A Randomized Trial of Collaborative Care for Perinatal Depression in Socio-Economically Disadvantaged Women: The Impact of Comorbid PTSD

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Abstract

Objective: The comorbidity of PTSD with antenatal depression poses increased risks for postpartum depression and may delay or diminish response to evidence-based depression care. In a secondary analysis of an 18-month study of collaborative care for perinatal depression, the authors hypothesized that pregnant, depressed, socio-economically disadvantaged women with co-morbid PTSD would show more improvement in the MOMCare intervention providing Brief Interpersonal Psychotherapy and/or antidepressants, compared to intensive public health Maternity Support Services(MSS-Plus).

Method: A multisite randomized controlled trial with blinded outcome assessment was conducted in the Seattle-King County Public Health System, July2010-January2014. Pregnant women were recruited who met criteria for a probable diagnosis of major depression (MDD) on the Patient Health Questionnaire-9 and/or dysthymia on the MINI-International Neuropsychiatric Interview (5.0.0). The primary outcome was depression severity at 3-,6-,12-and 18-month follow-ups;secondary outcomes included functional improvement,PTSD severity, depression response and remission,and quality of depression care.

Results: 65% of the sample of 164 met criteria for probable comorbid PTSD. The treatment effect was significantly associated with PTSD status in a group-by-PTSD severity interaction, controlling for baseline depression severity[Wald'sχ^2(1)=4.52,p=.03]. Over the 18-month follow-up, those with co-morbid PTSD in MOMCare (n=48), versus MSS-Plus(n=58),showed greater improvement in depression severity[Wald'sχ^2(1)=8.51,p=.004],PTSD severity[Wald'sχ^2(1)=5.55,p=.02]and functioning [Wald'sχ^2(1) =4.40, p=.04];higher rates of depression response[Wald'sχ^2(1)=4.13,p=.04]and remission [Wald'sχ^2(1)= 5.17,p=.02];and increased use of mental health services[Wald'sχ^2(1)=39.87,p<.0001],and antidepressant medication[Wald'sχ^2(1)=8.07,p=.005]. Participants without co-morbid PTSD in MOMCare(n=33) and MSS-Plus(n=25)showed equivalent improvement on these outcomes.

Conclusion: Collaborative depression care had a greater impact on perinatal depressive outcomes for socio-economically disadvantaged women with comorbid PTSD than for those without PTSD. Findings suggest that a stepped care treatment model for high-risk pregnant women with both MDD and PTSD could be integrated into public health systems in the US.

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Key Words: perinatal depression, antenatal depression, comorbid PTSD, childhood maltreatment, collaborative care, interpersonal psychotherapy.

Introduction

Depression during the perinatal period is a serious mental health condition,with a prevalence ranging from 25%-30% in socio-economically disadvantaged women in the US—about twice the rate of middle- and upper-income women.[1] Post-traumatic stress disorder(PTSD),a chronic debilitating psychiatric disorder, occurs among women at a rate of 10.4%, nearly double that found among men[2] and is often present in individuals with major depression(MDD),particularly those of lower socioeconomic status.[3-5] Of note is that in a large,diverse community sample of pregnant women, those with PTSD relative to those without were found to be three times more likely to meet diagnostic criteria for major depression.[6] The comorbidity of PTSD with antenatal depression poses increased risks for preterm birth,[7] persistent postpartum depression,[6,8]and impaired mother-infant bonding.[6] Yet,the comorbidity of PTSD with depression often goes unrecognized and untreated in Ob/Gyn clinics and public health settings serving pregnant and postpartum women in the US.

PTSD is a syndrome of intrusive re-experiencing, avoidance,emotional numbing or dysregulation,and autonomic hyperarousal symptoms that occur after exposure to a traumatic event or series of events. PTSD is prevalent among women who have experienced childhood abuse and adult interpersonal violence,with rates ranging from 26% to 52%.[3,9,10] PTSD arising from childhood trauma is associated in adulthood with interpersonal difficulties, emotion dysregulation,particularly anger management,[11]and multiple forms of re-victimization,including domestic violence.[12] Childhood maltreatment conveys a 12-fold risk of having PTSD in pregnancy and is associated with the comorbidity of antenatal depression and PTSD.[6]

Indeed, several studies looking more closely at this co-morbidity have found that PTSD and MDD most likely represent a joint vulnerability with regard to multiple forms of trauma exposure in both childhood and adulthood and may be interdependent in trauma survivors.[13]This set of associations suggests that those with depression alone and those with depression plus PTSD may represent two different populations. Given the increased risks of preterm birth and maternal and child mental health problems associated with the comorbidity of PTSD and depression during pregnancy,it is important to examine whether the impact of evidence-based depression care is differentially effective for depressed women with PTSD and those without PTSD during the perinatal period.

Findings from the few studies that have examined PTSD in the treatment of depression are mixed. In one study,depressed inpatients with comorbid PTSD, compared to those with depression alone, were found to be more clinically impaired and more likely to be discharged against medical advice,[14] suggesting that they may have been more difficult to engage in mental health treatment. In another study, patients with persistent depression and co-morbid PTSD had a lower probability of response to cognitive therapy than those without PTSD in the continuation phase of treatment.[15] Similarly, in a study of collaborative care with Problem-Solving Treatment and/or medications,relative to usual care, primary care patients with comorbid PTSD showed a *more delayed* depression treatment response.[16]

By contrast, in a study of depressed socio-economically disadvantaged women (33% with comorbid PTSD),results showed that cognitive-behavioral therapy and antidepressant medication, compared to community mental health referral, led to depression improvement over one year irrespective of PTSD status.[17] Similarly, in a small randomized trial of brief and maintenance IPT for perinatal depression, we found that pregnant women with more versus less childhood trauma exposure had greater depression severity and poorer outcomes at 3 months postpartum, but had achieved remission in depression and functioning by 6 months postpartum.[18] In sum, some empirical evidence suggests that PTSD comorbidity may diminish or delay response to depression treatment, whereas findings from the forementioned study[17] imply that treatment with extensive outreach to engage depressed individuals with PTSD into care can yield clinical benefits. Nevertheless, treatment at least 6 months or longer may be necessary to promote depression improvement because of the constellation of risk factors associated with comorbid PTSD.

In the present study we conducted a pre-planned secondary analysis to investigate whether comorbid PTSD moderated depressive outcomes and quality of care in "MOMCare,"an 18-month collaborative depression care intervention providing a choice of Brief Interpersonal Psychotherapy(Brief IPT)and/or antidepressants for pregnant women, compared to intensive public health Maternity Support Services(MSS-Plus) alone.[19] All of the women in the sample were socio-economically disadvantaged, depressed,and eligible for an array of county-funded MSS-Plus services. Sixty-five percent met criteria for probable comorbid PTSD. Previously, as hypothesized in our primary analysis,we observed that compared to MSS-Plus,the MOMCare intervention yielded significant,long-term improvement in

depression severity,depression remission,and quality of depression care (ClinicalTrials.gov NCT01045655).[19] We defined long-term improvement in these outcomes as *overall average* of the mean depression scores, controlling for baseline severity, at each of the 3-,6-,12-,and 18-months follow-ups from pregnancy at baseline(12-32 weeks gestation) up to 15 months postpartum(18-months follow-up).

Evidence from a number of randomized trials also suggests that interpersonal psychotherapy[20-22] is no less effective as prolonged exposure in treating PTSD in a community sample, and even more effective for patients with comorbid major depression. Likewise collaborative care[23,24] with cognitive behavioral therapy or cognitive processing therapy, in addition to pharmacotherapy with selective serotonin reuptake inhibitors (e.g., SSRIs such as sertraline[25] or paroxetine[26] as approved by the US Food and Drug Administration), has been found to be successful in treating civilians and veterans with PTSD, relative to usual care. Thus, by extension, we thought that collaborative care with IPT and /or pharmacotherapy, would be effective in treating depression and PTSD comorbidity. Based on the potential strengths of the MOMCare collaborative care intervention for addressing PTSD comorbidity,we hypothesized that depressed, pregnant women with comorbid PTSD in MOMCare,relative to MSS-Plus, would show significantly greater long-term improvement in depressive outcomes from pregnancy up to 15 months postpartum.

Method

A randomized,controlled trial with blinded assessment was designed to evaluate the *MOMCare* collaborative care intervention for perinatal depression. From ten county public health centers, pregnant women between 12-32 weeks gestation were randomized to an 18-month intervention added onto MSS-Plus,versus MSS-Plus alone,with 3-,6-,12-,and 18-month follow-up assessments. The University of Washington institutional review board approved the study and safety was monitored by a Data Safety Monitoring Board (DSMB). Details on study interventions and methods are described elsewhere.[19,27]

Participants

Study recruitment took place between January 2010 and July 2012. MSS social workers and nurses were the study's primary referral sources who routinely screened pregnant patients for depression on the Patient Health Questionnaire-9(PHQ-9)[28] and referred patients scoring $\geq$10 to the study. After referral, study MSW depression care specialists(DCSs) consented participants and conducted screenings

to assess inclusion criteria:≥18 years,diagnosis of probable major depression(at least five symptoms scored as ≥2 with one cardinal symptom on the PHQ-9,plus a functional impairment item),[28]and/or diagnosis of probable dysthymia based on the MINI-International Neuropsychiatric Interview(MINI 5.0.0[29]),12-32 weeks gestation,telephone access,and English-speaking. Inasmuch as the study was an effectiveness trial in ten busy public health centers,we decided to use the PHQ-9 and MINI by virtue of their excellent construct validity with structured clinical diagnostic interviews and their brevity and acceptability to patients. Hence all diagnoses in the study are considered "probable." Exclusion criteria included acute suicidal behavior or multiple(≥2) prior suicide attempts, schizophrenia (MINI[29]),bipolar disorder(MINI[29]),recent substance abuse/dependence(CAGE-AID[30]),severe intimate partner violence necessitating crisis intervention,or currently seeing a psychiatrist or psychotherapist. After description of the study and possible side effects to eligible participants, written,informed consent was obtained followed by randomization.

Randomization

Randomization to the MOMCare intervention or MSS-Plus proceeded by means of an adaptive block randomization scheme,stratified by initial depression severity[31](SCL-20≤ 2.0 or>2.0) and gestational age(<22 weeks or≥22 weeks).[32,33] Within each of the 4 strata, random orders of block sizes of either 2 or 4 study arm assignments were created to insure balance of intervention participants within each strata. Each DCS randomized subjects via a computerized program. All participants received a depression educational booklet, *The Depression Helpbook,* provided by the study.[34]

Intensive Maternity Support Services (MSS-Plus Comparison Condition)

Maternity Support Services(MSS) is the usual standard of care in the public health system of Seattle-King County (PHSKC) for pregnant women on Medicaid,delivered by a multi-disciplinary team of public health social workers, nurses, and nutritionists,who routinely screen, at least once,for depression from pregnancy up to 2-months postpartum. Goals of "usual" MSS include offering services to promote healthy pregnancies and positive birth and parenting outcomes,providing case management services to meet basic needs,and facilitating regular contact with an OB provider. Pregnant women scoring PHQ-9 ≥10 were eligible for *intensive* MSS-*Plus* services,entailing more frequent, longer visits from their multi-disciplinary team, such as 6-8 half-hour visits with a MSS-Plus social worker or nurse. With the patient's

consent, study staff notified MSS-Plus social workers and OB providers of the patient's depression status, after which patients were referred to their OB provider for pharmacotherapy or to community mental health centers for depression care. MSS-Plus social workers did not provide evidence-based depression care, systematic outreach, ongoing measurement, or stepped care–all of which are key "active ingredients" of the MOMCare intervention. All participants in the study received MSS-Plus visits in their respective public health centers. Despite improvements in perinatal depression screening, the leadership of PHSKC recognizes that only a minority of depressed, pregnant women are actually receiving evidence-based psychotherapy or pharmacotherapy in the community. This mirrors two decades of mental health services research, showing that depression screening alone and referral to care are inadequate to improve patient outcomes.[35] The *MOMCare* Collaborative Care Intervention differed from MSS-Plus in terms of providing evidence-based depression care and easy access to care in ten public health centers.

***MOMCare* Collaborative Care Intervention**

Collaborative care is a systematic approach with over a decade of empirical support for increasing quality of care (i.e., provision of an adequate dose of psychotherapy and/or pharmacotherapy) and reducing depression severity that includes: 1) the primary care or OB provider; 2) care management staff, such as a nurse or clinical social worker, who is based in primary care, an OB/Gyn clinic, or a public health setting, provides time-limited evidence-based psychotherapy, like IPT, and/or supports the implementation of medication initiated by the OB provider or primary care physician 3) a psychiatric consultant who advises the care management team and OB provider on the evidence-based depression care plan, jointly developed with the patient, and 4) active, sustained measurement of outcomes and follow-up according to stepped care principles by which treatment is systematically adjusted if patients are not improving as expected.[35,36] The *MOMCare* collaborative care intervention supplemented MSS-Plus in the public health setting and was specifically designed to provide an adequate dose of psychotherapy sessions and/or pharmacotherapy to decrease mental health treatment disparities in access to and quality of depression care.[27,36] The DCSs routinely collaborated with their patient's OB provider,informing the provider that the patient was receiving the MOMCare intervention for antenatal depression, providing updates on patient progress,and collaborating on medication management,if indicated. MOMCare sessions were provided in the public health centers, by phone, in community

settings,and infrequently at home. *MOMCare* included a number of novel design components, including an initial pre-treatment engagement session which included problem-solving barriers to care; patient choice of Brief IPT and/or pharmacotherapy; telephone plus in-person visits; proactive outreach after missed sessions,and case management to meet basic needs(i.e.,food, housing,job training,etc.).[27]

Brief IPT(8 sessions) was derived from Interpersonal Psychotherapy(IPT;16 sessions), which has demonstrated efficacy in treating acute and persistent depression,[37,38]and antenatal and postpartum depression.[39,40] It has received empirical support in studies of depressed pregnant and parenting women[41,42] and was designed to attenuate depressive symptoms by reducing treatment burden, strengthening social supports,building on patient strengths,resolving salient interpersonal problems,and employing "interpersonal" behavioral activation. Brief IPT was also enhanced to be relevant to the culture of race/ethnicity by incorporating into treatment the patient's cultural views of depression, treatment goals,and cultural strengths. After completion of acute treatment, maintenance sessions continued through the baby's first year.

Most pregnant participants were reluctant to take antidepressants before delivery for fear of possible harmful effects on the fetus. Most antidepressants, however, have been deemed safe to take during pregnancy (except paroxetine) and lactation.[43] For the women choosing an initial trial of or augmentation with antidepressant medication over the course of the study, the DCS collaborated with the patient, her OB provider, and the team psychiatrist to initiate effective guideline-based treatment. The psychiatrist via the DCS made recommendations usually for an SSRI to OB providers (typically not co-located in the public health clinics), based on a clinical algorithm,incorporating the patient's current medications and/or past response to antidepressants. The DCS, team psychiatrist, and study PI collaboratively made decisions made about whether a patient had had an adequate trial of medication in terms of dose and duration. The DCS met with the patient to monitor and track brief IPT treatment response and/or medication response, adherence, and side effects, utilizing the PHQ-9 and a computerized tracking system. The DCS reported patients' weekly feedback about brief IPT and/or medication dose, duration, and response to the team psychiatrist and study PI at weekly supervisory meetings where medication management and Brief IPT recommendations were made.

The DCS followed participants every 1-2 weeks(in-person or by telephone) during the acute phase of treatment (3-4 months post-baseline) and monthly during the maintenance phase(up to 18-months post-baseline)once a clinical response(≥50% decrease in PHQ-9 score from baseline) and/or remission(PHQ-9<5) was achieved. The study team employed a stepped-care treatment approach;women with less than 50% improvement in depressive symptoms by 6-8 weeks received a revised treatment plan. Women receiving Brief IPT alone could be augmented with antidepressant medication. Women on medication alone could receive an increased dosage, medication change,and/or augmentation with Brief IPT. Patients ending the study without a full remission were referred to community providers serving Medicaid recipients.

DCS training included a two-week instruction from the PI and study team in the engagement session(manualized), motivational interviewing, culturally relevant Brief IPT(manualized),case management,and general information on perinatal complications and pharmacotherapy. Using the IPT Therapy Rating Scale,[38] the study PI reviewed 75% of the audiotaped engagement and Brief IPT sessions to assess treatment fidelity and minimize drift.

Blinded Outcomes

Baseline and 3-,6-,12-,and 18-month outcomes were collected via phone by an independent interviewer blinded to intervention status. At the 3-month follow-up,88% of the sample was still pregnant. At the 6-,12-,and 18-month follow-ups,the baby was average of 3-months-old,9-months-old,and 15-months old, respectively. The primary outcome was depression severity on the Hopkins Symptom Checklist-20(SCL-20).[31] Secondary outcomes included functional impairment on the Work and Social Adjustment Scale(WSAS),[44] PTSD severity on the Post-Traumatic Stress Disorder Checklist-Civilian Version(PCL-C);[45] treatment response(≥50% reduction in SCL-20 score from baseline);and complete remission of depressive symptoms(SCL-20 score<0.5). Quality of mental health care was assessed by standardized questions about attending an initial treatment session, ≥4 treatment sessions,and antidepressant medication use in each 3-or 6-month period.[46] Data on the previous 3- to 6-month use of counseling, psychotherapy, utilization of medications (name, type, duration), as well as other health services, were collected via the Cornell Service Index (CSI) at baseline and at 3, 6, 12, and 18 months

post-baseline.[47] The CSI is a reliable method to assess adult health service use and was successfully used in the IMPACT trial.[48]

Demographic, PTSD Status, and Mental Health Variables

Demographic information included age,gestational age,participant-designated race/ethnicity, marital status,education,employment status, annual income,and homelessness. Probable PTSD was determined by a clinical algorithm from the PCL-C, shown to have the highest sensitivity and specificity for a DSM-IV diagnosis of PTSD.[45] Probable panic disorder and generalized anxiety disorder were measured via the *PHQ;*[28] history of child abuse and neglect was assessed on the *Childhood Trauma Questionnaire*;[49]and attachment orientations[i.e.,secure, anxious-ambivalent, avoidant, fearful]were measured via *The Relationship Quality Questionnaire*(RQ).[50]

Statistical Analyses

We used independent t-tests and chi-square analyses to compare the baseline characteristics of depressed women with PTSD to those without PTSD. To evaluate quality of depression care in the MOMCare intervention and in the MSS-Plus group, we used the Cornell Services Index. We also compared the number of in-person and telephone visits by PTSD status using data from the tracking program maintained by the DCSs. Because visits and telephone calls are count data,we used Poisson regression models to examine differences in the MOMCare arm by PTSD status.

For the secondary analysis in this study, generalized estimating equations were used to determine whether PTSD severity had an effect on the pattern of changes in depression symptoms between intervention groups. Generalized estimating equations are intent-to-treat longitudinal regression models that allow for the inclusion of all participants,regardless of missing outcomes. We employed an unstructured covariance model with robust error estimation. Using SCL-20 depression scores as the outcome measure at 3-,6-,12-,and 18-month follow-ups,controlling for baseline SCL-20,we expected that a moderation effect would be demonstrated by a significant two-way interaction of intervention group and PTSD severity. This expectation was based on our study's previous primary findings of significant main effects for the MOMCare intervention,relative to MSS-Plus,on depressive outcomes and depression remission.[19] In the event of a significant interaction effect,we planned to stratify the sample by PTSD status using the PCL-C clinical algorithm[45]and to conduct additional generalized estimating equation

models to test for treatment group differences within the PTSD/no PTSD subgroups on SCL-20 scores and secondary outcomes,controlling for baseline values.

For each of the treatment groups,we used logistic regression models to estimate odds ratios and 95% confidence intervals for categorical secondary outcomes[treatment response and remission, four or more mental health visits,adherence to antidepressants,and satisfaction with care]. Lastly, effect sizes for the continuous variables were computed using Cohen's d,[51]whereas for the dichotomous variables,effect sizes were calculated by converting the odds ratios.[52]

Results

Overall, 168 participants were randomized, 83 to MOMCare, 85 to MSS-Plus. The study attrition rate was 5% equivalent across treatment groups. Sixty-five percent met criteria for a diagnosis of probable PTSD and 53% reported moderate to severe childhood maltreatment. Table 1 shows baseline differences on demographic and clinical variables for the participants with MDD/dysthymia alone and for those with MDD/dysthymia and PTSD. Participants in the latter subgroup were more likely to be unemployed [$\chi^2(2)=7.34,p=.02$),to have experienced a previous depressive episode[$\chi^2(1)=12.46,p<.0001$], to have more prevalent GAD [$\chi^2(1)=14.66,p< .0001$]and more impaired functioning[$t(162)=6.61,p< .001$]. In addition,women with MDD/dysthymia and PTSD showed significantly higher scores on depression severity[$t(162)=6.61,p< .001$],and PTSD severity[$t(162)=12.14,p< .001$]. In particular, they reported significantly more moderate to severe childhood trauma[$\chi^2(1)=4.21,p=.03$], especially in the areas of emotional abuse[$\chi^2(1)=4.27,p=.04$], emotional neglect[$\chi^2(1)=4.69,p=.02$],and physical neglect[$\chi^2(1)=5.89,p=.01$]. Lastly, women with PTSD and depression reported a significantly more fearful attachment orientation relative to those with depression alone[$\chi^2(3)=10.18,p=.02$] which may negatively affect treatment engagement and retention.[53]

Of the women randomized to the MOMCare intervention,81.0% started treatment with Brief IPT alone (n=66),15.2% selected both Brief IPT and medication (n=12),and 3.8% preferred medication alone (n=3). Of the intervention patients who started with Brief IPT, 35% (n=23) augmented treatment with medication. Thus, over the course of the study, 47% of intervention patients (n=38) had received antidepressant medication. All women in MOMCare, regardless of PTSD status, received an average of 9.5(SD=4.0) acute treatment visits--a mean of 4.7(SD=4.1) in-person visits and 4.8(SD=4.3)telephone

visits. Regarding maintenance MOMCare patients received a mean of 7.3(SD=6.1) IPT and/or medication management sessions [2.4(SD=3.8) in person, 4.9(SD=4.7) by phone].

The most commonly prescribed antidepressants for women in MOMCare and in MSS-Plus were sertraline (48%), citalopram (15%), and bupropion (14%). Using the Cornell Service Index, we assessed adequate dosage of medication at each follow-up time point (3-,6-, 12-, 18-months) by whether or not the participant reported being on *at least or more than* the recommended starting dose on the packet insert.[54] Throughout the course of the study, *among women on antidepressants*, 95.7% of MOMCare and 77.3% of MSS-Plus participants reported being on an adequate or more than adequate dose of medication at one time point, and 74% (MOMCare) and 54% (MSS-Plus) reported adequacy of medication at two time points.

The treatment effect was significantly associated with PTSD status in a group-by-PTSD severity interaction,controlling for baseline depression severity[Wald'sχ^2(1)=4.52,p=.03]. We conducted a sensitivity analysis controlling for the Table 1 variables showing statistically significant differences between the PTSD/no PTSD subgroups. The interaction of group status and PTSD severity remained statistically significant [Wald'sχ^2(1)=4.71,p=.03]. Using the PCL-C clinical algorithm, we found that participants with comorbid PTSD had greater recovery from depressive symptoms,on average, over the 18-month study period with the MOMCare intervention than with MSS-Plus[Wald'sχ^2(1)=8.51,p=.004] (Table 2,Figure 1). In contrast, participants without comorbid PTSD showed similar declines in depression severity,regardless of treatment condition [Wald'sχ^2(1)= 0.01,p=.90]. The MOMCare effect size (*ES*) on the observed data for reduction in depression severity was about four times larger(0.39) for the PTSD subgroup relative to the MOMCare effect size (*ES*) for the no PTSD subgroup(.11). Also, women with comorbid PTSD in MOMCare showed significant improvement in work and social functioning [Wald'sχ^2(1)= 4.40,p=.04][*ES*=.41]and reduced PTSD severity [Wald'sχ^2(1)=5.55,p=.02] [*ES*=.24], compared to MSS-Plus[*ES*=.22,*ES*=.16, respectively].

With respect to remission of depressive symptoms,Table 2 and Figure 2 show that a significantly greater proportion(42%) of women with comorbid PTSD in the MOMCare condition reached remission at one time point [Wald'sχ^2(1)=5.17, p=.02][*ES*=.44] than their counterparts(25%) in MSS-Plus[*ES*=.02] across the study period. Enduring remission was defined as 2 or more consecutive time points at

remission on the SCL-20 or achieving remission by the final study assessment at 18-months post baseline. Once again, MOMCare participants with PTSD (29.2%) were significantly more likely to achieve an enduring remission than MSS-Plus women with PTSD (16.3%) [Wald's $\chi^2(1)=7.19,p=.007$]. Women with comorbid PTSD in MOMCare,relative to MSS-Plus, were significantly more likely to have achieved at least 50% decrease in SCL-20 depression severity from baseline(56% vs. 48%) [Wald's $\chi^2(1)=4.13,p=.04$][*ES*=.34] compared to MSS-Plus[*ES*=.21]. In general, women without comorbid PTSD showed similar improvement in functioning and PTSD severity and achieved similar high rates of depression remission and treatment response in both MOMCare and MSS-Plus.

Regarding quality of depression care outcomes(Table 3), for women with and without PTSD, study participants did not differ in amount of time spent in MSS-Plus visits. Most importantly,a higher proportion of women with comorbid PTSD in MOMCare,versus MSS-Plus, engaged in an initial treatment session [$\chi^2(1)=40.17,p=.0001$], had four or more mental health visits, including MOMCare sessions[Wald's$\chi^2(1)= 39.87,p< .0001$),received antidepressant medication in the past 3 or 6 months [Wald's$\chi^2(1)=8.07,p=.005$] or for ≥25 days in the past month [Wald's$\chi^2(1)=10.82$, df=1,p= .001], and were satisfied with care received[Wald's$\chi^2(1)=6.33$, p=. 01]. These utilization criteria indicate excellent fidelity to the collaborative care model.[35] In a post-hoc analysis, we examined whether increased antidepressant use as well as adequate duration of use mediated depressive outcomes for women in MOMCare with PTSD compared to their counterparts in MSS-Plus and found that they did not function as a mediators. Women without comorbid PTSD in MOMCare,relative to MSS-Plus, were significantly more likely to have four or more mental health visits[Wald's$\chi^2(1)=24.66,p< .0001$],but did not differ in receipt of antidepressant medication, or in satisfaction with care received.

Discussion

The MOMCare intervention was found to be more effective than MSS-Plus over the intervention period in reducing depression severity for depressed women with comorbid PTSD, compared to those without comorbid PTSD, who appeared to show similar improvement in both treatment conditions. In addition, the data suggest that the study intervention,more so than MSS-Plus, improved work and social functioning and reduced PTSD severity for women with comorbid PTSD. Women with PTSD who received MOMCare had consistently better access to and quality of depression care than did their

counterparts in MSS-Plus for whom the ease of making and receiving specialty mental health care appointments after referral has been found to be difficult, as reported by the leadership of the public health system of Seattle-King County (PHSKC) and in previous research.[35] Note that women in MOMCare, regardless of PTSD status, received slightly more than a full dose(8) of acute Brief IPT and/or medication sessions(9 on average) plus maintenance sessions (7 on average). The effect size found for the MOMCare intervention in the PTSD subgroup of women(0.39) is equivalent to the 0.34 effect size reported for collaborative depression care relative to usual care in a recent meta-analysis of 79 studies of collaborative depression care in primary care[55]and is higher than the average effect size of .22 found in a meta-analysis of psychotherapy trials with enhanced control conditions.[56]

It is noteworthy that at each 3-,6-,12-, and 18 months follow-up, a significantly higher proportion of MOMCare participants with PTSD took antidepressant medication (typically a SSRI) in the past 3 or 6 months compared to MSS-Plus patients with PTSD (range of 35% to 48% versus 12% to 29%). It is possible, therefore, that the pharmacological treatment rather than brief IPT was the mechanism by which depressive (and PTSD) symptoms were reduced. We did not find that increased antidepressant use mediated depressive outcomes for the women with PTSD in MOMCare and MSS-Plus, however. It is likely that our study design was underpowered to test mediation, inasmuch as a majority of pregnant and postpartum study participants were not taking antidepressant medication. Furthermore, treatment with antidepressants has not consistently yielded benefits in PTSD amelioration. Although sertraline and paroxetine have been approved by the FDA to treat PTSD, only 4 of 7 antidepressant trials relevant to PTSD in veterans have demonstrated a significant improvement in PTSD symptoms.[57]

On the other hand, given that over half of intervention patients with PTSD received brief and maintenance IPT alone without medication and that IPT has been observed to be effective in ameliorating PTSD symptoms,[20-22] it is likely that IPT had a significant effect on outcomes in this study. Potential advantages of IPT for PTSD is that it is patient-friendly and flexible,based not on exposure to the traumatic event(s) (which some patients do not want),but on the link between the patient's feelings and her interpersonal environment. Many PTSD symptoms involve interactions with others,such as interpersonal avoidance. IPT for PTSD is similar to IPT for depression, requiring little to no adaptation,and specifically includes attunement to the patient's affect in relationships, reduction of

interpersonal avoidance,increases in social support, resolution of interpersonal problems,and the exploration and validation of anger as a critical part of the therapeutic process.[58]

MOMCare was tested in a unique service environment, a county public health system where OB providers were typically not co-located. Moreover,MSS-Plus was routinely provided to pregnant public health patients scoring ≥10 on the PHQ-9,who were eligible to receive more supportive services and attention than is typically given in usual care, e.g.,referral to the patient's OB provider or community mental health. Indeed,usual care in randomized trials consists of heterogeneous conditions, ranging from minimal to strong routine psychotherapeutic services, and effect sizes(and group-by-time interaction effects) are reduced when the "usual care" group receives stronger services.[59] Perhaps the strengths of the pro-active MSS-Plus comparison condition,specifically the provision of educational services and ongoing support, account for the fact that depressed women without PTSD fared just as well in MSS-Plus as in MOMCare. Likewise,other educational, supportive interventions have shown benefit in reducing perinatal depressive symptoms.[60]

Limitations of the study include the self-report of antidepressant use which may reflect memory biases,although previous studies have found high rates of agreement between self-reported antidepressant use and pharmacy database prescription data.[35] Study results may not be generalizable to non-English-speaking populations or other US populations on Medicaid. It is also possible that we found that PTSD moderated outcomes by chance, although we had hypothesized this effect, a priori, based on a review of the literature. It would also be useful to know the nature of other traumas leading to PTSD symptoms that participants experienced as adults, in addition to childhood maltreatment, although current severe intimate partner violence was an exclusion criterion for this study. Strengths of the study include the randomized design,the strong public health comparison condition, patient diversity, perinatal depression heterogeneity, low study attrition(about 5%), high rates of intervention adherence,implementation in ten public health centers,and culturally relevant adaptations to engage and retain socio-economically disadvantaged women in care.

It is noteworthy that the women with PTSD comorbidity in the MSS-Plus condition were *less* likely to receive depression care(i.e., psychotherapy and/or antidepressant medication) in the community or from their OB provider than women with PTSD in the MOMCare intervention. Because of the

constellation of risk factors shown by the depressed participants with PTSD, such as more severe, persistent depression and impaired functioning, as well as higher rates of comorbid anxiety disorders, childhood trauma,and fearful attachment orientation, we expected that their depression would be more difficult-to-treat.[61] Consequently, a full 18-month intervention for difficult-to-treat perinatal depression on-site in public health settings that includes an initial engagement session and proactive outreach may be needed to improve clinical outcomes in settings serving depressed women with high poverty and anxiety symptoms.

From a stepped care model perspective, the key finding of this study is that women with MDD depression alone may require less intensive treatment, like intensive public health maternity support services,whereas women with MDD depression and PTSD comorbidity may need more aggressive, longer treatment with an evidence-based psychotherapy and/or medication. Personalized treatment for women suffering from different types of perinatal depression, from less to more complicated, has the potential to be more efficient in terms of time and cost.

Clinical Points

- The comorbidity of PTSD with antenatal major depression poses increased risks for persistent postpartum depression and impaired mother-infant bonding, and may delay or diminish response to evidence-based depression care.

- For socio-economically disadvantaged pregnant women with major depression and comorbid PTSD, a collaborative care model including acute and maintenance interpersonal psychotherapy up to one-year postpartum, helps to reduce depression severity and PTSD severity.

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Table 1: Baseline Demographic and Clinical Variables of Depressed Participants With and Without PTSD.

Variable	Total Sample (N = 164)	MDD/Dysthymia AND PTSD (N = 106)	MDD/Dysthymia NO PTSD (N = 58)	Statistical p Value
Treatment Group				
MOMCare	49.4 (81)	45.3 (48)	56.9 (33)	.19
MSS-Plus	50.6 (83)	54.7 (58)	43.1 (25)	
Age — M (SD)	27.0 (6.0)	26.4 (6.0)	28.0 (5.9)	.09
Race				
White	40.9 (67)	36.8 (39)	48.3 (28)	.17
African American	23.8 (39)	29.2 (31)	13.8 (8)	
Latina	23.2 (38)	21.7 (23)	25.9 (15)	
Asian/Pacific Islander	6.7 (11)	5.7 (6)	8.6 (5)	
Native American /Alaskan	5.5 (9)	6.6 (7)	3.4 (2)	
Non-White	59.1 (97)	63.2 (67)	51.7 (30)	.15
Marital Status				
Married	29.3 (48)	26.4 (28)	34.5 (20)	.56
Living with a partner	33.5 (55)	34.0 (36)	32.8 (19)	
Partner (not living with)	12.8 (21)	15.1 (16)	8.6 (5)	
No partner	24.4 (40)	24.5 (26)	24.1 (14)	
Education				
Less than high school	21.3 (35)	22.6 (24)	19.0 (11)	.64
High school degree/GED	20.7 (34)	18.9 (20)	24.1 (14)	
Some college/vocational	47.0 (77)	49.1 (52)	43.1 (25)	
College degree or higher	11.0 (18)	9.4 (10)	13.8 (8)	
Employment				
Full-time	15.2 (25)	16.0 (17)	13.8 (8)	**.02**
Part-time	19.5 (32)	13.2 (14)	31.0 (18)	
Unemployed	65.2 (107)	70.8 (75)	55.2 (32)	
Likely Depressive Disorders				
PHQ major depression (MDD)	96.3 (158)	96.2 (102)	96.6 (56)	.74
Dysthymia from MINI	23.8 (39)	25.5 (27)	20.7 (12)	.57
MDD and Dysthymia	20.7 (34)	21.7 (23)	19.0 (11)	.84
# Previous Depressive Episodes				
Any prior episode	82.3 (135)	90.6 (96)	67.2 (39)	**.0001**
Too many to count or always	49.4 (81)	60.4 (64)	29.3 (17)	**.0001**
# of episodes for those reporting at least 1 — M (SD)	5.6 (5.5)	5.4 (5.6)	6.0 (5.6)	.68
Likely Anxiety Disorders				
Panic disorder	21.3 (35)	24.5 (26)	15.5 (9)	.23
General Anxiety Disorder	41.5 (68)	52.8 (56)	20.7 (12)	**.0001**
Baseline Functioning				
[a]SCL-20 depression — M (SD)	1.8 (.6)	2.0 (0.5)	1.4 (0.5)	**.0001**
[b]PTSD severity — M (SD)	48.8 (11.3)	54.6 (9.0)	38.3 (6.7)	**.0001**
[c]WSAS functional impairment — M (SD)	21.4 (8.7)	23.2 (8.2)	17.9 (8.8)	**.0001**
Moderate/Severe Childhood Trauma				
Emotional abuse	31.7 (52)	37.7 (40)	20.7 (12)	**.04**
Physical abuse	15.2 (25)	18.9 (20)	8.6 (5)	.11
Sexual abuse (N = 161)	15.5 (25)	17.3 (18)	12.3 (7)	.50
Emotional neglect	37.8 (62)	44.3 (47)	25.9 (15)	**.03**
Physical neglect	15.2 (25)	20.8 (22)	5.2 (3)	**.01**
At least one type of trauma	53.0 (87)	59.4 (63)	41.4 (24)	**.03**
Attachment orientation				
Secure	16.5 (27)	15.1 (16)	19.0 (11)	**.02**
Preoccupied/anxious	25.0 (41)	18.9 (20)	36.2 (21)	
Dismissing/overly self-reliant	11.6 (19)	10.4 (11)	13.8 (8)	
Fearful	46.9 (77)	55.7 (59)	31.0 (18)	

[a] SCL-20 score of > 0.5 indicates possible depression, range 0-4.

[b] PTSD Severity (Post Traumatic Stress Disorder Checklist-Civilian Version; PCL-C) range 17-85.

[c] Work and Social Adjustment Scale (WSAS), range 0-45. Higher scores indicate more symptoms or greater impairment.

Note. Data are % and (N) unless otherwise noted.

Abbreviations:
GED: General Education Diploma
M: Mean
MDD: Major Depression Disorder
MINI: Mini-International Neuropsychiatric Interview
MSS: Maternity Support Services
PHQ: Patient Health Questionnaire
PTSD: Post Traumatic Stress Disorder
SCL: Symptom Checklist
SD: Standard Deviation
WSAS: Work and Social Adjustment Scale

Table 2. Clinical Outcomes for MOMCare Intervention versus Maternity Support Services-Plus (MSS-Plus) by PTSD Status.

	PTSD						No PTSD					
	MOMCare(n=48)		MSS-Plus(n=58)				MOMCare (n=33)		MSS-Plus(n=25)			
	Mean	SD	Mean	SD	Between-Group Difference (95% CI)	Statistical p Value	Mean	SD	Mean	SD	Between-Group Difference (95% CI)	Statistical p Value
SCL-20 depression[a]						**.004**[b]						.90[b]
3 months	1.12	0.55	1.42	0.76	-0.30 (-0.55 to -0.06)	**.02**	1.01	0.63	0.99	0.50	0.02 (-0.25 to 0.30)	.88
6 months	0.84	0.69	1.23	0.69	-0.39 (-0.67 to -0.12)	**.006**	0.81	0.46	0.79	0.50	0.03 (-0.23 to 0.28)	.84
12 months	0.96	0.69	1.14	0.76	-0.18 (-0.45 to 0.08)	.18	0.88	0.75	0.96	0.75	-0.08 (-0.30 to 0.46)	.68
18 months	0.84	0.62	1.15	0.69	-0.31 (-0.58 to -0.05)	**.02**	0.67	0.57	0.82	0.55	-0.14 (-0.14 to 0.42)	.32
WSAS functional impairment[c]						**. 04**[b]						. 41[b]
3 months	15.6	8.73	16.9	9.75	-1.25 (-4.78 to 2.28)	.49	11.7	7.18	9.5	7.55	2.27 (-1.59 to 6.12)	.25
6 months	12.6	9.29	15.2	8.08	-2.62 (-5.96 to 0.73)	.12	10.2	7.69	10.1	8.45	0.15 (-4.09 to 4.00)	.94
12 months	12.5	9.22	15.8	9.30	-3.34 (-6.89 to 0.21)	.06	11.4	9.64	10.1	9.90	1.31 (-3.79 to 6.42)	.61
18 months	10.4	8.665	14.8	9.45	-4.34 (-7.80 to -0.88)	**.01**	8.0	8.09	10.00	8.45	-2.00 (-6.30 to 2.29)	.36
PTSD severity[d]						**.02**[b]						.62[b]
6 months	36.7	11.71	41.6	13.79	-4.85 (-9.70 to -0.01)	**.05**	30.6	9.47	31.5	10.30	-0.95 (-6.14 to 4.24)	.72
12 months	36.4	13.58	40.2	12.95	-3.38 (-8.91 to 1.26)	.14	31.3	12.17	32.1	11.25	-0.80 (-7.30 to 5.70)	.81
18 months	33.4	12.75	40.3	13.94	-6.93 (-12.00 to -1.85)	**.008**	28.4	10.67	30.4	9.85	-1.96 (-7.27 to 3.36)	.47
	N	%	N	%	Odds Ratio (95% CI)	Statistical p Value	N	%	N	%	Odds Ratio (95% CI)	Statistical p Value
Response (at least 50% decrease in SCL-20 from baseline)						**.04**[b]						.36[b]
3 months	21	44.7	13	28.3	2.05 (-0.87 to 4.85)	.13	8	24.2	11	44.0	0.41 (-0.13 to 1.25)	.16
6 months	32	66.7	21	41.2	2.86 (1.26 to 6.48)	**.02**	15	45.5	12	48.0	0.90 (-0.32 to 2.56)	1.00
12 months	23	50.0	22	44.9	1.23 (-0.55 to 2.75)	.68	15	46.9	13	52.0	0.81 (-0.29 to 2.32)	.79
18 months	27	56.3	23	47.9	1.40 (-0.63 to 3.12)	.54	16	50.0	12	50.0	1.00 (-0.35 to 2.88)	1.00
Remission of depression symptoms (SCL-20 score <0.5)						**.02**[b]						.99[b]
3 months	8	17.0	6	13.0	1.37 (-0.43 to 4.30)	.77	8	24.2	5	20.0	1.28 (-0.36 to 4.52)	.76
6 months	19	39.6	12	23.5	2.13 (-0.89 to 5.07)	.13	11	33.3	7	28.0	1.29 (-0.41 to 4.00)	.78
12 months	16	34.8	8	16.3	2.73 (1.04 to 7.22)	**.05**	12	37.5	12	48.0	0.65 (-0.22 to 1.88)	.59
18 months	20	41.7	12	25.0	2.14 (-0.90 to 5.11)	.13	15	46.9	9	37.5	1.47 (-0.50 to 4.33)	.59

[a]Depression severity (SCL-20) range 0-4
[b]Main effect for group: 3-, 6-, 12-, and 18-months follow-ups, controlling for baseline values. Emboldened p-values are significant at least at p<.05.
[c]Work and Social Adjustment Scale (WSAS) range 0 – 45. Higher scores indicate more symptoms or greater impairment.
[d]PTSD Severity (Post Traumatic Stress Disorder Checklist-Civilian Version; PCL-C) range 17-85

Note. Baseline = 100% pregnant; 3 months = 88% still pregnant; 6 months = mean 3 months postpartum; 12 months = mean 9 months postpartum; 18 months = mean 15 months postpartum.

Abbreviations:
CI: Confidence Interval
MSS: Maternity Support Services
PTSD: Post Traumatic Stress Disorder
SCL: Symptom Checklist
SD: Standard Deviation
WSAS: Work and Social Adjustment Scale

Table 3. Quality of Care Differences for MOMCare Intervention versus Maternity Support Services-Plus (MSS-Plus) by PTSD Status.

	PTSD						No PTSD					
	MOMCare (n=48)		MSS-Plus (n=58)				MOMCare (n=33)		MSS-Plus (n=25)			
	N	%	N	%	Odds Ratio (95% CI)	Statistical p Value	N	%	N	%	Odds Ratio (95% CI)	Statistical p Value
Engagement in an initial specialty mental health session												
3 months	47	97.9	17	37.0	80.18 (10.12 to 634.88)	**.0001**[a]	32	97.0	8	32.0	68.00 (7.84 to 589.92)	**.0001**[a]
4 or more specialty mental health visits in prior 3 or 6 months						**.0001**[a]						**.0001**[a]
3 months	44	91.7	12	26.1	31.17 (9.23 to 105.24)	**.0001**	31	93.9	4	16.0	81.38 (13.65 to 485.19)	**.0001**
6 months	24	50.0	8	15.7	5.38 (2.09 to 13.80)	**.0001**	15	45.5	2	8.0	9.58 (1.94 to 47.43)	**.01**
12 months	29	63.0	5	10.2	15.01 (4.99 to 45.18)	**.01**	15	46.9	6	24.0	2.79 (-0.88 to 8.83)	.10
18 months	14	29.2	3	6.3	6.18 (1.64 to 23.22)	**.0001**	8	24.2	2	8.0	3.68 (-0.71 to 19.16)	.16
Any antidepressant medication in past 3 or 6 months						**.005**[a]						.53[a]
3 months	22	46.8	9	19.6	2.58 (1.23 to 5.39)	**.01**	9	27.3	5	20.0	1.50 (-0.43 to 5.20)	.56
6 months	23	47.9	15	29.4	2.21 (-0.92 to 5.05)	.07	12	36.4	6	24.0	1.81 (-0.57 to 5.77)	.40
12 months	20	42.6	12	24.5	2.28 (-0.96 to 5.46)	.08	12	37.5	8	32.0	1.28 (-0.42 to 3.84)	.78
18 months	17	35.4	6	12.5	3.84 (1.36 to 10.86)	**.02**	6	18.8	5	20.0	-0.92 (-0.25 to 3.46)	1.00
Any antidepressant for ≥25 days in the past month						**.001**[a]						.19[a]
3 months	19	40.4	5	10.9	5.56 (1.86 to 16.65)	**.002**	7	21.2	2	8.0	3.10 (-0.58 to 16.42)	.28
6 months	15	31.3	7	13.7	2.86 (1.05 to 7.80)	**.05**	7	21.2	4	16.0	1.41 (-0.36 to 5.49)	.74
12 months	14	30.4	4	8.3	4.92 (1.48 to 16.34)	**.008**	8	25.0	4	16.0	1.75 (-0.46 to 6.65)	.52
18 months	12	25.0	4	8.3	3.67 (1.09 to 12.35)	**.05**	5	15.6	4	16.0	-0.97 (-0.23 to 4.08)	1.00
Satisfaction with all care received during intervention period[b] (moderately or very satisfied)						**.01**[a]						.24[a]
3 months	41	87.2	30	65.2	3.62 (1.43 to 9.14)	**.02**	30	90.9	20	80.0	2.50 (-0.54 to 11.65)	.27
6 months	44	91.7	40	78.4	3.02 (-0.89 to 10.26)	.09	27	81.8	16	64.0	2.53 (-0.76 to 8.44)	.14
12 months	40	87.0	32	65.3	3.54 (1.25 to 10.02)	**.02**	28	87.5	21	84.0	1.33 (-0.30 to 5.96)	.72
18 months	37	80.4	37	77.1	1.22 (-0.45 to 3.30)	.80	25	78.1	20	80.0	-0.89 (-0.25 to 3.24)	1.00
	Mean	SD	Mean	SD	Between-Group Difference (95% CI)	Statistical p Value	Mean	SD	Mean	SD	Between-Group Difference (95% CI)	Statistical p Value
MSS-Plus Visits in Units (MSS Administrative Data)[c]												
Baseline – 2 months postpartum	12.96	11.88	9.22	12.26	3.74[d] (-8.49 to 1.02)	.06	12.97	15.44	15.96	14.13	-2.99 (-4.92 to 10.90)	.22

[a]Main effect for group: 3-, 6-, 12-, and 18-months follow-ups, controlling for baseline values. Emboldened p-values are significant at least at p<.05.

[b]Satisfaction with all care received for mood problems or stress during intervention period includes MSS-Plus services, community mental health provider, MOMCare depression care specialist, obstetrics provider.

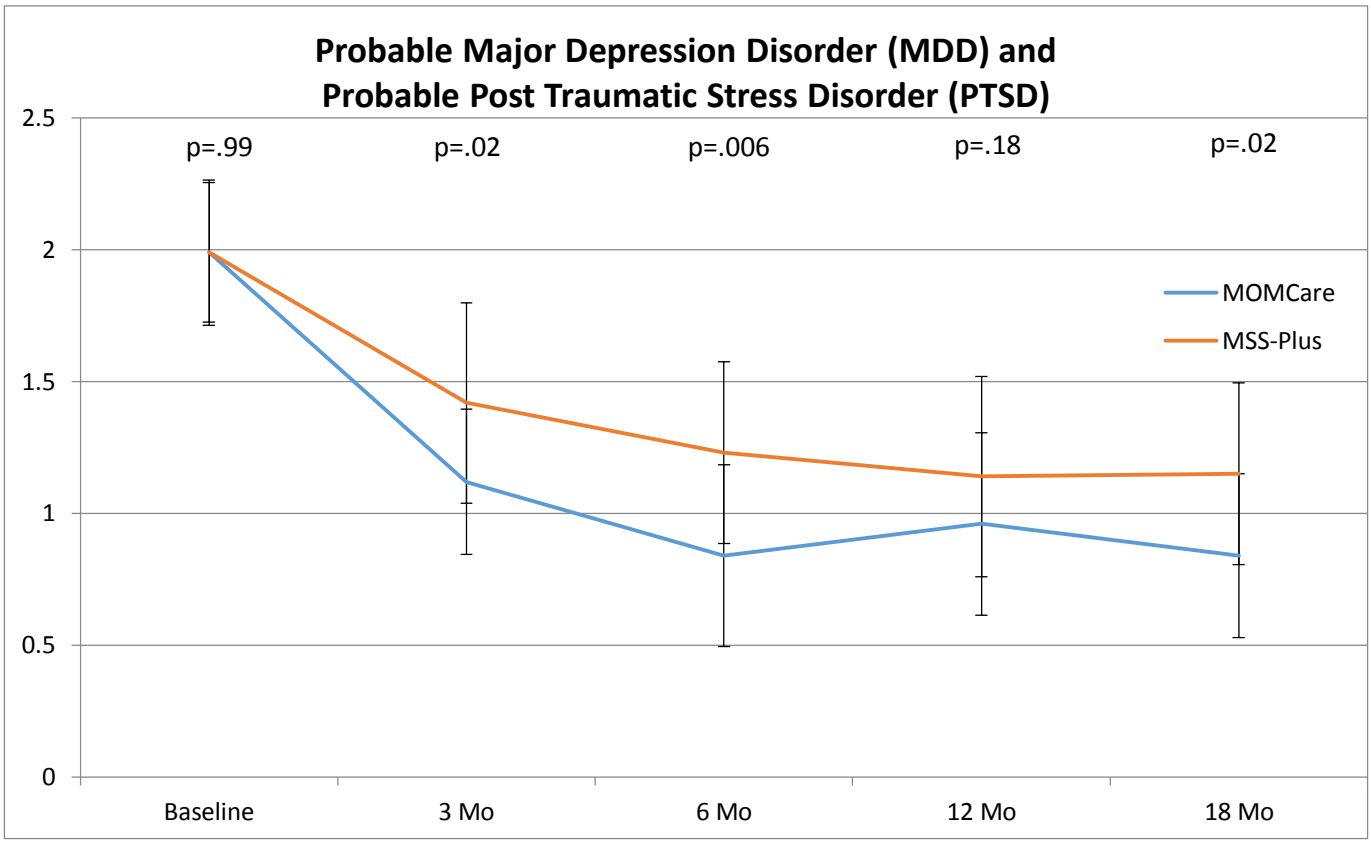
[c]Each unit of public health MSS-Plus = 15 minutes.

[d]Mean difference between groups.

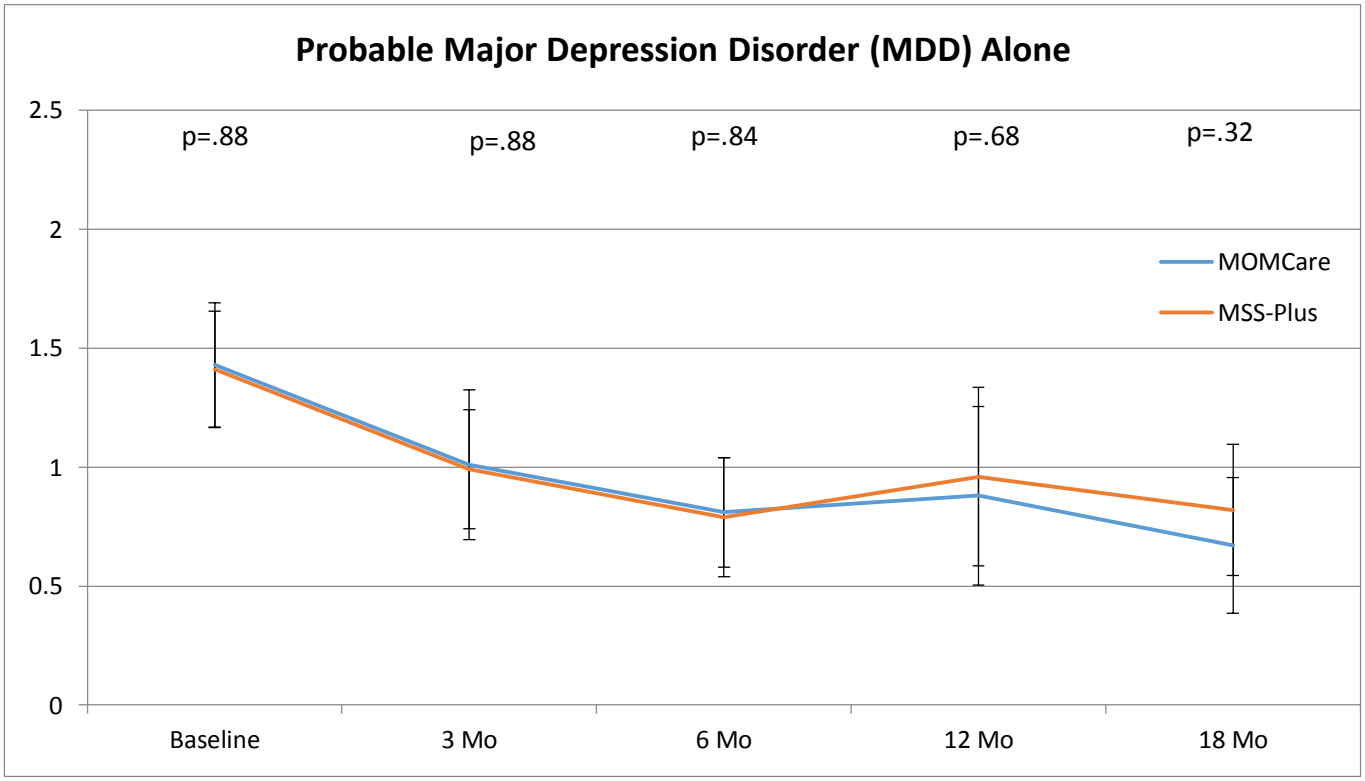
Note. Baseline = 100% pregnant; 3 months = 88% still pregnant; 6 months = mean 3 months postpartum; 12 months = mean 9 months postpartum; 18 months = mean 15 months postpartum.

Abbreviations:
CI: Confidence Interval
MSS: Maternity Support Services
PTSD: Post Traumatic Stress Disorder
SD: Standard Deviation

Figure 1. Depression Outcomes across the 18-Month Follow-Up for Women with Probable Major Depression and Probable Post Traumatic Stress Disorder, and Probable Major Depression Alone.

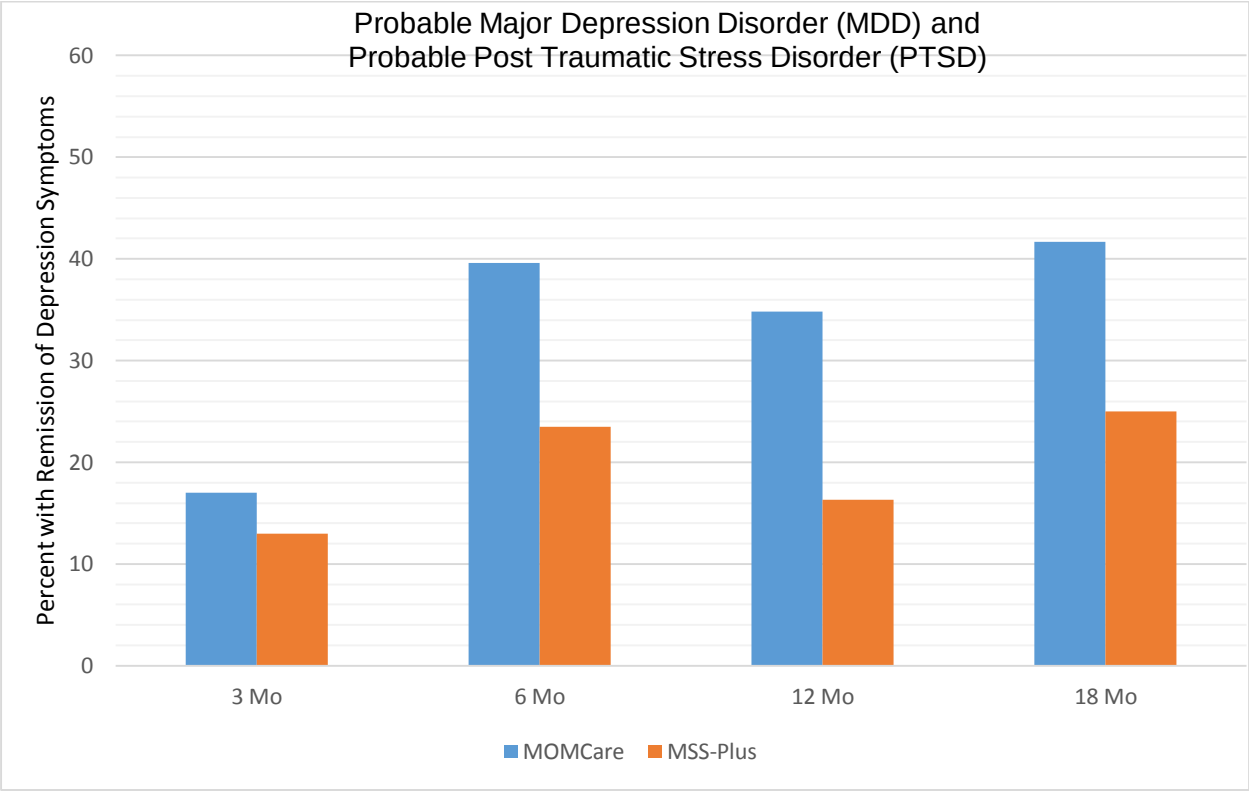


Note. Significant main effect for treatment group (p=.004). Effect size=.39.

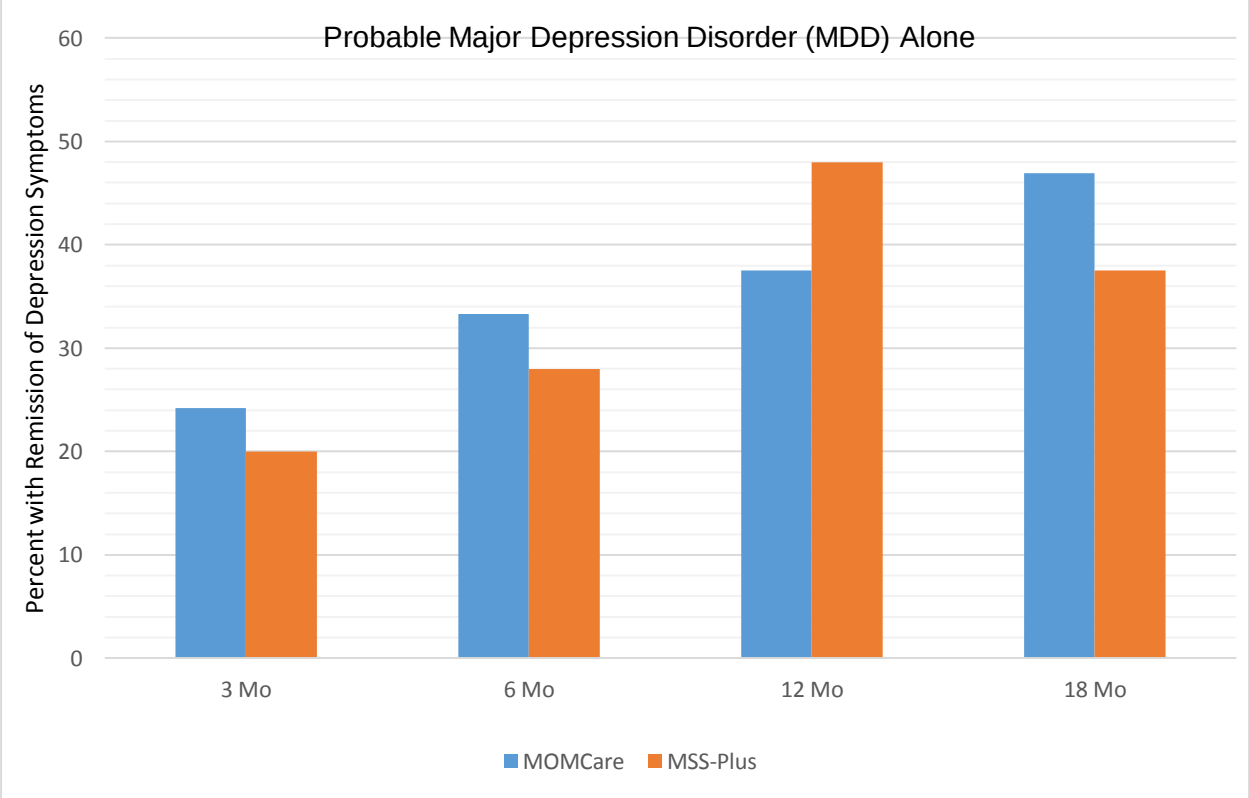


Note. No significant differences by treatment group (p=.90). Effect size=.11.

Figure 2. Remission of Depression Symptoms (SCL-20<.5) between Women Receiving MOMCare Intervention and Those Receiving Maternity Support Services-Plus (MSS-Plus).



Note. Main effect for group: p=.02.



Note. Main effect for group: p=.99.