Coaching Alternative Parenting Strategies (CAPS) Study: Targeting Neurobiological and Behavioral Mechanisms of Self-regulation in High-risk Families

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Statistical Analyses Plan

First, intent-to-treat (ITT) analysis will provide a stringent assessment of PCIT efficacy. Repeated-measures ANCOVAs will take into account variability between and within subjects and enable the detection of group differences by reducing the effects of high individual variability in the sample. We will specify latent models (LGM) comparing linear and possible nonlinear trajectories for mediating and focal outcomes in the PCIT group. Although several related approaches to ITT analysis for LGM are available, including multigroup analyses and parallel slope processes, we will primarily specify treatment assignment as a binary covariate to evaluate tests of mediated pathways hypothesized. Thus, for example, we will use an LGM approach with rate of change in parent self-regulation and parenting behavior regressed on the ITT contrast, allowing for tests of indirect mediating pathways from treatment to intermediate parent variables (i.e., parent self-regulation) to focal outcomes (i.e., parenting). Following recommendations for indirect effects, we will estimate bootstrapped standard errors for the asymptotic multiplicative indirect terms as well as bias-corrected confidence intervals. We also plan to identify the biobehavioral markers of self-regulation that best forecast risk for early treatment drop-out.

We will also employ Complier Average Causal Effect (CACE) analyses to estimate the effects of intervention for those who comply with treatment at varying degrees, as well as would-be compliers in the control group. CACE models, implemented as latent growth mixture models, will use estimated categorical profiles with compliance status included as a training variable to estimate class membership. Utilizing known compliance status in the treatment group and missing values for compliance in the control group will provide an unbiased estimate of how PCIT works by estimating what would happen to the control group, had they been offered the treatment.

Given the high comorbidity of physical abuse and neglect, pure subtypes are not as frequent in the CM population. Nonetheless, CM subtype moderation of intervention effects will be examined because important neurobiological and behavioral differences have been observed. Focusing on simultaneously assessed parent RSA, PEP, ERPs, and behavior taken at pre-, mid-, and post-treatment, we will explore targeted CM group differences in mediational pathways to test whether mediation between treatment and outcome is dependent on CM group characteristics. Greater intervention gains are hypothesized for physically abusive parents.

Within-treatment trajectories of session-to-session change in parenting behavior over time will be estimated and those changes mapped onto growth in parent self-regulation. The LGMs will first identify the nature and pattern of change trajectories for both positive and negative parental responses by allowing for linear and polynomial models. Parents' behavioral response percentages will be set as dependent variables for each PCIT session, with session number and response type nested within participants. Once change trajectories are isolated, piecewise growth models that use a segmented coding scheme may be used to test empirically grounded hypotheses for critical intervention change points.

A priori sensitivity analyses will be conducted to probe the effects of intervention non-compliance and protocol modifications. Thus, in addition to planned ITT analyses and CACE complier modeling, *a priori* sensitivity analyses will be conducted and results reported, highlighting significance levels and direction of effects. We used prior results and R 3.5.0, powerMediation and pwr (v1.2-2) packages to estimate power for tests of PCIT main effects *via* ITT analyses and tests of change in parent self-regulation scores as a mediator of PCIT effects on focal parent and child outcomes. For ITT analyses, estimated power was found to be greater than.80 to detect small-to-moderate main intervention effects (Cohen's d = .4). For the mediational models, using the product of standardized beta coefficients comprising the indirect effects (i.e., treatment condition to parenting and parenting to outcome) based on Cohen's standards, b = .01 (small), b = .09

(medium), and *b* = .25 (large;.5 ×.5), thus, power is greater than.80 to detect small-to-moderate mediational effects (*b* = .04).