Perinatal mental health services in pregnancy and the year after birth: the ESMI research programme including RCT

Louise M Howard,[1*] Kathryn M Abel,[2] Katie H Atmore,[1] Debra Bick,[3] Amanda Bye,[1] Sarah Byford,[4] Lauren E Carson,[1] Clare Dolman,[1] Margaret Heslin,[4] Myra Hunter,[5] Stacey Jennings,[1] Sonia Johnson,[6] Ian Jones,[7] Billie Lever Taylor,[6] Rebecca McDonald,[1] Jeannette Milgrom,[8] Nicola Morant,[6] Selina Nath,[1] Susan Pawlby,[9] Laura Potts,[10] Claire Powell,[1] Diana Rose,[11] Elizabeth Ryan,[10] Gertrude Seneviratne,[12] Rebekah Shallcross,[1] Nicky Stanley,[13] Kylee Trevillion,[1] Angelika Wieck[14] and Andrew Pickles[10]

[1]Section of Women's Mental Health, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[2]Centre for Women's Mental Health, The University of Manchester, Manchester, UK
[3]Division of Women and Children's Health, Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, King's College London, London, UK
[4]King's Health Economics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[5]Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[6]Division of Psychiatry, University College London, London, UK
[7]Institute of Psychological Medicine and Clinical Neuroscience, Cardiff University, Cardiff, UK
[8]Department of Clinical and Health Psychology, Parent–Infant Research Institute, University of Melbourne, Melbourne, VIC, Australia
[9]Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[10]Biostatistics and Health Informatics, King's College London, London, UK
[11]Service User Research Enterprise, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[12]Perinatal Service, South London and Maudsley NHS Foundation Trust, London, UK
[13]School of Social Work, Care and Community, University of Central Lancashire, Harrington, UK
[14]Greater Manchester Mental Health NHS Foundation Trust, Manchester, UK

*Corresponding author louise.howard@kcl.ac.uk

Declared competing interests of authors: Louise M Howard chaired the National Institute for Health and Care Excellence (NICE) Antenatal and Postnatal Mental Health Guidance [Clinical Guidance 192 (CG192); 2014], has worked for NICE Scientific Advice (London, UK) and was partly funded (2018–19) by the National Institute for Health and Care Research (NIHR) Biomedical Research at the South London and Maudsley NHS Foundation Trust (London, UK) and King's College London (London, UK). Louise M Howard was also supported by a NIHR Research Professorship (NIHR-RP-R3-12-011). Debra Bick was supported by the NIHR Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust (London, UK) and is an active member of the NIHR Health Services and Delivery Research (HSDR) Funding Committee (2020 to present). Ian Jones reports grants from Takeda Pharmaceutical Company Limited (Tokyo, Japan) and personal fees from Sanofi SA (Paris, France), outside the submitted work. In addition, Ian Jones is a trustee of Action on Postpartum Psychosis (Swansea, UK) and is a trustee of the Maternal Mental Health Alliance (London, UK). Rebecca McDonald reports personal fees from Improving Outcomes in the Treatment of Opioid Dependence (London, UK), other funding from Mundipharma Research Ltd (Cambridge, UK) and personal fees from the United Nations Office on Drug Crime (Vienna, Austria), outside the submitted work. Elizabeth Ryan is funded by the Medical Research Council (London, UK; grant MR/N028287/1). Rebekah Shallcross is funded by a NIHR HSDR grant (16/117/03) and grants from the Wellcome Institutional Strategic Support Fund Return to Work Fellowship, outside the submitted work. Kylee Trevillion is funded by a NIHR HSDR grant (16/117/03). Andrew Pickles received support from the NIHR King's College London/South London and Maudsley NHS Foundation Trust Biomedical Research Centre (IS-BRC-1215-20018).

Published June 2022
DOI: 10.3310/CCHT9881

Scientific summary

The ESMI research programme including RCT

Programme Grants for Applied Research 2022; Vol. 10: No. 5
DOI: 10.3310/CCHT9881

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

There is growing evidence that mental disorders are a significant problem during and after pregnancy. National policy emphasises the importance of early identification and appropriate treatment by perinatal mental health services; however, it is not known how best to identify women with perinatal mental disorders and if, and to what extent, specialist services are more clinically effective and cost-effective than generic services.

Research questions

- What is the effectiveness and cost-effectiveness of the two Whooley depression screening questions, compared with the 10-item self-complete Edinburgh Postnatal Depression Scale (EPDS), as a tool for identification of depression at antenatal booking? [Work package (WP) 1(i).]
- What is the prevalence of depression and other common mental disorders among pregnant women booking for maternity care? [WP1(i).]
- What is the efficacy of a guided self-help (GSH) intervention for mild to moderate antenatal depression delivered by psychological well-being practitioners? [WP1(ii).]
- What are the experiences of services for women with common and severe mental disorders and their partners/significant others, and what are the barriers to and facilitators of optimal care (from a service user, significant other and health-care professional perspective)? [WPs 2 and 3(i).]
- What is the effectiveness and cost-effectiveness of psychiatric mother and baby units (MBUs) compared with general psychiatric wards or care from intensive crisis resolution teams (CRTs) (also known as home treatment teams) for acute severe postnatal disorders? [WP3(ii).]

Methods

Design

Work package 1(i)
A cross-sectional survey stratified by response to depression screening questions, with a random sample of women answering 'no' to both questions.

Work package 1(ii)
An exploratory randomised controlled trial.

Work package 2
A qualitative study with thematic analysis of individual and focus group interviews.

Work package 3(i)
Psychometric testing of a new user-derived measure of service satisfaction and qualitative analysis of free-text responses.

Work package 3(ii)
An observational cohort study with propensity scores with imputation. We also examined geographical variation in MBU services as a source of instrumental variables (IVs) to account for unmeasured selection effects.

Pan-programme standard operating procedures for research associates in the field were developed to include safeguarding, suicidality and domestic abuse.

Setting

Work package 1
English maternity services.

Work package 2
Universal secondary and specialist secondary inpatient and outpatient care.

Work package 3
Generic psychiatric services (i.e. inpatient units and CRTs) and specialist psychiatric services (i.e. MBUs) caring for women with acute severe post-partum disorders in the first year after birth.

Participants

Work package 1
Pregnant women attending a south London maternity service.

Work package 2
Women and significant others in contact with universal secondary or specialist secondary inpatient and outpatient care.

Work package 3
Women with acute severe post-partum disorders in the first year after birth cared for in generic services (i.e. inpatient units and CRTs) or specialist psychiatric MBUs.

Interventions

Work package 1
Guided self-help.

Work package 2
All interventions/services provided for perinatal mental disorders across the diagnostic spectrum.

Work package 3
Psychiatric MBUs compared with other services for women with acute severe post-partum disorders in the first year after birth (with MBU classified as the highest, most specialist, form of care, acute ward admission as an intermediate form of acute care and CRT care as an alternative form of generic acute care).

Main outcome measures

Work package 1(i)
Measures included specificity, sensitivity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratio, acceptability of Whooley questions and the EPDS [compared with the Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders Axis I Disorders* (SCID-I)] and population prevalence estimates.

Work package 1(ii)
Measures included participant recruitment rate, depressive symptoms and attrition at follow-up, and adverse events.

Work package 2
The main outcome measure was experiences of care.

Work package 3(i)
The main outcome measure was validity and reliability of the new user-derived perinatal VOICE (Views On Inpatient CarE) measure.

Work package 3(ii)
In the first year after discharge, measures included the proportion of participants readmitted to acute care (primary outcome) and loss of custody of infant (secondary outcome). Secondary outcomes measured 4 weeks after discharge included unmet needs (using the Camberwell Assessment of Need – Mothers), satisfaction [using the Client Satisfaction Questionnaire (CSQ) and perinatal VOICE], perceived bonding (using the Parental Bonding Questionnaire), the Child & Adult Relational Experimental Index measures of maternal sensitivity and unresponsiveness, infant co-operation and passivity, and cost-effectiveness.

Results

Work package 1(i)
The diagnostic accuracy of the two Whooley depression screening questions was as follows: a weighted sensitivity of 0.41, a specificity of 0.95, a PPV of 0.45, a NPV of 0.93 and a likelihood ratio (positive) of 8.2. For the EPDS, the diagnostic accuracy was as follows: a weighted sensitivity of 0.59, a specificity of 0.94, a PPV of 0.52, a NPV of 0.95 and a likelihood ratio (positive) of 9.8. Cost-effectiveness analysis supported the use of both the Whooley questions and the EPDS, compared with a combination of the Whooley questions followed by the EPDS or a no-screen option.

The population prevalence estimate was 11% [95% confidence interval (CI) 8% to 14%] for depression and 27% (95% CI 22% to 32%) for any mental disorder for women in early pregnancy.

Being asked about depression at antenatal booking appointments was reported as acceptable by most women, although less so for women with mental disorders and/or experiences of abuse because of the triggering of emotional responses and the way disclosures were handled.

Work package 1(ii)
Over an 18-month period, 53 women with depression in pregnancy were recruited and randomised (less than half the numbers planned). Twenty-six women were randomised to GSH modified for antenatal depression [with 18 (69%) women attending four or more sessions] and 27 women were randomised to usual care. Three women were lost to follow-up (follow-up rate for primary outcome: 92%). At 14 weeks post randomisation, women receiving GSH reported fewer depressive symptoms than women receiving usual care (adjusted effect size −0.64, 95% CI −1.30 to 0.06). There were no trial-related adverse events. Costs and quality-adjusted life-years (QALYs) were similar in the two groups, resulting in a 50% probability of GSH being cost-effective, compared with usual care, at National Institute for Health and Care Excellence cost-per-QALY thresholds, although this result was sensitive to the assumptions made and data applied.

Work package 2
Women valued (and usually preferred) specialist perinatal expertise across all settings; however, some women perceived generic services as helpful, as they were associated with continuity of care from the preconception period and during the perinatal period and beyond, particularly when staff liaised effectively with specialist services. Involvement of family members and community care after discharge from acute services was perceived as poor across generic and specialist acute services.

Work package 3(i)

For the perinatal VOICE, eigenvalues and goodness-of-fit measures from exploratory factor analysis suggested that two factors gave an adequate fit (comparative fit index = 0.97). Items loading on these two dimensions were (1) those concerning aspects of the service relating to the care of the mother and (2) those relating to care of the baby. The factors were positively correlated (0.49; $p < 0.0001$). Total scores were strongly associated with service (with higher satisfaction for MBUs, 2 degrees of freedom; $p < 0.0001$) and with the 'gold standard' Client Service Questionnaire total score (test–retest intraclass correlation coefficient 0.784, 95% CI 0.643 to 0.924; $p < 0.0001$).

Work package 3(ii)

A total of 279 women were recruited (with 108 women admitted to MBUs, 62 women admitted to acute wards and 109 women assigned to CRTs). Many women used more than one service. The median duration of ward admission was 14 days, compared with a median 49 days for MBU admission. Twenty-three prespecified variables were used in the propensity scores.

A total of 278 women were followed up for the primary outcome at 1 year post discharge. The readmission rate was 22.2% for women admitted to a MBU, compared with 25.3% for women who received other forms of acute care. After women were excluded because the sample lacked women with comparable characteristics within the alternative treatment group, a total of 263 women were included in the primary analysis, which compared readmission for MBU admission with other forms of acute care (adjusted odds ratio 0.95, 95% CI 0.86 to 1.04; $p = 0.29$). One of the sensitivity analyses (an IV) found a markedly significant effect of admission to MBU ($p < 0.001$).

Complete-case analysis using propensity scores for safeguarding status at 1 year post discharge found no difference for loss of custody of infant between MBU care and other acute care ($n = 211$ after exclusion because of region of common support; coefficient 0.01, 95% CI –0.04 to 0.06; $p = 0.72$).

There was no difference between the two groups for other secondary outcomes at 1 month post discharge other than for satisfaction, which was higher for women admitted to MBUs than for women admitted to other forms of acute care, whether measured using the CSQ (coefficient 1.62, 95% CI 0.20 to 3.05; $p = 0.03$) or the perinatal VOICE (coefficient 34.08, 95% CI 28.23 to 39.93; $p < 0.001$).

Total costs from index admission to 1 month post discharge were significantly higher for MBUs (mean difference £44,049, 95% CI £36,638 to £51,461; $p < 0.001$) than for acute wards or CRTs because of a combination of higher unit costs for MBUs and longer lengths of stay. QALYs were not significantly different (mean difference 0.007, 95% CI –0.013 to 0.027, $p = 0.496$). As a result, economic evaluation did not support the cost-effectiveness of MBUs over the short term.

Cost and effectiveness data over the longer term (to 1 year post discharge) also suggest that a cost-effectiveness advantage for MBUs is unlikely, given similar costs and QALYs over this follow-up period. However, if the primary analysis has not accounted for an unmeasured confounding variable and the IV analysis is valid, MBUs may significantly reduce readmission rates. Cost-effectiveness advantages might then exist in the longer term, by offsetting the high cost of MBUs through savings from reduced subsequent readmissions.

In WP3, 51% of significant others (i.e. partners, family members or friends) of women responding to our survey ($n = 96$) were 'cases' on the General Health Questionnaire-12, meaning that they themselves had symptoms warranting clinical assessment for treatment.

Limitations

Policy and service changes influenced recruitment to studies of interventions. In addition, as with all observational studies, residual confounding is likely in WP3(ii).

Conclusions

Specialist services adapted for pregnancy and the year after birth may be more effective and valued more highly by women than generic services. Moreover, IV analysis suggests that the benefits of MBU admission could be larger than our propensity score-based estimator suggested. Evidence of cost-effectiveness was more positive for GSH modified for antenatal depression than for MBUs. Across all services, involvement of other family members was generally perceived as poor, and there was evidence that common mental disorders might have prevalence in significant others caring for women with acute severe postnatal mental disorders.

Trial registration

This trial is registered as ISRCTN83768230 and as study registration UKCRN ID 16403.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme and will be published in full in *Programme Grants for Applied Research*; Vol. 10, No. 5. See the NIHR Journals Library website for further project information.

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PGfAR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/pgfar. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Programme Grants for Applied Research* journal

Reports are published in *Programme Grants for Applied Research* (PGfAR) if (1) they have resulted from work for the PGfAR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Programme Grants for Applied Research programme

The Programme Grants for Applied Research (PGfAR) programme, part of the National Institute for Health and Care Research (NIHR), was established in 2006 to fund collaborative, multidisciplinary programmes of applied research to solve health and social care challenges. Findings are expected to provide evidence that lead to clear and identifiable patient benefits, in the relatively near future.

PGfAR is researcher led and does not specify topics for research; however, the research must be in an area of priority or need for the NHS and the social care sector of the Department of Health and Social Care, with particular emphasis on health and social care areas that cause significant burden, where other research funders may not be focused, or where insufficient funding is available.

The programme is managed by the NIHR Central Commissioning Facility (CCF) with strategic input from the Programme Director. For more information about the PGfAR programme please visit the website: https://www.nihr.ac.uk/explore-nihr/funding-programmes/programme-grants-for-applied-research.htm

This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-1210-12002. The contractual start date was in September 2013. The final report began editorial review in June 2020 and was accepted for publication in June 2021. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).