

**Cover Page  
Study Protocol**

**Official title of the study:** Collaborative Perinatal Mental Health and Parenting Support in Primary Care

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## Research Plan and Methodology

### Study Design

This study was a randomized control trial. The effects of the intervention were tested using a two-arm randomized controlled trial, comparing PFR (Arm 1) to Resource and Referral (Arm 2). Assessments were completed at T1 (before randomization), immediately after the intervention (T2), and a 6-month follow-up.

### Participants

The *Moms and Babies Program/Programa para Mamás y Bebés* (MBP) research procedures were reviewed and approved by the University of Washington Institutional Review Board. Between November 2015 and June 2019, 252 mothers with their infants living in King County, Washington were enrolled in the study. The flow of participant recruitment, assignment, and completion of assessments is shown in Figure 1. Information on demographic and other baseline characteristics, including mental health concerns (PHQ-9 depression and GAD-7 anxiety, Spitzer et al., 1999; PCL-C-SF post-traumatic stress disorder, Lang & Stein, 2005) is shown by condition in Table 1.

**Eligibility and recruitment.** Participants were eligible if they had received mental health treatment during pregnancy at one of the participating health centers, were conversant in English or Spanish, had an infant under three months of age, had access to a telephone, were planning to remain in the study area until the child's first birthday, and had not already received PFR. All aspects of the study, including the intervention and research visits, were offered in English and Spanish.

Study recruitment was conducted in collaboration with the Mental Health Integration Program (MHIP) and Maternity Support Services (MSS) of Public Health Seattle and King County, Washington. MHIP is based on a public health approach that uses a collaborative care model to treat behavioral health problems like depression, anxiety, and trauma symptoms through primary care clinics in low-resourced settings. Public Health in Seattle/King County (PHSKC) targets pregnant and parenting women for collaborative care through the MHIP Moms program. Five community health clinics offering MHIP agreed to assist in study recruitment. In addition to MHIP Moms, PHSKC offers MSS, provided by public health social workers, nurses, and nutritionists who deliver case management plus referral to community mental health services from pregnancy through two months postpartum. Mothers were recruited for the study through both mechanisms.

Eligible mothers were identified via the Mental Health Integrated Tracking System (MHITS), the data base for MHIP managed by PHSKC in King County, or the PHSKC MSS database. Each MHIP participating community health center 'owns' the list of its patients and agreed for the county public health department to generate a monthly list of eligible pregnant women receiving mental health services at each clinic. The monthly list contained the names of their own eligible patients who were pregnant or had an infant less than three months of age. MHIP care managers and MSS social workers talked with women on the list by phone or at a clinic visit, briefly outlining the study. If the mother spoke, English or Spanish and interested in learning more about the study, the care manager or social worker connected her to the study recruitment coordinator either immediately or through a follow-up phone call. The recruitment coordinator conducted additional screening and answered any questions the mother had. If the mother was eligible and interested, the study research visitor scheduled and conducted the first research visit when the baby was between 6 and 12 weeks old. Written informed consent was obtained at the first research visit.

The project director initiated the randomization after the first research visit was completed. Randomization into the PFR intervention or control condition was computer generated, blocked on language group. Sample attrition was very low. Follow-up research visits were conducted when infants were 6 and 12 months old. At both follow-up timepoints, over 94% of families in both conditions completed the assessments. Overall, 95.2% completed all three research visits, 2.0% completed only the first visit, 1.6% completed the first and second visits, and 1.2% completed the first and third visits. Comparing the 240 cases with complete data with the 12 cases that missed one or both follow-up timepoints, attrition did not differ significantly by condition, nor did tests of condition-by-baseline characteristics reveal any evidence of differential attrition by condition with respect to language, race/ethnicity, age of mother, baseline mental health measures, or any of the primary outcome measures. At baseline, mothers with incomplete data were more likely to be separated, divorced or widowed, had lower incomes, and had more children.

### ***Promoting First Relationship® (PFR) Intervention***

The manualized PFR intervention was delivered by seven female master's-prepared mental health professionals. Six were employees of a community agency, and one was employed by the University of Washington. Four primary providers, who were all employed by a community agency, worked with 93% of the study families, and three fill-in providers administered the intervention to the remaining 7%. Three of the providers were fluent in Spanish, and all were fluent in English. The providers completed PFR training and were certified before meeting with study families. Throughout the study, fidelity was monitored by a PFR master trainer. The providers were required to submit videotapes of themselves working with the families during the sixth session for each family on their caseload, which the master trainer reviewed to rate the quality of delivery. If a provider did not meet fidelity (i.e., received a rating of less than 4 on a 5-point scale), she received additional one-on-one mentoring from the master trainer until her fidelity to PFR was reestablished. Of 98 fidelity videotapes that were coded, 6% did not meet fidelity. Providers were not assigned additional families to work with until they reestablished fidelity. The PFR training model includes weekly reflective practice group sessions, facilitated by a PFR consultant, to support providers in their work with vulnerable families.

The majority of the 127 mothers randomized to PFR received a full dose of the intervention: 82% received 9-10 weekly sessions, 9% had 5-8 sessions, 8% had 1-4 sessions, and 2% did not start the intervention. The sessions typically ranged from 60 to 75 minutes and took place in the families' homes. The providers delivered activities and instructional content as prescribed in the PFR manual; however, the pace of delivery of these components was tailored to individual mothers, and some sessions were adapted for very young infants. A key component of PFR is videotaped caregiver-child interaction, completed during five sessions and serving as the focus of reflective video feedback during alternating weeks. The tapes were viewed together by the mother and intervention provider, who guided discussion focusing on parenting strengths and interpretation of her baby's cues.

### **Control Condition**

The 125 mothers randomized to the control condition were mailed a resource packet containing a listing of a variety of local resources, child development handouts, and parenting handouts. Packets were provided in the mother's desired language. The materials did not overlap with the content of PFR. To help minimize attrition, mothers in the control condition also

received two check-in phone calls before the second research visit to see if their contact information had changed and to answer any questions about the study.

### **Measures and Procedures**

Infants and their mothers were assessed in three 90-minute in-home research visits: at baseline (infant age 6-12 weeks), and when the babies were 6 months and 12 months old. The intervention was completed between the baseline and 6-month research visits. Assessments were conducted by three bilingual study research visitors who had bachelor's or master's degrees, who were blinded to intervention assignment, and whose offices were not near the intervention staff. One primary research visitor completed 96% of the research visits. The time from baseline to the 6-month research visit averaged 4.4 months, and the time from the 6-month to 12-month research visit averaged 6.0 months. Time between visits did not differ by intervention group. The research visits included standardized interview questions and videotaped mother-infant interactions. The consent form and all study measures were read to the participants to ensure understanding and minimize missing data. All measures have been used with mothers from different cultural backgrounds, including Latina mothers, in other studies. Research visits were conducted by telephone if the family moved outside of the study area after the first research visit (15 research visits), and also for the final five families completing the 12-month research visit due to stay-at-home requirements caused by the COVID-19 pandemic. Research visits were conducted in-person and in-home for 98% of the assessments. Study participants received \$50 in cash or gift card after each research visit to compensate for their time.

### ***Primary Caregiver Outcomes***

*Parenting sensitivity* was an observational measure collected at each research visit using the Nursing Child Assessment Teaching Scale (NCATS; Barnard, 1994). Mothers were presented with a list of activities and instructed to select the first activity that their infant could not yet do (e.g., hold onto a rattle, transfer an object from one hand to another, play pat-a-cake), to attempt to teach their infant. A standard set of manipulatives were provided for the activities. Teaching interactions were videotaped. Videotapes were scored by a blinded coder on 50 caregiver items measuring sensitivity to cues, response to distress, and fostering of social, emotional, cognitive growth, and continency between caregiver and child. Items were scored yes (1) or no (0) and summed for a total sensitivity score. A single bilingual and bicultural coder, blind to intervention condition, was trained to reliability by a certified NCATS instructor and passed biannual reliability checks with a minimum of 85% inter-rater agreement with a master trainer.

The Infant CARE-Index (ICI, Crittenden, 1979-2010) assesses parent-infant interaction during play and was included at each research visit. The mother was asked to play with her child as she usually would, and the interaction was filmed for 3-5 minutes. If mothers wanted to use toys, they were offered toys that they could use, or they could choose their own toys. The videos were scored by 16 coders certified to code the ICI for research purposes. To be certified, coders rated videos from a collection of videos gathered in multiple countries and that represented the full range of potential scores on the ICI constructs. Coders had to meet a standard for inter-rater reliability of  $r = .80$  on the measure of dyadic synchrony and an average of  $r = .70$  across all scales. Prior to coding the full sample in this study, coders coded 20 MBP study tapes, coder agreement was somewhat lower in this selection of videos ( $r = .74$ , range = .66 to .87). The coders' work was overseen by the author of the coding scheme (Crittenden). To address the study's primary hypotheses regarding caregiver outcomes, the rating for *dyadic synchrony* in play was used in the current study. Dyadic synchrony is any mutual pattern of behavior that

enables the infant to explore the activity with interest and spontaneity and without inhibiting or exaggerating negative affect. Dyadic synchrony scores of 11-14 are sensitive, with mutual delight or a smooth, pleasing interaction. Scores between 7 and 10 are adequate, with satisfactory play but noticeable periods of desynchrony. Scores between 5 and 6 reflect clear, unresolved problems and limited playfulness, but no evidence of hostility or unresponsiveness. Scores between 0 and 4 reflect high risk, with a clear lack of empathy, insufficient or unsuccessful attempt to respond to the infant, or total failure to perceive or attempt to soothe the infant, and no play. As a further check of reliability, approximately 20% of the videos were randomly selected to be coded by a reliability coder. Inter-rater correlations for dyadic synchrony between the two coders averaged  $r = .67$ .

*Understanding of infant and toddler behavior* was measured by the Raising a Baby Scale (RAB; Kelly, Korfmacher, & Buehlman, 2008). The RAB is a measure of caregiver knowledge of infant and toddler social-emotional needs and developmentally appropriate expectations. At each research visit, mothers rated the 16 RAB items on a 4-point scale (*strongly agree* to *strongly disagree*;  $\alpha$  ranged from .68 to .71 across the three time points). The scale was summed, and higher scores indicate greater parental knowledge.

*Maternal confidence*, the perceptions mothers have of their ability to care for and understand their infants, was measured at each research visit using the *Maternal Confidence Questionnaire (MCQ)*; Zahr, 1991). Mothers rated 14 items on a 5-point scale (*never* to *always*;  $\alpha$  ranged from .66 to .76 across the three time points). Maternal confidence is reflected by the mean of the scale, with higher scores indicating greater confidence.

### ***Secondary Infant Outcomes***

The Infant CARE-Index (described above) also yields scores for the infant's contribution to the interaction. We included *infant difficulty*. Scores could range from 0 to 14. Higher scores reflect more infant difficult behaviors, such as crying and fussing, turning away, negative facial expressions, avoidance of eye contact, high arousal, and lack of engagement in a developmentally satisfying shared activity. Inter-rater correlations for difficulty on the 20% of videos selected for coding by an additional coder averaged  $r = .49$ .

At the final research visit, when infants were 12 months old, infant *externalizing* behavior, *internalizing* behavior, and *dysregulation* were measured with mother's report on the *Infant Toddler Social Emotional Assessment (ITSEA)*; Carter & Briggs-Gowan, 2006). The ITSEA was not included at the baseline or 6-month research visits because it is not valid for children younger than 12 months. The ITSEA has been standardized and normed on a nationally representative sample that was stratified to match the 2002 United States Census. Mothers rated their infant on an extensive list of behaviors from 0 (*not true/rarely*) to 2 (*very true/often*). T-scores were calculated for externalizing, internalizing, and dysregulation domains. In the study sample, alpha reliabilities for the domains were  $\alpha = .81$  for externalizing,  $\alpha = .68$  for internalizing, and  $\alpha = .80$  for dysregulation.