BJPsych | The British Journal of Psychiatry (2026)
1–3. doi: 10.1192/bjp.2025.10516

Commentary

Women at the heart of mental science: commentary, Pinto da Costa et al

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Keywords
Women; mental health; psychiatry; science; research.

Women's mental health is shaped by the intersection of rights, cultural norms and stigma, which together create a silent architecture that structures both vulnerability and resilience. In many societies, overt restrictions on women's rights (e.g. access to education, employment or healthcare) reinforce unequal power and limit opportunities for autonomy and well-being. Gendered expectations may also dictate how distress can be expressed, often silencing women's experiences. Stigma frames mental health conditions as moral weakness or dishonour, deterring women from seeking help and perpetuating cycles of exclusion. Addressing mental health conditions requires broader social transformation, advancing gender equality and dismantling cultural stigma to promote psychological well-being.

As highlighted in a recent editorial,[1] the US government's move to restrict language and research funding focusing on sex and gender poses a direct threat to scientific progress, especially for vulnerable populations. Among the terms targeted are 'female' and 'women', groups that represent nearly half the world's population. This is not a semantic issue: it undermines decades of effort to redress historical exclusion. Women have long been underrepresented, not only as research participants but also in the framing of research questions, generating research and in scientific leadership across preclinical, translational and clinical research, including psychiatry.[2] This exclusion has resulted in scientific data largely derived from males, based on the priorities of men. It has shaped our understanding of mental health conditions, their aetiology, symptomatology, pathophysiology and treatment.

Sex differences in diagnosis and treatment response

Historic male-centric bias has contributed to disparities at multiple levels of care and research. Women's presentations are often mislabelled, and diagnostic frameworks (largely derived from male populations) reinforce both under- and misdiagnosis. Fundamental questions about sex-specific conditions, such as puerperal psychosis, remain underexplored. Treatment evidence is also limited. For example, the CLARITY-AD phase III clinical trial of lecanemab, an anti-amyloid drug, revealed overall therapeutic benefit[3] but sex-specific analyses showed improvements only in males. Females experience adverse drug reactions nearly twice as often as males, with higher hospitalisation rates.[4] Sex-balanced trial design and sex-disaggregated analyses are essential to ensuring that mental health treatments are safe and effective for all.

Beyond biological sex, comprehensive understanding of health and disease requires consideration of gender and other social identities. These factors profoundly influence neurobiology, disease prevalence, symptom burden, help-seeking behaviours and treatment outcomes.[2] Suppression of inclusive language exacerbates health disparities faced by women and other marginalised groups. Frameworks such as MESSAGE, which guides the integration of sex and gender in clinical trials, and INCLUDE, which promotes broader inclusivity in research, offer practical approaches. Mental health research must actively incorporate sex, gender and other sociodemographic factors to address the unique health needs of women across the lifespan.

Pregnancy and perinatal exclusion from research

Historical events, such as the thalidomide tragedy in which prenatal exposure caused severe birth effects, have fostered a risk-averse approach among regulators and the pharmaceutical industry. This cautious stance, together with the inherent risks of early-phase trials – namely potential unknown teratogenic effects, adverse maternal outcomes and uncertainties around dosing – have led to the default exclusion of pregnant and breastfeeding women from randomised controlled trials. As a consequence, clinicians lack evidence-based guidance for managing mental health conditions in pregnancy. To overcome this, more rigorous preclinical reproductive-toxicity studies, well-designed observational and natural-experiment studies using linked health records, and adaptative trial designs that allow inclusion of participants as evidence grows, are needed.

Ethical considerations in perinatal mental health research are complex, given the dual responsibility to both the mother and child, the need to balance risks and benefits to both, participant vulnerability and study burden. Nevertheless, a systematic review on the ethics of randomised placebo controlled trials of antidepressants in pregnancy concluded that such trials are ethically justified and desired by potential participants.[5] In line with this, a recent publication outlined five key actions for optimisation of fair inclusion in biomedical research: fostering reciprocal partnerships, prioritising multidisciplinary research, raising awareness of the need for pharmaceutical innovation, conducting regulatory analyses and promoting responsible inclusion rather than presumptive exclusion.[6]

Addressing these inequities not only requires active inclusion and carefully designed strategies, but also real-world evidence,

post-licensing studies, tailored consent procedures, ongoing risk monitoring, participant engagement in study design and transparent communication of risks and benefits. As new health challenges arise, including pandemics, pregnant and breastfeeding women must not be automatically excluded from research. Careful risk–benefit assessment and strategies to minimise potential harm to the child, together with greater regulatory support through explicit requirements and incentives, are crucial for the safe integration of these populations into research agendas.

Reproductive transitions

In psychiatry, female reproductive transitions (menarche, stages of the menstrual cycle, pregnancy, postpartum and menopause) are often overlooked, despite their biological, cultural and psychological impact.[7] While menarche, the menstrual cycle and menopause are almost universal, they are particularly understudied and remain peripheral in mental health research, often reduced to hot flushes and hormone charts.

Menopause and menarche also represent neurobiological thresholds during which symptoms may emerge and flare, diagnoses shift and resilience is tested. During menopause, declining oestrogen and progesterone levels are central. but emerging research highlights additional alterations in brain structure, cognition and sleep. Differential hormone sensitivity may explain reproductive endocrine-related mood disorders, such as women with premenstrual symptomatology who develop perinatal depression.

Menopause also coincides with midlife, a period of social, occupational and personal transitions. Cultural framings often diminish its significance, with many societies stigmatising it and portraying menopause as a decline rather than a new life stage.[8] In contrast, some cultures re-frame menopause positively, as a liberating phase, free from reproductive expectations or a period of enhanced societal authority. Among Native American communities, menopause is associated with respect, maturity and wisdom. Cultural perspectives influence symptom expression: negative framings exacerbate distress, while positive framings buffer it.[8] Nevertheless, psychiatry rarely incorporates this cultural variability and often lacks frameworks for culturally responsive care during menopause.[8]

To address both biological and social determinants of mental health, future research should consider menopausal stage, exogenous hormone exposure and cultural context in clinical trials, including lived-experience perspectives and co-production. A precise and responsive science must not overlook these transitions. Research should also differentiate between types of menopause and investigate the impact of menopausal hormone replacement therapy. Recognising menopause as an important life stage, rather than framing it in terms of decline or hormone deficiency, is essential for challenging its stigma.

Women's leadership and engagement in research

Ensuring equitable representation of women in science is crucial, not only as research participants but also as members of research and clinical teams. Nonetheless, few clinical academics, and even fewer women, hold these roles.[9] Women's perspectives and expertise are essential to advancing inclusive and accurate research that addresses the health needs of all patients, with women at the heart of these efforts. Meaningful involvement must include patient and public involvement and engagement, valuing women's lived experience and expertise, and ensuring that women have an active role in shaping research priorities, design and implementation.

In the UK, the National Institute for Health and Care Research (NIHR) has recently published policy on sex and gender in research, accounting for sex- and gender-related characteristics across the research life cycle (including participant selection, study design and data analysis), which is now a core requirement for funding, reinforcing the need for women to be represented as both research participants and leaders in research activities. We hope that this approach inspires similar initiatives in other parts of the world.

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First received 15 Nov 2025, final revision 15 Nov 2025, accepted 18 Nov 2025

Data availability

Data availability is not applicable to this article as no new data were created or analysed in this study.

Acknowledgements

M.P.d.C. and G.M.M. are supported by the National Institute for Health and Care Research (NIHR) Maudsley Biomedical Research Centre, and A.N.d.C. and R.U. are supported by the NIHR Oxford Health Biomedical Research Centre. The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR or the Department of Health. E.D. is supported by the Brain and Behaviour Research Foundation. E.C. receives funds from the Swedish Research Council. None of these bodies played a significant role in the writing, editing or decision to publish this article.

Author contributions

M.P.d.C. conceptualised this manuscript. M.P.d.C., A.N.d.C., E.D., G.M.M., R.U. and E.C. contributed to writing and revision of the manuscript.

Funding

This study received no specific grant from any funding agency, commercial or not-for-profit sectors.

Declaration of interest

M.P.d.C., A.N.d.C. and E.C. are members of the *BJPsych* Editorial Board, but did not take part in the review or decision-making process of this manuscript. The other authors have no conflict of interests to declare.

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