Statistical Analysis Plan

Title: Reducing Maternal Depression and Promoting Infant Social-Emotional Health & Development

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Analytic Strategy

Constructs. We will use a systematic approach to construct development to create two parent outcomes (mother positive/negative) and one infant outcome (infant social emotional functioning). *For our outcomes of maternal depression, parenting knowledge and stress, we will examine single indicants. To view potential intervention moderating effects, we will attempt to create a maternal contextual risk indicant (e.g., isolation/support, relationship status, conflict, economic hardship); for maternal depression prior to intervention as a potential moderator, we will view depression onset, chronicity, and severity as well as presence of other treatment including medication to examine each of these and their effect on intervention outcomes.* For factor analysis, given appropriate internal consistency and inter-rate reliability, we will examine questionnaire scales and observational codes using factor analytic techniques [99], retaining a 5:1 subject to parameter ratio. Scale factor loadings above .30 and communality estimates above .15 will be confirmed within SEM methodology to produce fit indices to view how each indicant set fits into their specified domain. If satisfactory, unit-weighting of the standardized score for each indicant will be summed. If not, we will select an index variable within each domain to represent the outcome.

Random Sampling/Attrition Analysis. Though mother-infant pairs will be randomly assigned to the intervention, condition differences may exist due to random sampling failures or differential attrition. To address this issue, 2 x 2 (Group x Attrition Status) MANOVAS will be performed using the baseline assessment for mother, infant and contextual risk variables. The presence of a statistically significant Group main effect would provide evidence that random assignment was not effective in equating groups. A second possible source of nonequivalence is differential attrition by condition. A Group x Attrition Status significant interaction provides evidence of differential attrition between groups. In general, analyses will proceed using an “intent to treat” approach and all participants recruited will be included in subsequent analyses.

Examination of Acute Intervention Effects (Aim 2)

(**Aims 2.1 - 2.3**) Our post-assessment n, to examine acute intervention effects, is expected to be 150 (75/condition). We will initially view intervention effects on our mother/infant outcomes using a 2 (pre-post) x 2 (MBN intervention group) repeated measure analysis of variance. We will examine the inter-correlations among outcomes and, if significant, will us a MANOVA approach to examining MBN intervention effects. The F test is robust to non-normality if such non-normality is caused by skewness rather than outliers. We will take appropriate measures to reduce outlier influences. (**Aim 2.4)** To examine the relations between mother change (parenting and maternal depression) and infant change, one approach will be to create individual beta estimates for mothers and infant utilizing the polynomial contrast function within MANOVA to produce individual trajectory scores reflecting parent and infant change from pre to post that can then be used in external between-condition covariate analysis. The trajectory scores will be subjected to an analysis of covariance with infant change trajectories as the dependent variable and parent change as the covariate. We will determine whether the parent change covariate is significantly related to the dependent variable (demonstrating that changes in parenting behavior and child functioning covary). We will determine the statistical significance and effect sizes of intervention effects (ignoring the covariate). We will then determine if entering the parent functioning covariate modifies the intervention effect size and statistical significance. If parent change is strongly linked to infant change, then entering the covariate should result in nonsignificant intervention effects. Estimates of covariance-adjusted effect sizes will provide estimates of the proportion of intervention effect size that can be explained by the parenting change variable. We will test for between-group heterogeneity of covariance to determine whether the strength of association between change in parenting and infant functioning differs by intervention group.

Examination of Moderating Influences (Aim 3) Dosage & Skills Acquisition. To evaluate moderating influences on parent and infant behavior our first focus is on how maternal depression prior to intervention *(i.e., chronicity, severity, receipt of psychiatric treatment/medication) affects MBN intervention dosage* (**3.1**); secondly, we are interested in the moderating effect of dosage on mother and infant change (**3.2)**. For **3.1**, we will examine a 2 (hi/lo dosage) x 2 (intervention) ANOVA, using maternal depression indicants *(e.g., chronicity) as the dependent measure.* A significant main effect for dosage would indicate that higher levels of maternal depression are found at different dosage levels; it is anticipated that higher depression will be evidenced in the low dosage group. A significant interaction would indicate a higher level of maternal depression is found within a dosage by condition cell. Though we would not anticipate a significant interaction, we will examine if higher levels of depression are associated with low dosage only within the Mom and Baby Net (MBN) intervention group; this could indicate that the skills focus of MBN learning may have been too intense for highly depressed mothers. For **3.2**, examining dosage as a moderating influence on mother and infant change, we will utilize the individual beta-slope estimates reflecting parent and infant change from Aim 2 as the dependent measures in separate 2 (intervention) x 2 (hi/lo dosage) ANOVA designs. We hypothesize a significant interaction term indicating the highest positive change trajectories will be for the intervention mothers with high dosage, when compared to low dosage intervention mothers and Depression and Developmental Awareness (DDAS) mothers regardless of dosage level. If a significant dose-effect relationship exists within the MBN condition, we will determine if an effective dosage level can be identified that is less than the maximum number of intervention sessions offered. **3.3** analysis will examine Pearson correlations between contextual risk and level of maternal depression and a bi-serial correlation for the relation between contextual risk and dosage (hi/lo) to determine if contextual risks are related to both initial levels of depression and subsequent engagement in intervention. To further examine the contextual risk on mother and infant change, we will form a hi/lo risk categorical variable, based on median split, and utilize the same 2 (intervention) x 2 (hi/lo risk). If a main Intervention effect is significant, we would expect MBN mothers and infants, regardless of risk level, to evidence the greatest improvements when compared to DDAS mothers. If significant interaction effects occur, we would expect mothers and infants within the MBN condition with lower levels of risk to evidence the greatest improvement in functioning and, though not statistically significant, that MBN mothers and infants, even in the presence of high risk, would evidence higher positive change trajectories than those of DDAS mothers and infants.

Maintenance of Effects (Aim 4)

Maintenance affects will be viewed by single indicants for maternal and infant functioning. We estimate that our maintenance sample will be at a minimum n=150 (overall 17% attrition). For this aim, we will examine mother-infant change trajectories utilizing SEM methodology, performing Latent Growth Curve Model (LGCM) analyses, and include an Intervention indicant predicting intercept and slope estimates. This analysis will supplement our Aim 2 analyses and, if the index variables within this analysis generally reflect the acute intervention trajectories (e.g., significant intervention acute effects demonstrate with constructs reflect the same differential pre-post index variable trajectory), will allow us to more strongly view the trajectory of change across time. Given the restricted nature of follow-up assessments, balancing participant burden and desire to maximize assessment completion across time, we will view these maintenance trajectories with caution.

Power Analysis

We expect a pre-post attrition rate of 17% (n=150). For traditional PALS, across a series of randomized control studies, attrition rates ranged from 9% to 24% [26,97]; within our recent Baby-Net R01 study, we evidenced 7% attrition from pre-to- post assessment and 15% at 6-month follow-up working with low-income mothers in KS and OR, some of whom were experiencing elevated levels of depressive symptoms. In this study, a moderate to large effect size (d=.5 – 1.03) is anticipated for maternal outcomes and a small to moderate effect size for the infant outcome (d=.2-.4 for infants), based on PALS program evidence [18,27], our Baby-Net preliminary results, and evidence of CWDC [100] and Internet-based CBT treatment success [101]. We calculated the smallest effect size to be detected within a 2 x 2 analysis based on .05 alpha, a sample of n=75 per condition and viewed effects relative to a high (r=.68) and low (r=.21) repeated measures correlation. We found that with power at .95, we could detect an effect as low as d=.37 (with low repeated correlation) and d=.23 (with high correlation); with power of .80 we could detect an effect size as low as d=.29 (with low repeated correlation) and d=.18 (with high correlation). Viewing LGCM maintenance trajectories, the number of cases per estimated parameter needs to be sufficient, with a rough guideline of 5:1 [102,103]. Using this guideline, we will have sufficient sample size to estimate 34 parameters within our initial follow-up sample, with 3 time-points and a condition predictor. For our maintenance examination, as noted, we will not statistically view condition differences in trajectories, but rather will hold these examinations to a preliminary view of intervention.