sample (n = 50) revealed a significant Time × Symptom interaction, $F(3, 147) = 3.35$, $p = .021$, *partial* $\eta^2 = .064$, indicating that the degree of change from T1 to T3 differed between symptom dimensions. Pairwise comparisons (Bonferroni-adjusted) showed no significant change in contamination symptoms (T1: M = 5.54, SD = 4.89; T3: M = 5.72, SD = 5.05, p = .631) or symmetry symptoms (T1: M = 4.74, SD = 4.16; T3: M = 4.94, SD = 3.80, p = .636). In contrast, harm symptoms significantly decreased from T1 (M = 8.92, SD = 3.79) to T3 (M = 7.66, SD = 4.08, p = .024), as did unacceptable-thought symptoms (T1: M = 8.46, SD = 4.44; T3: M = 7.44, SD = 3.96, p = .022).

Hypothesis 2

Sensitivity analysis on the restricted sample examining PDS across the cycle was conducted using a repeated-measures ANOVA, which found no significant change in PDS scores from T1 (M = 30.06, SD = 6.05) to T3 (M = 29.52, SD = 5.92), F(1, 49) = 0.67, p = .419, partial η^2 = .013. For anxiety, a repeated-measures ANOVA indicated a significant decrease in GAD-7 scores from T1 (M = 14.14, SD = 4.21) to T3 (M = 12.36, SD = 5.30), $F(1, 49) = 4.96$, $p = .031$, *partial* $\eta^2 = .092$. For depression, a repeated-measures ANOVA showed a non-significant trend toward reduced depressive symptoms from T1 (M = 12.80, SD = 5.50) to T3 (M = 11.58, SD = 6.08), F(1, 49) = 3.54, p = .066, partial η^2 = .067.

Hypothesis 3

A sensitivity analysis restricting to cycle lengths of 26 to 30 days (n=43) was conducted using a repeated-measures ANOVA, which similarly revealed significant main effect of time for anxiety $F(2, 84) = 4.78$, p = .011, $\eta^2_p = .102$ and depression, $F(2, 84) = 4.72$, p = .011, $\eta^2_p = .101$.

Hypothesis 4

A sensitivity analysis was conducted by repeating the correlational analyses in those with cycle lengths between 26 and 30 days (n=50), which similarly revealed that change in PDS was positively associated with change in DOCS–contamination from T1 to T3, $r(48) = .29$, $p = .040$, 95% CI [.01, .53].

Appendix U: TDRP – Demographic Comparisons by Hormone-Sensitivity

Table 6
Comparison of Characteristics by Hormone Sensitive Group

Variable	Non-Hormone Sensitive (*n*=47)	Hormone Sensitive (*n*=14)	
Gender			
Woman	43 (91.5%)	13 (92.9%)	
Gender-diverse	4 (8.5%)	1 (7.1%)	Fisher's exact *p* = 1.000;
Age Group			
18–24	17 (36.2%)	1 (7.1%)	
25–34	18 (38.3%)	11 (78.6%)	Fisher-Freeman-Halton Exact Test p=.023*
35+	12 (25.5%)	2 (14.3%)	
Marital Status			
Single	16 (34.0%)	2 (14.3%)	Fisher-Freeman-Halton Exact Test, *p* = .278
In a relationship	28 (59.6%)	11 (78.6%)	
Other/previous	3 (6.4%)	1 (7.1%)	
Sexual Orientation			
Heterosexual	26 (55.3%)	9 (64.3%)	
Queer-spectrum	17 (36.2%)	4 (28.6%)	Fisher-Freeman-Halton Exact Test, *p* = .889
Other / Prefer not to say	4 (8.5%)	1 (7.1%)	
Ethnicity			
White British/Irish	31 (66.0%)	10 (71.4%)	Fisher-Freeman-Halton Exact Test, *p* = .809
White Other	11 (23.4%)	2 (14.3%)	

Ethnic Minority	5 (10.6%)	2 (14.3%)	
Education Level			
Low / Other	6 (12.8%)	1 (7.1%)	Fisher-Freeman-Halton Exact Test, p =.590
Medium	12 (25.5%)	2 (14.3%)	
High	29 (61.7%)	11 (78.6%)	
Employment Status			
Employed	31 (66.0%)	11 (78.6%)	
Student	8 (17.0%)	1 (7.1%)	Fisher-Freeman-Halton Exact Test, p=0.802
Not working / Other	8 (17.0%)	2 (14.3%)	
Income			
< £15k	12 (25.5%)	2 (14.3%)	
£15k–£24k	7 (14.9%)	1 (7.1%)	
£24k–£55k	21 (44.7%)	9 (64.3%)	Fisher-Freeman-Halton Exact Test, p=0.504
£55k+	3 (6.4%)	2 (14.3%)	
Prefer not to say	4 (8.5%)	0 (0.0%)	
PMS			
Yes – diagnosed	3 (6.4%)	2 (14.3%)	Fisher-Freeman-Halton Exact Test, p = .208
Yes – undiagnosed	37 (78.7%)	8 (57.1%)	
No	7 (14.9%)	4 (28.6%)	
PMDD			
Yes – diagnosed	3 (6.4%)	0 (0%)	Fisher-Freeman-Halton Exact Test, p = .660
Yes – undiagnosed	13 (27.7%)	3 (21.4%)	
No	31 (66%)	11 (78.6%)	
Pregnancy Onset			
Yes	1 (2.1%)	0 (0%)	Fisher's Exact Test, p = 1.000
No	46 (97.9%)	14 (100%)	
Menses Onset			

Yes	10 (21.3%)	4 (28.6%)	Fisher's Exact Test, p = .718
No	37 (78.7%)	10 (71.4%)	
Comorbidities			
Yes	39 (21.3%)	11 (78.6%)	Fisher's Exact Test, p = .703
No	8 (17.0%)	3 (21.4%)	
Cycle length			
Mean (mean ranks)	27.6 (30.04)	27.9 (34.21)	U = 284.00, p = .432
Age of OCD onset			
Mean (mean ranks)	13.3 (34.02)	9.2 (20.86)	U = 187.00, Z = -2.445, p = .014
Reason for hormonal contraceptive cessation			
Emotional Side effects	17 (36.2%)	3 (21.4%)	Fisher-Freeman-Halton Exact Test, p = .355
Physical Side Effects	4 (8.5%)	4 (28.6%)	
Other			
No Particular Reason	4 (8.5%)	1 (7.1%)	
Not applicable	17 (8.5%)	4 (28.6%)	
Other	5 (10.6%)	2 (14.3%)	
Medication for OCD			
Yes	16 (34.0%)	5 (35.7%)	Fisher's Exact Test, p = 1.000
No	31 (66.0%)	9 (64.3%)	
Medication for OCD in past 6 weeks			
Yes	2 (4.3%)	0 (0%)	Fisher's Exact Test, p = 1.000
No	45 (95.7%)	14 (100%)	
Psychological Therapy for OCD			

Yes	13 (27.7%)	3 (21.4%)	Fisher's Exact Test, p = .742
No	34 (72.3%)	11 (78.6%)	
Psychological Therapy in past 6 weeks			
Yes	2 (4.3%)	0 (0%)	Fisher's Exact Test, p = 1.000
No	45 (95.7%)	14 (100%)	
Medication for other mental health disorders			
Yes	35 (74.5%)	10 (71.4%)	Fisher's Exact Test, p = 1.000
No	12 (25.5%)	4 (28.6%)	
Medication for other MH disorders past 6 weeks			
Yes	1 (2.1%)	0 (0%)	Fisher's Exact Test, p = 1.000
No	46 (97.9%)	14 (100%)	

Note. Percentages reflect the proportion within each group