Effectiveness of two systems-level interventions to address perinatal depression in obstetric settings (PRISM): an active-controlled cluster-randomised trial

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Summary

Background Perinatal depression is a common and undertreated condition, with potential deleterious effects on maternal, obstetric, infant, and child outcomes. We aimed to compare the effectiveness of two systems-level interventions in the obstetric setting—the Massachusetts Child Psychiatry Access Program (MCPAP) for Moms and the PRogram In Support of Moms (PRISM)—in improving depression symptoms and participation in mental health treatment among women with perinatal depression.

Methods In this cluster-randomised, active-controlled trial, obstetric practices across Massachusetts (USA) were allocated (1:1) via covariate adaptive randomisation to either continue participating in the MCPAP for Moms intervention, a state-wide, population-based programme, or to participate in the PRISM intervention, which involved MCPAP for Moms plus a proactive, multifaceted, obstetric practice-level intervention with intensive implementation support. English-speaking women (aged ≥18 years) who screened positive for depression (Edinburgh Postnatal Depression Scale [EPDS] score ≥10) were recruited from the practices. Patients were followed up at 4–25 weeks of gestation, 32–40 weeks of gestation, 0–3 months postpartum, 5–7 months postpartum, and 11–13 months postpartum via telephone interview. Participants were masked to the intervention; investigators were not masked. The primary outcome was change in depression symptoms (EPDS score) between baseline assessment and 11–13 months postpartum. Analysis was done by intention to treat, fitting generalised linear mixed models adjusting for age, insurance status, education, and race, and accounting for clustering of patients within practices. This trial is registered with ClinicalTrials.gov, NCT02760004.

Findings Between July 29, 2015, and Sept 20, 2021, ten obstetric practices were recruited and retained; five (50%) practices were randomly allocated to MCPAP for Moms and five (50%) to PRISM. 1265 participants were assessed for eligibility and 312 (24-7%) were recruited, of whom 162 (51.9%) were enrolled in MCPAP for Moms practices and 150 (48.1%) in PRISM practices. Comparing baseline to 11–13 months postpartum, EPDS scores decreased by 4·2 (SD 5·2; p<0·0001) among participants in MCPAP for Moms practices and by 4·3 (SD 4·5; p<0·0001) among those in PRISM practices (estimated difference between groups 0·1 [95% CI –1·2 to 1·4]; p=0·87).

Interpretation Both the MCPAP for Moms and PRISM interventions were equally effective in improving depression symptoms. This finding is important because the 4-point decrease in EPDS score is clinically significant, and MCPAP for Moms has a lower intensity and greater population-based reach than does PRISM.

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Introduction

According to a study published in 2013, perinatal depression affects one in seven women during pregnancy or within a year of giving birth in the USA.1 The condition also negatively affects maternal,2 infant, and child outcomes.3 Despite the prevalence and negative impact of perinatal depression, less than 25% of individuals who screen positive for the condition worldwide receive any psychiatric assessment or treatment, according to systematic reviews published in 2015 and 2016.4,5

Although outdated, the available data suggest that the care pathway for perinatal depression (ie, prevention, screening, assessment, and treatment until symptom remission) has many gaps and barriers.6-11 These barriers disproportionately affect individuals from marginalised racial, ethnic, or economic groups.6-11

Professional societies and policy makers recommend integration of depression care into obstetric practice.12 At the time of this study, the patient safety bundle for maternal mental health,12 a collection of evidence-informed best practices, recommended screening for perinatal depression twice during pregnancy and once postpartum. This bundle provided guidance on what obstetric practices needed to do to address perinatal depression.12

Conclusion

Both the MCPAP for Moms and PRISM interventions were equally effective in improving depression symptoms. This finding is important because the 4-point decrease in EPDS score is clinically significant, and MCPAP for Moms has a lower intensity and greater population-based reach than does PRISM.
mental health, but not on how to implement this standard of care.

Persistent challenges in implementing these recommendations are well documented. Most obstetric practices do not have access to the resources they need to detect, assess, and manage depression. For example, obstetric practices do not have required training in mental health, self-efficacy among providers and staff, or established workflows to address perinatal depression. We also found that obstetric provider training, strengths-based interactions between health-care provider and patients, and systematic implementation of screening, assessment, and treatment for perinatal depression can facilitate access to mental health care.

Added value of this study

This study adds to the literature by evaluating two interventions designed to address these barriers to perinatal depression treatment, both of which we found to be effective in reducing symptoms of perinatal depression. We also found that both interventions are equally effective in helping patients initiate and sustain treatment. In this cluster-randomised trial, we compared the effectiveness of two approaches—the Massachusetts Child Psychiatry Access Program for Moms (MCPAP), a state-wide, population-based programme that has already been implemented in Massachusetts, and the Program In Support of Moms (PRISM), which involves the MCPAP for Moms plus a proactive, multifaceted, obstetric practice-level intervention with intensive implementation support—in supporting the implementation of screening, assessment, and treatment of women with perinatal depression in Massachusetts (USA). Both MCPAP for Moms and PRISM were equally effective in improving depression symptoms (with improvements in Edinburgh Postnatal Depression Scale (EPDS) scores from baseline of around 4 points in each group) and rates of treatment initiation and sustainment. Nevertheless, more than 50% of participants with depressive symptoms did not initiate treatment and at least 75% did not sustain treatment in this trial. MCPAP for Moms has a lower intensity and a greater population-based reach than does PRISM.

Implications of all the available evidence

Our study has implications for how perinatal depression can be effectively addressed on a large scale, given the population-based implementation and reach of Perinatal Psychiatry Access Programs such as MCPAP for Moms. However, rates of treatment initiation and sustainment need to be further addressed.

Methods

Study design and setting

We conducted a cluster-randomised, active-controlled trial to compare the effectiveness of the MCPAP for Moms, a state-wide, population-based programme (active), and the practice-level PRISM intervention that includes MCPAP for Moms plus intensive imple-
m entation support in improving depression symptoms and participation in mental health treatment among women in the obstetric setting. The cluster-randomised design was chosen to minimise intervention contamination at the level of patients and perinatal care professionals, and involved obstetric practices in eight different towns and cities spanning Massachusetts, USA (Boston [two practices], Worcester [two practices], Hyannis, Leominster, Fall River, Springfield, Greenfield, and New Bedford). In Massachusetts, most prenatal care is funded by health insurers and is provided in ambulatory obstetric practices. Quality care expectations are uniform across delivery hospitals (appendix pp 1–2).

Obstetric practices were recruited to ensure geographical distribution across the state, diversity of practice environment, and socioeconomic and racial diversity among patients served. Practice types included those that were (1) nested within an academic medical centre, (2) not nested within an academic medical centre yet had an affiliation with an academic university (ie, academic affiliation), and (3) not nested in an academic medical centre and had no university affiliation (ie, private practice).

All practices that participated in this study were enrolled in MCPAP for Moms before randomisation. MCPAP for Moms is a state-wide programme that increases the capacity of obstetric care professionals and practices to provide evidence-based care for women with perinatal depression through training and toolkits, perinatal psychiatric consultation via telephone and face-to-face as needed, and mental health resource and referral linkages (panel).34–36 The programme does not provide assistance with practice-level implementation. MCPAP for Moms is considered to be an active intervention because it was the only such programme in the USA at the start of the study and was not the standard of care. During the course of the study, access to MCPAP for Moms was available to all individuals who gave birth in Massachusetts. In this trial, we recruited and followed a subpopulation of the obstetric practices in Massachusetts that had access to MCPAP for Moms.

PRISM is an intensive, proactive, practice-level intervention that helps obstetric practices to integrate depression care into their practice workflow, to engage in systematic screening, assessment, and a stepped treatment response for depression until remission of patient symptoms (panel).13,14,16,17 PRISM involves MCPAP for Moms plus additional training, technical assistance, support with implementation and change in management, and a person referred to as a navigator who monitors care for patients who screen positive for depression. The practices implementing PRISM during the study period were the only practices in Massachusetts that implemented this intervention type.

MCPAP for Moms and PRISM were both designed and refined on the basis of iterative feedback from patients with lived expertise, obstetric care professionals, and system-level leaders.13,14,16,17 Before this trial, we beta-tested PRISM with an obstetric practice and refined it on the basis of feedback. This study was designed and conducted on the basis of iterative feedback from a community advisory council of ten members, comprising representatives from professional societies, public health agencies, community organisations, and individuals with lived experience. We followed CONSORT reporting guidelines (appendix pp 4–7). The institutional review board of the primary institution, University of Massachusetts Chan Medical School (MA, USA), approved this study. The full protocol has been published previously.14

Participants
Under a Health Insurance Portability and Accountability Act waiver, all participating practices provided a list of patients who completed an initial obstetric visit to the central study team. Patient exposure to the intervention was not dependent on study recruitment. We contacted all patients served by the participating practices implementing either MCPAP for Moms or PRISM and invited them to participate in the study. To avoid contaminating any changes made at the practice level (eg, screening implementation), all participant recruitment and data collection occurred outside of the obstetric practice setting and workflow. Recruitment continued during the COVID-19 lockdown period (March 10, 2020, to June 15, 2021). The study team made telephone contact with patients on the practice list to assess initial eligibility for study enrolment. Adult women (age ≥18 years) who spoke English were eligible for inclusion in the study. Because these interventions were not designed to address bipolar disorder or substance use disorders, we excluded individuals who screened positive in the Mood Disorders Questionnaire for bipolar disorder, and those who responded yes to the following question in the 4 Parents, Partner, Past, and Present Plus screen for substance use: “In the month before you knew you were pregnant, did you have a problem with alcohol or drugs?”

If participants met the initial eligibility criteria, they were screen for full study eligibility (see appendix p 9 for recruitment and interview completion workflow). To meet the criteria for the full study, participants needed to screen positive for depression (Edinburgh Postnatal Depression Scale [EPDS] score ≥10). Participants who screened positive for depression in the first study window were enrolled at that time. Participants who screened negative for depression (EPDS score <10) in the first study window were placed in a holding pool, and recontacted and rescreened for depression during a subsequent window. Participants from the holding pool who met EPDS criteria during a subsequent study window were then enrolled in the study. We recruited patients at multiple timepoints to ensure that recruitment occurred soon after the onset of depression symptoms.
Panel: Characteristics of MCPAP for Moms and PRISM

MCPAP for Moms

- 30–60 min training on perinatal depression delivered in person by a perinatal psychiatrist to obstetric practice providers, nurses, and other clinical team members.
- Access to a provider toolkit, which includes assessment and treatment protocols.
- Access to psychiatric consultation with a MCPAP for Moms perinatal psychiatrist for obstetrics and gynaecology providers via telephone.
- Access to a one-time, face-to-face evaluation in which a MCPAP for Moms psychiatrist meets with and assesses the patient and then provides treatment recommendations to the obstetrics and gynaecology provider. As a provider-facing programme, MCPAP for Moms aims to build the capacity of obstetric care professionals to prescribe medication treatment themselves, when indicated. If the obstetric provider is uncomfortable doing so after a telephone consultation with a perinatal psychiatrist, a MCPAP for Moms psychiatrist can meet with the patient for a one-time consultation and provide recommendations to the obstetric provider.
- For psychotherapy or other psychological treatments, a specialist in MCPAP for Moms resources and referrals uses a statewide database created for the programme to find referrals. The specialist then calls the patient and provides resources and referrals.
- As a provider-facing programme, patients cannot self-refer to MCPAP for Moms. If a patient calls MCPAP for Moms, they are redirected back to the obstetric provider who can call MCPAP for Moms for consultation and resources.
- Staffed by four to six psychiatrists who collectively provide full-time coverage for the programme and three to four resource and referral specialists.

PRISM

- Access to MCPAP for Moms.
- Supports clinic-specific implementation using the Addressing Problems Through Organizational Change implementation platform.
- Core elements:
  - Assessment of practice readiness to implement PRISM.14
  - Identification of practice-level champions and a working group to implement change plans through practice-identified strategies.
  - Provider and staff training and toolkit customisation to facilitate stepped care within the specific practice environment.
  - On-site implementation assistance by the investigative team.
  - Ongoing sustainment meetings and support to sustain change.
- Monitoring of patients with depression symptoms to ensure that patients initiate and engage in treatment.
- A non-physician navigator, who is already employed at the obstetric practice (eg, medical assistant, nurse, or case manager) is designated. The grant funded up to 1 day per week of the navigator’s time for depression-related care.
- Navigators maintain a registry of all patients who screen positive for depression and follow them up at regular intervals. Navigators receive training in perinatal depression, patient monitoring, patient engagement, care coordination and transition, and patient registry upkeep.
- Navigators facilitate treatment engagement through psychoeducation, patient outreach, referrals, engagement (and re-engagement as needed) in recommended medication, treatment, and mental health appointments via monthly follow-up calls. Navigators work with patients until illness remission or depression care is transferred to another provider (typically at 3 months postpartum).
- Ongoing observation of symptoms, allowing perinatal care professionals to decide whether a higher level of care is warranted.
- A MCPAP for Moms perinatal psychiatrist reviews cases approximately twice per month with the navigator to provide consultation on management and engagement.
- PRISM includes the cost of MCPAP for Moms plus the cost of an additional implementation team, including a psychiatrist, obstetrics and gynaecology specialist, project director, and additional research staff.
- PRISM is implemented in three phases:

  Phase 1 (1–2 months): planning: prepare and organise
  - Establish implementation champions.
  - Establish the practice quality improvement team.
  - Complete baseline assessment.
  - Draft specific, measurable perinatal mental health-care goals.
  - Develop a workflow to address perinatal mental health conditions.
  - Identify tasks, roles, and responsibilities to achieve goals.

  Phase 2 (1 month): implementation: change, integrate, and adapt
  - Provide training for perinatal care providers and clinical staff.
  - Implement changes on the basis of goals and workflow.

  Phase 3 (ongoing): sustainment: assess and revise
  - Evaluate implementation and review progress towards goals.
  - Revise procedures on the basis of lessons learned and continue the iterative improvement process.

MCPAP for Moms—Massachusetts Child Psychiatry Access Program for Moms.
PRISM—Program In Support of Moms.
Gender identity was not assessed. Sex assigned at birth was assessed through medical records. The institutional review board determined that this was a minimal risk study, thus participants provided oral informed consent.

**Randomisation and masking**

Randomisation was at the level of obstetric practice cluster. Covariate adaptive randomisation based on the Mahalanobis distance matching method was used to randomly allocate practices (1:1) to either MCPAP for Moms or PRISM. Estimates of depression severity per EPDS score, non-White race, public insurance, and Practice Readiness Index score were used to characterise practices and formed the basis for restricted randomisation. The Practice Readiness Index quantified the extent to which individual obstetric practices were ready to implement interventions for perinatal depression. Mahalanobis distances were used to establish the optimal matches of practices, given the covariates under consideration. Practices were then randomised within the matched pairs. Participants were masked to the intervention because they were not told the intervention to which their obstetric practice was randomised. During analyses, letters were used to identify each practice, thus the staff analysing the data were also masked. The staff delivering the intervention and assessed outcomes were unmasked.

**Procedures**

Before randomisation, we conducted a run-in phase, in which we tested whether it was feasible for practices to participate in the randomised controlled trial phase and collected patient-level data to inform the randomisation. During the run-in, we obtained the baseline practice and provider-level data for the trial and recruited 25 patients per practice. We conducted one assessment with patient participants, in which we assessed depressive symptomatology and demographics. To meet criteria for randomisation, each practice needed to have at least 25 participants enrolled and at least one participant who screened positive for depression.

Consistent with national recommendations, MCPAP for Moms recommends universal screening for depression at the initial obstetric visit (8–13 weeks of gestation), during the time window for the oral glucose tolerance test (26–28 weeks gestation), and at 6 weeks postpartum. Screenings are typically administered by nursing staff and are reviewed and followed up by the obstetric provider. Because MCPAP for Moms is a state-wide programme that is free to all providers across Massachusetts, all practices in the study had access to the same consultation, assessment, and referral pathways available through MCPAP for Moms.

With PRISM, every aspect of the implementation occurred at the practice level. For example, rather than implementing screening themselves, the PRISM study team guided obstetric practices in implementing universal depression screening for all patients in the practice. The PRISM implementation team worked with obstetric practices to customise and tailor the integration of screening, assessment, and treatment for depression into their practice workflows.

Individual participants consented to audiotaped interviews for data collection via telephone. A structured interview that included questions about demographics, obstetric, reproductive, and psychiatric history, social support, and social services was conducted at baseline. In each window, depression symptoms were assessed by administering the EPDS during the telephone interview. To assess initiation and sustainment of depression treatment, as well as barriers and facilitators to treatment participation, participants were asked about mental health-care visits and treatment, and medication use at all timepoints. Although we did not include psychiatric hospitalisations or emergency room visits in our operational definition of initiation or sustainment of mental health treatment, these were assessed at all timepoints.

The EPDS is a widely used and well validated measure of severity of depression symptoms in perinatal women. Scores range from 0 to 30, with a score of 10 indicating depression symptoms and possible depression diagnosis. A 4-point decrease in EPDS score is considered to be clinically significant.

Study data were collected and managed with research electronic data capture tools hosted at the University of Massachusetts Chan Medical School. Collection of data outside the practice setting allowed the same assessments to be conducted in both groups, regardless of obstetric practice workflow. Feedback on patient-level data was not provided to participating obstetric practices. Participants were provided US$25 for each assessment and $30 for the final assessment. There were no deviations from the study protocol.

Participants were followed up over five study windows. In accordance with previous research, the first three study windows were designed to capture depression onset and course of depression symptoms at different timepoints in pregnancy and postpartum. The first three study windows were 4–25 weeks of gestation, 32–40 weeks of gestation, and 0–3 months postpartum to capture the experience of depression in early pregnancy, late pregnancy, and early postpartum, respectively. For the first two study windows, gestational age was calculated from the patient’s due date as reported by the practice, and then confirmed or updated by the participant at the time of consent. For the third study window, number of months postpartum was calculated on the basis of the delivery date provided by the participant. The last two study windows were designed to capture the ongoing course of depression for the first year postpartum and were at 5–7 months and 11–13 months.

Although the study was conducted during the COVID-19 pandemic, contact with participants by the study team did
not change during the course of the study because all patient recruitment and assessments occurred via telephone. The study team did not make changes to either intervention during the pandemic. Obstetric practices adjusted their workflow as needed on the basis of guidance to facilitate care by telehealth when possible, to postpone any elective visits, and to collaboratively decide on the need for in-person visits with the patient (appendix p 3).

Outcomes
The primary outcome was change in depression symptoms (EPDS score) between the baseline assessment, which could have been at 4–25 weeks, 28–40 weeks of gestation, or 0–3 months postpartum, and the final assessment at 11–13 months postpartum. The secondary outcomes were participation in and sustainment of mental health treatment. Based on expert consensus among the study team and the community advisory council, treatment initiation was defined as participant attendance at one initial mental health assessment or treatment visit. Treatment sustainment was defined as a participant seeing a health-care or mental health-care provider about mental health concerns at least three times during the previous 3 months (an average of more than one visit every month), or a participant being prescribed medication for depression at the time of the study interview. The proportion of participants with an EPDS score below 10 at 11–13 months was analysed as a post-hoc outcome.

Statistical analysis
Based on a previous study involving perinatal women with depression,25 in which the mean EPDS score was 14·8 (SD 5·3), we expected PRISM to be associated with a decrease in EPDS score of 5 points. We expected that MCPAP for Moms would be associated with a decrease of 3 points in EPDS score, resulting in a net difference between the two treatment arms of 2 points at follow-up. As detailed in the previously reported protocol,7 after accounting for clustering, use of an intraclass correlation coefficient of 0·001 to maintain 80% power to detect a 2-point difference in the EPDS score between groups and assuming an SD of 5·3, a sample size of 115 participants per group after dropout was needed. Expecting a 20% dropout, we aimed to recruit 150 patients per intervention (six practices per intervention with 25 patients per practice). Anticipating that not all practices would be eligible for the full study and accounting for clustering of participants within each practice. Generalised linear mixed models, accounting for clustering of patients within each practice and using a binomial link and unstructured correlation structure, were used to examine MCPAP for Moms versus PRISM as a predictor of treatment initiation and sustainment. Based on the method of Barnett and colleagues,26 we examined the possibility of regression to the mean within the MCPAP for Moms group. Using a cut point of 10, a mean value of EPDS score in a general population of pregnant women of 5·3,1 and estimates from this study of a within-subject correlation coefficient (ICC) of 0·77 and an SD of over-time change in the MCPAP for Moms study arm of 3·5, we estimated the regression to mean value to be approximately 0·42.26 To assess assumptions about missing data, those missing EPDS scores at the two timepoints were calculated with paired t tests. Unadjusted between-group changes in EPDS score were assessed with t tests for each time comparison. Adjusted linear mixed models for change in EPDS score over time included age, insurance status, education, and race, and accounted for clustering of participants within each practice. We calculated descriptive statistics for patient characteristics. Means and SDs were calculated for normally distributed continuous variables, whereas medians and IQRs were computed for skewed continuous data. To describe the distribution of EPDS scores at baseline, we computed median values, whereas we analysed change in EPDS scores with mean values. The primary outcome was differential—the difference in mean EPDS score over time in participants receiving care from MCPAP for Moms practices versus PRISM practices—and analysed in the intention-to-treat population. Within-group changes in EPDS score at two timepoints were calculated with paired t tests. Unadjusted between-group changes in EPDS score were assessed with t tests for each time comparison. Adjusted linear mixed models for change in EPDS score over time included age, insurance status, education, and race, and accounted for clustering of participants within each practice. 

Outcomes
14 obstetrics and gynaecology practices were enrolled in the run-in phase to support data collection for this aim. These practices participated in the run-in phase of patient data collection between May 3, 2016, and June 9, 2017. Four practices were excluded before practice randomisation. Two practices were excluded because the number of patients experiencing depression was too low to provide sufficient participant recruitment. Two other practices were excluded because of delays in acquiring research approval, which would have made it not feasible to keep our study timeline. In June 2017, the remaining ten practices were randomised to either PRISM or enhanced usual care (MCPAP for Moms) for the randomised controlled trial phase.

We calculated descriptive statistics for patient characteristics. Means and SDs were calculated for normally distributed continuous variables, whereas medians and IQRs were computed for skewed continuous data. To describe the distribution of EPDS scores at baseline, we computed median values, whereas we analysed change in EPDS scores with mean values. The primary outcome was differential—the difference in mean EPDS score over time in participants receiving care from MCPAP for Moms practices versus PRISM practices—and analysed in the intention-to-treat population. Within-group changes in EPDS score at two timepoints were calculated with paired t tests. Unadjusted between-group changes in EPDS score were assessed with t tests for each time comparison. Adjusted linear mixed models for change in EPDS score over time included age, insurance status, education, and race, and accounted for clustering of participants within each practice. Generalised linear mixed models, accounting for clustering of patients within each practice and using a binomial link and unstructured correlation structure, were used to examine MCPAP for Moms versus PRISM as a predictor of treatment initiation and sustainment. Based on the method of Barnett and colleagues,26 we examined the possibility of regression to the mean within the MCPAP for Moms group. Using a cut point of 10, a mean value of EPDS score in a general population of pregnant women of 5·3,1 and estimates from this study of a within-subject correlation coefficient (ICC) of 0·77 and an SD of over-time change in the MCPAP for Moms study arm of 3·5, we estimated the regression to mean value to be approximately 0·42.26 To assess assumptions about missing data, those missing EPDS scores at the three follow-up timepoints were assigned either the same EPDS score they had at baseline, a value 10% lower than their baseline score or a value 10% lower than their baseline score for that timepoint. After calculating the difference between baseline and follow-up scores for each participant, we ran adjusted linear mixed models with the differences as outcomes. We adjusted for age, insurance status, education, and race, and accounted for clustering of participants within each practice.
An alpha level of 0·05 was used to establish significance across all analyses. All statistical analyses were performed with SAS version 9.4. This trial is registered with ClinicalTrials.gov, NCT02760004, and is complete and awaiting final review.

Role of the funding source
At the request of the University of Massachusetts team, epidemiologists (JYK and CLR) from the Centers for Disease Control and Prevention (CDC) collaborated on the analysis and interpretation of data, and the writing of the report. They did not play a role in the study design or data collection.

Results
Between July 29, 2015, and Dec 2, 2016, 16 obstetric practices were recruited, of which four practices were excluded before randomisation due to challenges with either data collection or study procedures during the run-in phase. After the exclusion of four practices, we retained a balance in the geographical distribution and diversity of practices, and the demographic factors of patients served by those practices (table 1). Randomisation took place on June 19, 2017. Of the ten participating practices, four (40%) were nested in academic medical centres (one [25%] MCPAP for Moms and three [75%] PRISM), three (30%) had academic affiliations (two [67%] MCPAP for Moms and one [33%] PRISM), and three (30%) were private practices (two [67%] MCPAP for Moms and one [33%] PRISM). Births per year ranged from 350 to 1486 per practice. Practice-level resources for depression treatment varied across the ten practices (appendix pp 2–3).

Participant enrolment took place between Sept 22, 2017, and Nov 23, 2020. Of the 10051 patients who were contacted, 1265 (12·6%) consented and were screened for eligibility (figure), 312 (24·7%) of these patients met eligibility criteria, 162 (51·9%) of whom were enrolled in MCPAP for Moms practices and 150 (48·1%) of whom were enrolled in PRISM practices. In addition to inclusion and exclusion criteria (EPDS, Mood Disorders Questionnaire, the 4 Parents, Partner, Past, and Present Plus [4P’s] screen for substance use), all enrolled participants were asked about demographic information (eg, race, ethnicity, education, insurance, pregnancy, and previous pregnancy information), psychiatric history, and mental health service use. 813 (64·3%) of 1265 individuals were placed in the holding pool, of whom 71 (8·7%) became eligible for inclusion after the first study window. 273 (87·5%) of 312 enrolled participants were screened for eligibility and enrolled into the study before the onset of the first COVID-19 lockdown in Massachusetts on March 10, 2020. Participant demographics are shown in table 1. Although age, EPDS scores at screening, ethnicity (ie, Hispanic or Latina or not Hispanic or Latinx), and the primary source of payment for prenatal care were similar across practices assigned to PRISM and those assigned to MCPAP for Moms, distributions of race (p=0·01) and education (p=0·001) differed significantly between groups. All 312 (100·0%) participants were assigned female at birth. Baseline EPDS scores were skewed, thus median and IQRs were computed (table 1). The mean EPDS score at baseline was 13·1 (SD 4·4) among participants in MCPAP for Moms practices and 12·9 (3·3) among those in PRISM practices. In both MCPAP for Moms and PRISM practices, EPDS scores were around 4·0 points lower than baseline scores at 0–3 months postpartum, 5–7 months postpartum, and 11–13 months postpartum (p<0·0001; table 2). Mean EPDS scores decreased from baseline by 4·2 (SD 5·2) points among participants in MCPAP for Moms practices and by 4·3 (4·5) points among those in PRISM practices at 11–13 months postpartum (estimated difference between groups 0·9 [95% CI –1·2 to 1·1]; p=0·87; table 2). Of the observed 4-point change in EPDS score for MCPAP for
Participants at PRISM practices (n=150)  

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<th>Time Period</th>
<th>Mean (SD) n (%)</th>
<th>p value</th>
<th>Time Period</th>
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<td>0–3 months postpartum</td>
<td>4.1 (4.6) 107 (71.3%)</td>
<td>&lt;0.0001</td>
<td>0–3 months postpartum</td>
<td>3.9 (5.2) 111 (68.5%)</td>
<td>&lt;0.0001</td>
<td>0–3 months postpartum</td>
<td>0.2 (-1.1 to 1.6)</td>
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<tr>
<td>5–7 months postpartum</td>
<td>4.2 (5.3) 115 (76.7%)</td>
<td>&lt;0.0001</td>
<td>5–7 months postpartum</td>
<td>3.8 (4.8) 119 (73.5%)</td>
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<td>0.5 (-0.8 to 1.8)</td>
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<tr>
<td>11–13 months postpartum</td>
<td>4.5 (4.5) 118 (78.7%)</td>
<td>&lt;0.0001</td>
<td>11–13 months postpartum</td>
<td>4.2 (5.2) 117 (72.2%)</td>
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PRISM=P Rogram In Support of Moms. MCPAP for Moms=Massachusetts Child Psychiatry Access Program for Moms. *Adjusting for age, insurance status, education, and race, and accounting for clustering of patients within practices.

Table 2: Changes in Edinburgh Postnatal Depression Scale scores from baseline assessment at the three follow-up visits
Moms practices, approximately 3.6 points were unlikely to be explained by regression to mean. 47 (39.8%) of 118 participants in PRISM practices and 43 (36.8%) of 117 participants in MCPAP for Moms practices continued to have symptoms of depression at 11–13 months postpartum (ie, EPDS score ≥10). 71 (60.2%) participants in PRISM practices and 74 (63.3%) in MCPAP for Moms practices no longer had EPDS scores suggestive of depression at 11–13 months. The differences in EPDS scores from baseline to 0–3 months postpartum, 5–7 months postpartum, and 11–13 months postpartum did not differ significantly in participants receiving care from MCPAP for Moms practices versus PRISM practices (table 2). The observed ICC was 0.02. Results for the main study effect were robust to significant variation in assumptions about missing data (appendix p 8). We calculated the ICC for repeated measurements of patients over time to be 0.07. Based on a range of plausible ICCs centred on the study value, we found that regression to the mean was unlikely to account for more than 0.5 points of the 4-point change in the MCPAP for Moms group.

78 (52.0%) participants in PRISM practices and 70 (43.2%) in MCPAP for Moms practices initiated treatment, and 38 (25.3%) participants in PRISM practices and 32 (19.8%) in MCPAP for Moms practices sustained treatment. Among participants who sustained treatment, 36 (94.7%) in PRISM practices and 22 (68.8%) in MCPAP for Moms practices attended a mental health visit, 28 (73.7%) in PRISM practices and 24 (75.0%) in MCPAP for Moms practices were prescribed medication for depression, and 26 (68.4%) in PRISM practices and 14 (43.8%) in MCPAP for Moms practices had both. After accounting for clustering, differences in treatment initiation and sustainment rates were not significant between groups (table 3).

Discussion
In this cluster-randomised, active-controlled trial, we evaluated two interventions that support obstetric practices in implementing screening, assessment, and treatment of women with perinatal depression. Both the more intensive PRISM intervention and MCPAP for Moms alone were associated with an improvement in symptoms of depression and in rates of treatment initiation and sustainment. EPDS scores among participants decreased at a similar rate from baseline to 11–13 months postpartum in both groups, suggesting that the two interventions were equally effective in improving depression symptoms. The two interventions also appeared equally effective in helping patients initiate and sustain treatment.

The Extension of Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) to Enhance Sustainability (Extension of RE-AIM) implementation science framework provides a structure for intervention implementation, evaluation, and adaptation with a focus on sustainability. The Extension of RE-AIM recognises that impact is a function of reach and effectiveness. Although we found that both interventions were equally effective, it is possible that PRISM reached more perinatal women within the obstetric practice, particularly given that PRISM focuses on implementing depression screening.

A 4-point decrease in EPDS scores among participants in both MCPAP for Moms and PRISM practices is important for several reasons. First, this magnitude of change is considered to be clinically significant among individuals with depression symptoms, and is associated with a perceived improvement in symptoms among individuals with symptoms of perinatal depression. Second, screening for depression alone does not lead to an improvement in depression outcomes. Although there is a dearth of data examining how many individuals with symptoms of perinatal depression recover spontaneously without intervention, studies examining symptom trajectories of perinatal depression over time suggest a persistent course of symptoms into the postpartum year among individuals with elevated symptoms antenatally. A clinically significant change represents a change that is unlikely to be due to measurement error given the reliability of the instrument. An individual who shows a 4-point reduction in EPDS score from above to below 10 can be said to be recovered, whereas an individual who shows a 4-point reduction but still scores above 10 can be considered to be improved. Our finding that 60.2% of participants in PRISM practices and 63.3% of those in MCPAP for Moms practices had EPDS scores that were not suggestive of depression (ie, <10) at 11–13 months postpartum can be considered to be a treatment response, especially given that other studies have considered a treatment response to be indicated by an EPDS score of less than 13.

In other studies, when individuals were exposed to screening and usual care, less than 25% who screened positive for depression initiated treatment. By contrast, we found that 43% of participants in MCPAP for Moms practices initiated treatment. MCPAP for Moms was also associated with treatment sustainment rates that were 10–20 times higher than the rate of 0–2% found in previous studies. Nevertheless, more than 50% of participants in our study did not initiate treatment and at
least 75% did not sustain treatment, indicating that unmet needs remain.

Our findings have implications for the implementation of perinatal depression care because MCPAP for Moms is designed to increase access to perinatal mental health care across the state, whereas PRISM is designed to increase access at the level of the obstetric practice. During the course of the study, MCPAP for Moms was available to all individuals who gave birth in Massachusetts, which was approximately 71000 patients per year. In this trial, we recruited and followed a subpopulation of the obstetric practices in Massachusetts that had access to MCPAP for Moms. By comparison, the five practices implementing PRISM during the study period were the only practices in Massachusetts that implemented this intervention type, which collectively covered 4440 individuals. Thus, MCPAP for Moms had a greater population reach across the state than did PRISM. MCPAP for Moms costs up to US$14 per individual (eg, 71000 births) covered per year. Although we did not collect the data needed to calculate the exact cost of PRISM per individual covered, we know that the cost is substantially more than that of MCPAP for Moms because PRISM includes the cost and resources of MCPAP for Moms plus the costs needed for the team personnel required for practice-level implementation and sustainment. Given its reach and low cost, MCPAP for Moms might be a scalable intervention as suggested by the implementation of programmes modelled on it, which are known as Perinatal Psychiatry Access Programs. There are now 28 regional or state-based Perinatal Psychiatry Access Programs across the USA, funded with either federal or state-based funding mechanisms. These programmes are also beginning to be implemented beyond the USA. For example, in 2022 the Canadian province of Ottawa obtained funding for the implementation of an access programme; however, data on its effectiveness do not yet exist. Programmes in other high-income countries have largely examined approaches such as increased resources for community mental health services and mother and baby units. Although some progress has been made in implementing system-level interventions to address perinatal depression, challenges remain. For example, a 2022 systematic review found that approaches implemented in low-income and middle-income countries did not incorporate ways to increase the intensity of treatment for more severe illness, including pharmacotherapy, referrals to mental health specialists, and training and supervision for non-mental health professionals.

Our study had several strengths. For example, we examined the effects of both interventions on symptoms of depression over time. In addition, participant demographics were similar between MCPAP for Moms and PRISM practices in terms of race, ethnicity, and age, and were consistent with observed demographics of pregnant and postpartum individuals in Massachusetts. Although the demographics were overall similar between study interventions, differences in race were seen between groups; there were more Black or African American individuals in the PRISM group than in the MCPAP for Moms group. This difference could have affected our results, particularly given that barriers to care are higher and treatment rates are lower among Black perinatal women than among White women.

Furthermore, participants were recruited over several eligibility windows to capture the onset of depression at three different timepoints in the perinatal period and were followed up until 11–13 months postpartum, with minimal attrition. Finally, we recruited and retained diverse practice types and patients, even amid the challenges of the COVID-19 pandemic.

This study also had various limitations. Despite having cost estimates for MCPAP for Moms, we do not have cost estimates for PRISM. Additionally, our study was not powered to detect differences in rates of treatment initiation and sustainment because they were not primary outcomes. A larger study might have identified a significant difference between groups in these outcomes, given that our calculated ICC indicators were underpowered. This study’s generalisability to other populations is limited because the trial covered only ten practices across a single state in the USA, the study cohort was limited to English-speaking participants, and obstetric care in the USA differs from that in other countries. It is possible that the study’s recruitment, screening, and assessment procedures affected the depression care delivered by obstetric providers. To mitigate this possible risk, all recruitment and assessments were conducted outside of practice settings. We also observed higher attrition rates among participants served by practices randomised to MCPAP for Moms than among those in PRISM practices, which might have been because this was the less intensive intervention. To mitigate this potential effect, we recruited more participants in MCPAP for Moms practices. Finally, we did not examine the effects of the COVID-19 pandemic on the outcomes of interest.

Our study design allowed for the effects of both PRISM and MCPAP for Moms to be tested. Given that MCPAP for Moms is available state-wide and the study setting was Massachusetts, it was not possible to have a control group in which Massachusetts practices did not have access to this intervention. However, we found that regression to the mean was unlikely to account for more than 0.5 points of the 4-2-point change among participants in MCPAP for Moms practices. In addition, previous studies have shown that screening alone does not improve depression symptoms or increase treatment engagement, and that elevated antenatal EPDS scores remain elevated in the postpartum period.

In conclusion, we found that the PRISM and MCPAP for Moms interventions were equally effective in
improving depression outcomes, as well as rates of treatment initiation and sustainment among women in the perinatal and postpartum period. However, more than 50% of participants with depressive symptoms did not initiate treatment and at least 75% did not sustain treatment in this trial, which needs to be addressed in future studies. Findings from our study will help to inform the delivery of effective interventions for perinatal depression within the obstetric setting, given the improvement in depression symptoms observed in this study compared with that of previous studies and the wide implementation and population-based reach of Perinatal Psychiatry Access Programs.

Contributors
NB is the lead author of this Article and led all aspects of the study, including manuscript preparation and revisions. TAMS contributed to the conceptualisation and design of the project, critical aspects of the conduct of the study (including the choice and administration of measures, recruitment, implementation of the interventions, and interpretation of findings), and drafting and revising the manuscript. LB contributed to the design and coordination of the study, and manuscript preparation. PS contributed to the design and coordination of the study, and manuscript preparation. JS contributed to the design and coordination of the study, and manuscript preparation. PW contributed to the conceptualisation, design, and statistical analysis of the study, and accessed and verified the data. JA contributed to the conceptualisation and design of the project, critical aspects of the conduct of the study (including the choice of measures and interpretation of findings), and drafting and revising the manuscript. JYK and CLR collaborated on the analysis and interpretation of data, as well as on writing the manuscript. MZ contributed to the preparation, drafting, and revision of the manuscript. Each author was actively involved in the conceptualisation of the project and provided feedback throughout the project and manuscript preparation. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests
NB has received salary and funding support from Massachusetts Department of Mental Health via MCPAP for Moms; is the Medical Director of Research and Evaluation for MCPAP for Moms and the Executive Director of the LifeLine for Families Center at University of Massachusetts Chan Medical School (Worcester, MA, USA); has served on the Medscape Steering Committee on Clinical Advances in Postpartum Depression; has received honoraria from Global Learning Collaborative, Medscape, and Mathemacica; and has served as a consultant for The Kinetix Group, VentureWell, and JBS International. TAMS is a consultant for MCPAP for Moms as the Obstetric Engagement Liaison; is the Obstetrics Director of the University of Massachusetts Chan Medical School Lifeline for Moms Program; has served on the American College of Obstetricians and Gynecologists obstetric clinical practice guidelines committee and co-chaired the perinatal mental health expert work group, the Council on Patient Safety in Women’s Health and the subsequent Alliance on Innovation in Maternal Health perinatal mental health patient safety bundle work groups, and the Institute of Healthcare Innovation perinatal mental health patient safety bundle change package working group. LB, PS, PW, JS, JYK, CLR, MZ, JA, and SP declare no competing interests.

Data sharing
Individual participant data (including data dictionaries) will not be made publicly available. The study protocol is available upon request to the corresponding author.

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