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Statistical Analysis Plan

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

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Analysis Plan

All analyses were conducted as intention-to-treat, analyzing all 252 cases as randomly assigned to the PFR and control group (CG). Multiple linear regression was used to examine the treatment effect of PFR (0 = CG, 1 = PFR) on study outcomes including the primary caregiver outcomes (parenting sensitivity, dyadic synchrony, understanding of infant and toddler behavior, and maternal confidence) and the secondary infant outcomes (infant difficultness, internalizing behavior, externalizing behavior, and dysregulation). Covariates included preferred language (0 = English, 1 = Spanish) and the baseline measure (unavailable for the ITSEA scales). Covariates were decided upon prior to analyzing outcome data to align with stratification in the randomization design (Moher et al., 2021) and obtain precise and unbiased estimates of the intervention effect (Van Breukelen, 2006). Adjusting for the baseline measure, which was expected to be the strongest correlate of outcomes, increases the precisions of intervention effect estimates. Standardized effect sizes (*d*) were calculated based on the unstandardized effect coefficient for PFR divided by the pooled standard deviation of the measure at baseline (if available) or at the follow-up time point (when the baseline measure was not available). The sign of the standardized effect was coded so that a positive *d* would reflect a desired positive effect of PFR on the given outcome (e.g., a positive *d* would reflect higher parent sensitivity or reduced externalizing behavior associated with PFR). We interpret *d*s as small (0.20), medium (0.50), and large (0.80; Cohen, 1988).

Regression analyses were conducted in Mplus Version 7.31 (Muthén & Muthén, 1998-2015). Covariate missingness was modeled to allow for inclusion of all 252 cases in all regression models, including cases with partially missing data (Muthén, et al., 2016; Muthén & Muthén, 1998-2015). Maximum likelihood parameter estimates with conventional standard

errors were obtained using the default maximum likelihood estimator (Muthén & Muthén, 1998-2015), which provides unbiased estimates assuming data are missing at random after adjusting for model covariates (Graham, 2012). There was a small amount of missing data at baseline (< 2% on any given measure). Missing data were also minimal among dyads completing the follow-up assessments (< 8% on any given measure at any given time point). Descriptive statistics were examined in IBM SPSS Version 19 (IBM Corp., 2010).

Analysis Population Description

The analysis population was all 252 cases with baseline data, analyzed by Mplus. The *n*'s for sample size in the outcome table reflect small amounts of missing outcome data at the two follow up timepoints, due to scoring problems or a module being skipped for some reason.

References

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