Study Title: Connect to Baby: A Pilot Study of a Parenting and Coparenting Program for New Parents

FAIN: R21HD108499

Date: June 26, 2023

STATISTICAL ANALYSIS AND POWER

Aim 1. Examines the effect on targets of parenting and co-parenting.

Aim 2. Examines the effect on outcomes, parent well-being and child language and socio-emotional development.

Intent-to-treat (ITT) estimates look at the effect on everyone assigned to receive treatment, regardless of whether or not they actually took advantage of the program. The alternative is to estimate the treatment effect on the treated (TOT).

Analytic Strategy for Testing Specific Aims 1 and 2. The Intent-to-treat (ITT) analyses will examine the effect of random assignment on all targets and outcomes regardless of whether participants complete the intervention to test the efficacy of the EHS-CTB hybrid model at enhancing CTB targets and direct outcomes. Models will use a two-level hierarchical linear structure to account for the fact that mothers and fathers are nested within dyads. Level one will encompass parent-specific variables, including parent gender and age, while level two will specify family-level variables, including random assignment group. Note, if unconditional models with a third level for EHS center suggest an ICC of greater than .10 for center-level variance, models will assume a three-level structure, with center at level three. In either case, the effect of EHS-CTB assignment on each target measure, and each outcome measure, at both the post-treatment and 6-month follow ups will be predicted. Distinguishing analysis of the post-treatment and 6-month assessments will separately identify short-term effects of CTB from whether those effects persist after program completion. Models will take the following general form:

$$Y(PostTar/Out)_{ij} = \gamma_{00} + \gamma_{01}CTBH_j + \gamma_{10}Parent_{ij} + \gamma_{20}PreTar/Out_{ij} + \gamma_{11}(CTBH_j)(Parent_{ij}) + \gamma_{30}Cov_{ij} + \mu_{0j} + r_{ij}$$

where Y_{ij} is target or outcome measure at either 3 months or 6 months post random assignment predicted from assignment to CTB-hybrid (CTBH), parent identity (mother versus father), the analogous pre-random assignment score ($PreTar/Out_{ij}$), and interactions between treatment group and parent identity, along with demographics such as age and race/ethnicity, with the intercept for dyads varying randomly. The sign and significance of coefficient γ_{01} will indicate the effect of CTBH, on each outcome compared to EHS only. The interaction between treatment group and parent identity, γ_{11}, will indicate whether treatment effects differ across coparents. Controlling for pre-intervention scores on targets and outcomes, where possible, will ensure that any random pretreatment differences across groups are held constant and restrict estimated treatment effects to the change in target and outcome scores affected by treatment. We note, controlling for pretreatment scores on child outcomes will not be possible given infants' initial age.

We will also run models to estimate the treatment effect on the treated (TOT) in which we estimate the effect of participation in CTB, rather than random assignment alone, on those who engaged in CTB. The TOT is a weighted average of the treatment receipt on compliers, estimated using instrumental variable (IV) methods. The IV estimator performs well only if sample members' randomly assigned status has a strong association with compliance, which we anticipate.

Power Calculations. Assuming 2 conditions, the 2-level multi-level analytic data structure with parents nested within couples[102], and an alpha of .05, we predict 80% power to detect an effect size (in terms of Cohen's D) of .40 with n=80 in each group. This effect size aligns with those of parent-report outcomes in the pilot study (see above), as well as effect sizes for coparenting and parenting behavior, and child outcomes, in multiple FF trials, and accounts for the theorized amplifying effects of our dual targets, parenting and coparenting.[54,61,70] As we will enroll n=100 in each group, and anticipate a ~20% attrition rate based on prior FF trials, there are sufficient subjects available to adequately power the primary aims of the study.