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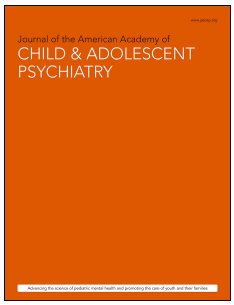

The Differential Contribution of the Components of Parent Child Interaction Therapy Emotion Development for Treatment of Preschool Depression

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The Differential Contribution of the Components of Parent Child Interaction Therapy Emotion Development for Treatment of Preschool Depression

RH = PCIT-ED for Preschool Depression

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Editorial
Supplemental Material

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Abstract

Objective: An adaptation of Parent Child Interaction Therapy (PCIT) with a novel Emotion Development(ED) module has shown efficacy for the treatment of early childhood depression. Children who received PCIT-ED also showed healthy alterations in neural response to reward. We investigated whether the novel ED module made a unique contribution to the treatment of depression and neural response to reward and whether child directed intervention (CDI) and parent directed intervention (PDI) modules (standard elements of PCIT) were also effective.

Method: Dyads who participated in a randomized controlled trial of PCIT that compared the active PCIT-ED to a wait list (WL) condition were assessed at the completion of each module of PCIT-ED (CDI, PDI, ED) or WL time equivalent for child depression and other symptoms, parenting styles, stress, and depression. Event related potentials (ERPs) during a reward task were obtained at the end of standard PCIT and after the novel ED module.

Results: Study findings showed that the ED module as well as some elements of standard PCIT were effective in reducing child depression and other forms of psychopathology. Changes in the child's neural response to reward and parental response to child emotional expression were specific to the ED module.

Conclusion: Study findings suggest that the novel ED module has added efficacy for the treatment of early childhood depression, as well as unique efficacy in changing neural responses to reward and parenting response to child emotional expression. These findings can inform clinical uses of this treatment in a modular fashion. Future studies are needed that control for session number and order of PCIT-ED modules.

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Clinical trial registration information: A Randomized Controlled Trial of PCIT-ED for Preschool Depression; https://clinicaltrials.gov/; NCT02076425.

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Introduction:

Parent Child Interaction Therapy (PCIT) is a well-tested, manualized early intervention with proven efficacy and large effect sizes for the treatment of externalizing behaviors in young children aged 3-7 [1,2]. Based on this large empirical database, PCIT is widely used worldwide (www.pcit.org). While the efficacy of PCIT has been well established for the treatment of disruptive behavior, it has not yet been adequately tested for the treatment of other forms of early childhood psychopathology, in particular internalizing disorders.[3] Based on this gap in the literature and the developmental appropriateness, safety, and powerful effects shown for PCIT, an adaptation of PCIT for the treatment of preschool depression that added a novel Emotion Development (ED) module was developed.[4] We have tested PCIT-ED for the treatment of depression in children aged 3-6 and found large effects when compared to a wait list (WL) control condition.[5] The current study sought to investigate the effects of each module of PCIT-ED: the Child Directed Intervention (CDI), the Parent Directed Intervention (PDI) and the Emotion Development (ED) on improvements in young child depression. We also investigated whether there were any unique effects of these modules on other forms of child psychopathology and adaptive function, parenting practices and parental depression.

PCIT was designed based on social learning and attachment theories and has two components: 1) the "child-directed interaction" (CDI) to teach parents to positively interact with their children in play in an affirming way without criticism or negativity; 2) the "parent-directed interaction" (PDI), which teaches parents how to use firm yet nurturing limit-setting techniques consistent with "authoritative" parenting to address misbehavior. PCIT also utilizes innovative techniques that capitialize on re-directing parenting during live in vivo interactions observed by

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the therapist through a one-way mirror while coaching the parent who wears a small microphone "bug" in their ear. In contrast to standard forms of therapy in which problematic behaviors are recalled and discussed, PCIT uses this live in vivo teaching and coaching method to modify parental behavior in the moment and to allow the therapist to observe and intervene in active parent-child conflicts. The use of such "hot" emotional interactions is a unique feature that likely contributes to PCIT's powerful effects.

Despite a significant body of empirical research demonstrating that clinical depression can arise as early as age 3, is characterized by a chronic and recurring course, and is associated with alterations in brain structure and function, [6-15] there is a dearth of knowledge regarding treatments for early childhood depression. To begin to address this gap, a large scale randomized controlled trial of PCIT-ED, the source of data for this report, was conducted.[5] As depression is characterized by internally experienced emotions and cognitions not directly addressed by standard PCIT, the novel ED module was developed and investigated. The ED module was designed to target core MDD symptoms such as anhedonia (inability to enjoy activities and play or reduced response to positive stimuli and reward) and excessive guilt, as well as excessive sadness and inability to regulate negative affect. The aim of the ED module was to train the parent to serve as an emotion teacher and coach to the child to facilitate their emotional development. It focuses on teaching the parent to validate and help label the child's emotions as well as help the child more adaptively experience and regulate emotions instead of using distraction or punishment in response to expressions of intense negative emotions.

In addition to being effective for decreasing childhood depressive symptoms, PCIT-ED also

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had a positive effect on parental depression and parenting stress, even though they were not direct targets of treatment. Further, an important novel finding was significant improvements in children's neural response to reward, a neural correlate of depression measured using event-related potentials (ERP).[16] The finding of neural changes in response to a psychotherapy in such young children lends further weight to the efficacy findings based on the use of this objective neurobiological measure of reward response and the notion that a psychotherapy can serve to alter brain function. As a first step in addressing the question of whether this adaptation of PCIT for depression was necessary, the current analysis aimed to test whether the novel ED module or the standard CDI and PDI were critical or unique for ameliorating early childhood depression and neural response to reward.[1]

The studies described above provide promising evidence that PCIT-ED may be an effective new approach for treating preschool-onset depression. However, it is unknown whether the ED modification is truly a necessary component of treatment above the effects of standard PCIT. Thus, in this study we sought to examine whether the novel ED module provided added or unique symptom improvement in depression (and in other domains), distinct from change arising during CDI and PDI modules. We tested specific child and parent outcomes after completion of each module (CDI, PDI, and ED) to investigate if change in child and parent symptoms, parenting styles, and parental skills at addressing the child's emotional expression occur as a result of each of these different modules in PCIT. Further, neural measures of reward response using ERP were also obtained at completion of standard PCIT as well as at the end of PCIT-ED. Therefore, we also investigated the differential effects of standard PCIT versus the additional ED module on neural change. These analyses allowed us to address two key aims, first whether the

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components of standard PCIT (CDI and PDI) was effective for treating preschool depression compared to a WL condition, a question that has not yet been answered in the field, and second, whether there was any unique or additional value to PCIT-ED with the novel ED module.

Method:

PCIT-ED study methods are detailed in Luby et al., 2018,[5] with ERP methods further detailed in Barch et al, 2019.[16] To review, subjects were recruited from preschools, primary care sites, and mental health clinics in the St. Louis metropolitan area using a screening checklist. Those meeting all inclusion and exclusion criteria (MDD without co-morbid Autism Spectrum Disorder or neurological disorders) were invited for a comprehensive in-person assessment. N=229 subjects meeting all criteria who were not on antidepressant medications or currently in active psychotherapy were randomized to either the active PCIT-ED treatment immediately or to a WL control condition for 18 weeks, after which they received the active treatment. Relevant to the current analyses, to investigate whether the ED module had any specific effects on depression and other symptoms of psychopathology as well as parenting style and stress, we conducted interval assessments of several key outcomes of interest at the completion of the time-limited CDI (or 6 weeks post-randomization in WL subjects) and PDI (or 12 weeks post-randomization in WL subjects), in addition to more comprehensive assessments at baseline and after completion of PCIT-ED (or 18 weeks post-randomization in WL subjects). In addition, to measure neural response to treatment, ERPs during a reward task were conducted at baseline, at the completion of standard PCIT (or 12 weeks post-randomization in WL subjects) and at the completion of treatment after the ED module (or 18 weeks post-randomization in WL subjects; Figure 1).

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Overview of PCIT-ED: PCIT-ED consists of CDI and PDI limited to 6 sessions each. This contrasts with standard PCIT modules, in which CDI and PDI vary in length depending upon how long it takes for caregivers to achieve proficiency. The novel ED module follows CDI and PDI and is 8 sesssions. The ED module utiltizes the basic teach and coach and bug in the ear methods to address parental response to the child's expression of intense and/or dysregulated emotion by validating the child's emotion, helping them to label it, and teaching adapative emotion regulation. Live in vivo stressors designed to induce frustration, guilt, and sadness are utiltized, and the parent is coached by the therapist during interactions with the child. Homework designed to practice emotion skills is also administered (similar to homework during CDI and PDI).

Measures: Interval assessments were conducted upon completion of CDI and PDI (or 6 and 12 weeks post-randomization in WL subjects), and the longer and comprehensive post assessment was conducted upon completion of ED (post-PCIT-ED or 18 weeks post-randomization in WL subjects; see Figure 1). The measures collected at the baseline, interval and post assessments included parent reports of child depression, child psychopathology, parental depression and parenting styles as well as therapist ratings of parental behaviors related to goals of PCIT-ED. For all interval and post treatment measures the time frame used was last 2 weeks to obtain change over the module. Neural ERP measures of reward response, were measured upon completion of standard PCIT and again after ED, representing completion of PCIT-ED.

Parent Ratings of Child Psychopathology:

Child Behavior Checklist (CBCL) [17,18] The caregivers of all children completed the CBCL, a

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widely used dimensional measure of early childhood psychopathology at baseline, post-CDI, post-PDI, and post-ED.

Preschool Feelings Checklist and Scale (PFC) [19,20] The PFC is a validated screener used to identify children at high risk for MDD. The PFC-Scale, a 23-item Likert scale, adapted from the PFC screener, was administered at baseline, post-CDI, post-PDI, and post-ED to measure depression severity via caregiver report.

Eyberg Child Behavior Inventory (ECBI) [21] The ECBI is a 36-item parent report of the child's behavioral functioning completed at each therapy session. ECBI data collected at sessions 1 (baseline), 6 (post-CDI), 12 (post-PDI), and 19 (post-ED) were included in the analyses. The measure has high reliability and validity across age and socioeconomic status and has been shown to be a sensitive measure of PCIT treatment response.[22]

Parental Depression/Stress and Parenting Approach:

Beck Depression Inventory II (BDI-II) [23] The BDI-II is a widely-used, reliable, and valid self-report measure and was used in this study to assess severity of depression in caregivers. This was completed at baseline, post-CDI, post-PDI, and post-ED.

Parenting Stress Index (PSI) [24] The PSI is a reliable and valid caregiver-report measure designed to assess the magnitude of stress within the parent-child dyad. This measure focuses on three major domains of stress: child characteristics, parent characteristics, and situational life stress, and was completed at baseline, post-CDI, post-PDI, and post-ED.

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Coping with Children's Negative Emotions (CCNES) [25] The CCNES is a valid and reliable caregiver-report measure consisting of six subscales that reflect different ways parents cope and use strategies in response to children's expressions of negative emotion such as anger, sadness, and fear.[26] This measure assesses the use of minimization of emotions and the use of distraction during intense negative emotions, two commonly used parenting strategies deemed maladaptive, and which PCIT-ED was designed to change. The CCNES was completed at baseline, post-CDI, post-PDI, and post-ED.

Neural Reward Task using ERP:

Children completed a modified version of the Doors Guessing Task, a task used in numerous previous studies of children with depression.[16,27-29] Children were first shown containers of prizes with increasing attractiveness to the child and the amount of "points" required to earn each prize. During the task, children were shown a graphic displaying two doors and told to select a door to open. Following the child's choice, feedback stimuli appeared on the screen informing the child whether he/she lost or gained points. Children received negative feedback on 50% of trials and positive feedback on 50% of trials. The EEG was recorded using a BrainVision ActiChamp recording system and actiCAP active electrodes (Brain Products GmbH, Munich, Germany). The electrodes were mounted in an elastic cap using a subset of the International 10/20 System sites with a ground electrode located at FPz. The EEG data were recorded and referenced to Cz. Offline analysis was performed using Brain Vision Analyzer software (Brain Products GmbH, Munich, Germany). EEG data were re-referenced offline to the average of TP9 and TP10 (located adjacent to the mastoids) and band-pass filtered with cutoffs at 0.1 and 30 Hz.

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The EEG for each trial was corrected for blinks and eye movements using the Gratton et al. method [30]. Physiological artifacts were removed using a semi-automatic procedure with a maximum allowed voltage step of 50μV, a maximum absolute difference between any two points of 175μV, and a minimum allowed activity of .50μV in a 100-ms interval.

Analysis:

To investigate how each module of PCIT-ED addressed key symptom domains and areas of functioning, therapy and WL groups were compared on the measures above, collected at baseline, post-CDI, post-PDI, and post-ED assessments. Therefore in contast to the original paper that focused on change from baseline to post-treatment, this analysis focuses on those measures also used at the interval assessments (and therefore available at all 4 timepoints).

Multilevel models (MLMs) were utilized to compare trajectories of the above measures across the four timepoints in therapy and WL groups. The time variable was module, which was centered at the post-PDI assessment. Quadratic and higher order effects of time were included in the models if they were significant at $p<0.05$. Weeks between assessments was included as a covariate in the MLMs, because WL subjects were assessed at pre-scheduled intervals, while subjects in treatment were assessed after completion of each module, which could vary depending on missed weeks due to vacation, illness, etc. Several different covariance structures were tested for each MLM, and the covariance structure that provided the best model fit was selected. All of the MLMs used either an unstructured or variance components covariance structure. For MLMs with a significant group by time interaction, 3 post-hoc MLMs were conducted. One evaluated the CDI module by including data from only the baseline and post-

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CDI assessments, the second evaluated the PDI module by including data from only the post-CDI and post-PDI assesments, and the third evaluated the ED module by including data from only the post-PDI and post-ED assessments.

All subjects randomized to the WL group were offered therapy upon completion of the post assessment. In order to increase the sample size to include all participants who received treatment, and as such, increase power to detect treatment effects in standard PCIT and the ED module, subjects randomized to therapy were then combined with subjects randomized to WL (post-wait) to investigate change across therapy based on the ECBI, the gold standard measure for response to PCIT, for all subjects who received treatment. The post-assessment (which occurred just prior to treatment) was used as a basline assessment when the WL group was included in the analysis of treatment response as detailed below.MLMs similar to those described above, although without the independent variable group, were conducted in the combined therapy sample with ECBI intensity and problem T-scores as the outcome variables. ECBI scores from the 1st, 6th, 12th, and 19th therapy sessions were included in the MLM's regardless of whether the subject was randomized to therapy or wait list first. Cohen's d was calculated for each module using change in scores from the beginning to the end of the module in therapy and WL groups.

The false discovery rate (FDR) method was used to control for multiple comparisons. FDR corrected p-values were calculated for each of the time by group interactions in all of the primary MLM's. The ECBI MLM's did not include a group variable, so the p-value of the time effect was corrected for these models. The 3 post-hoc MLM's for each measure with a significant time by group interaction underwent separate FDR correction. The significance of the

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primary MLM results were unchanged after FDR correction, but several significant findings from the post-hoc MLM's were lost after correction for multiple comparisons, as detailed in the results section.

To examine neural change from baseline to the end of standard PCIT and neural change specific to the ED module (end of standard PCIT to the end of the ED module), therapy and WL groups were compared on neural reward ERP responses to win and loss at baseline, post-standard PCIT (CDI and PDI) and post-PCIT-ED. The mean amplitude of responses to win and loss was measured separately between 300 and 500 milliseconds at electrode site Pz, with a 200 millisecond baseline correction prior to feedback onset. Pz was chosen based on prior work in this sample.[14,16] As previously done in the literature and our work, [16,31,32] we used linear regression to create residualized scores to examine treatment effects for wins, partialing out the effect of loss (Win_{resid}) and vice versa ($Loss_{resid}$) at each assessment (baseline, post-PCIT, post-PCIT-ED).

To maintain consistency across previous treatment analyses using neural indices and to assess response to reward changing as a function of treatment, we completed four ANCOVAs with treatment group as a between-subject factor (therapy vs. WL). The first ANCOVA examined Win_{resid} post-standard PCIT as the dependent measure, controlling for baseline Win_{resid}, age, baseline PFC-Scale score, and post-standard PCIT $Loss_{resid}$. This was compared to previously reported findings assessing Win_{resid} and $Loss_{resid}$ in identical ANCOVA's post-PCIT-ED. [16] As a follow-up analysis to test the independent effects of the ED module, we then examined parallel ANCOVA's for Win_{resid} post-PCIT-ED (controlling for post-standard PCIT Win_{resid}, age, post-

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standard PCIT PFC-Scale score and post-PCIT-ED $Loss_{resid}$) and $Loss_{resid}$ (controlling for post-standard PCIT $Loss_{resid}$, age, post-standard PCIT PFC-Scale score and post-PCIT-ED Win_{resid}).

Results:

Therapy and Wait List Group Comparisons

Subject charactersistics by randomization group are detailed in Table 1.

Child Psychopathology. Trajectories of the PFC-Scale total score and CBCL depression, anxiety, internalizing, and externalizing T-scores all differed significantly in the therapy and WL groups (see Table S1, available online). As shown in Figure 2 (and Table S2, available online), post-hoc MLMs determined that all measures except for CBCL anxiety and externalizing T-scores showed significant group by time differences during the ED module, with greater improvement in therapy subjects. There was a significant time by group interaction during the ED module for CBCL anxiety T-scores, but this finding did not remain significant after FDR correction. This suggests an added benefit of the ED module over the previous CDI and PDI modules. In addition, the post-hoc MLMs indicated that PFC-Scale trajectories improved more during CDI in therapy versus WL groups, and CBCL internalizing and externalizing T-scores decreased significantly more in therapy than WL subjects during PDI. Effect sizes are shown in Table 2.

Parent Depression, Stress, and Parenting Behavior. There was not a significant group by time interaction in the MLM of BDI-II total score (see Table S3, available online). Trajectories of PSI total stress score, however, differed significantly in therapy and WL groups, with post-hoc

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analyses indicating significantly greater improvement in the therapy group compared to WL during the ED module (Figure 3), again suggesting a unique benefit of ED. There was a significant time by group interaction during the CDI module, but this finding did not remain significant after FDR correction. Effect sizes are shown in Table 2.

All CCNES subscales had a significant group by time interaction except for problem-focused reactions (see Table S4, available online). As shown in Figure 4, post-hoc MLMs indicated that CCNES distress reactions, punitive reactions, expressive encouragement, and emotion-focused reactions showed greater improvement in the therapy than WL group only during the ED module. Only the CCNES minimization reactions subscale had a significant group by time interaction during the CDI module, and none had a significant interaction during the PDI module. Effect sizes are shown in Table 2.

ECBI Change in the Combined Therapy Sample

To further investigate whether additional global measures of change using the standard PCIT measure of change, the ECBI, was significant during the abbreviated CDI, PDI modules and the novel ED module, we conducted MLMs with all children during therapy (including the children who were randomized to WL and were then offered PCIT-ED). The ECBI was only administered during therapy, not during the WL period so the groups were combined to increase power. ECBI intensity T-scores and problem T-scores decreased significantly during therapy (see Table S5, available online), and post-hoc MLMs revealed T-scores decreased significantly during each of the three PCIT-ED modules (Figure S1), including the ED module. Notably 35% of parents achieved proficiency in CDI and 72% achieved proficiency in PDI during the course

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of this time limited form of PCIT. We did not determine proficiency in ED.

Neural Response to Reward ERP Component

Grand average waveforms for Win and Loss feedback across groups and assessment points are shown in Figure 5. We first examined whether the therapy and WL groups differed in change in neural reward responding during standard PCIT. The baseline to end of standard PCIT ANCOVA for Win_{resid} (controlling for age, baseline PFC-Scale score, Win_{resid} at baseline and $Loss_{resid}$ at post-standard PCIT) showed no significant effects of treatment group ($F_{1,82}$=.29, p=.59, partial η^2=.003), with similar null findings for $Loss_{resid}$ ($F_{1,82}$=.35, p=.56, partial η^2=.004). This compares to our previous report of a significant effect of Win_{resid} for the therapy compared to WL group from baseline to post PCIT-ED (as reported in [16] $F_{1,86}$=5.45, p=.02, partial η^2=.06) but no effect of $Loss_{resid}$. In follow-up analyses examining the change in neural reward responding from post-standard PCIT to post-PCIT-ED in therapy and WL groups, the ANCOVA for Win_{resid} showed a significant effect of treatment group after controlling for age, post-standard PCIT PFC-Scale score, Win_{resid} at post-standard PCIT and $Loss_{resid}$ at post-PCIT-ED ($F_{1,72}$=7.78, p=.007, partial η^2=.10), such that the Win_{resid} became more positive post-PCIT-ED in the therapy group compared to WL. The ANCOVA for $Loss_{resid}$ post-PCIT-ED was not significant ($F_{1,72}$=3.36, p=.07, partial η^2=.05).

Discussion:

Overall trajectories of the child and parent measures all differed significantly in the therapy and WL groups. Results from post-hoc analyses comparing these trajectories of child and parent

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outcomes during each component of PCIT-ED (CDI, PDI and ED) in therapy and WL subjects showed that child depression severity measured by the PFC-Scale decreased significantly more in therapy subjects during both the CDI and ED modules. Trajectories of depression severity did not differ by group during PDI, a finding which may be attributable to the stress of implementing limit setting to parents, and the fact that PDI initially increases rather than deceases parent-child conflict. CBCL Depession scores were significantly improved compared to WL only during ED. As would be expected from the extant literature, child CBCL externalizing scores were significantly reduced in therapy compared to WL subjects only in PDI [1]. These findings suggest that CDI and ED are each key components of the treatment that improve depressive symptoms in the child.

These findings combined with results from the analyses comparing child neural reward responding after standard PCIT and after PCIT-ED suggest that the novel ED module may provide unique or added efficacy in the treatment of child depression. Specifically, findings showed that change in neural reward responding did not differ between groups during standard PCIT, but instead, an increased reward response to wins only occurred following ED treatment in therapy compared to WL subjects. The overall finding comparing therapy to WL groups on neural change from baseline to post-PCIT-ED was previously reported, [16] but this new analysis now directly adds the test of ED efficacy by comparing neural change in the two groups during the ED module. The specific effect of the ED module on neural response to reward suggests that the ED component may be the element that effectively changes an increasingly recognized neural endophenotype for depression evident across the age span including in very young children.[14] These findings combined with the findings of depression severity change using the

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PFC-Scale and the CBCL depression subscale suggest that the ED module may have played a significant added role in reducing child depressive symptoms and a unique role in enhancing neural response to reward. However, an optimal design where the order of the modules is randomized would be needed to confirm the specificity of these effects for the ED module, as it is also possible that the effect detected was a delayed response to the CDI and PDI modules.

Improvement in parenting behaviors related to the child's expression of negative emotion, a direct target of the ED module, was also a key finding. Specifically, the ED module was uniquely associated with improvements in parental approach to the child's expression of emotions in therapy relative to the WL group. These included behaviors such as increased encouragement of emotional expression, decreased use of distraction as a method of coping with negative emotions, and decreased punitive reactions. This improvement was not surprising, as the ED module directly targets specific parental response to the child's emotional expression hypothesized to be critical to enhancing the child's emotional development , an area not directly addressed in CDI or PDI, despite the fact that PDI targets diminishing punitive parenting behaviors. However, it was notable that improvements in parental minimization of child emotions was only seen during CDI in post-hoc models.

The finding that depression severity also decreased during CDI in therapy compared to WL subjects on the central measure of depression severity, the PFC-Scale, was a notable new finding and provides the first support for the utility of this standard PCIT component for the amelioration of child depression. This finding is particularly notable given the low rates of CDI proficiency achieved in this abbreviated CDI module. Together with the results from the ED, the findings

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overall suggest that both CDI and ED are key components of PCIT-ED that effectively target child depression. As CDI is a key component to strengthening the parent child relationship, its contribution to improvement in depression was not surpising. It was notable that despite improvements in parental depression on the BDI during the course of treatment overall, the ED module did not seem to have a unique effect on parental depression suggesting it may be more related to overall improvement in the parent child relationship and parenting approach more generally.

An important study limitation is that we cannot rule out that these findings could arise on the basis of the additional sessions rather than the specific content of the ED module. The post-hoc findings from each individual module suggest the pattern of change is more complex and that each module may impact specific symptoms in different ways over and above the effect of number of sessions. Given this, further investigation that randomizes the order of modules or compares standard PCIT to PCIT-ED over the same period is warranted to provide a definitive test of this question. The latter design is more logical based on the fact that CDI is necessary as the first step of treatment to build the parent-child relationship foundation to implement next treatment steps. In addition, the fact that CDI and PDI were time-limited in this study and only a sub-set of parents achieved proficiency (lower in CDI and higher in PDI) in these skills is also a limitation. Despite this, as the standard PCIT modules do not target the key features of depression, it seems unlikely in principle that simply additional sessions independent of content, would have made a difference in child and parental depression and emotion skills. Relatedly, there could have been delayed carryover effects such that change exhibited from the CDI and PDI modules might not have evidenced immediately, and effects from these modules carried

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over into the ED module, again speaking to the importance of future studies with module order randomization. Delayed carryover effects could also be present with our neural findings, as we are unable to determine whether the changes present in reward responding from post-standard PCIT to post PCIT-ED are not due to delayed carryover of changes occurring to neural responding during the prior modules. That is, even though a significant effect was found during the post-standard PCIT to post-PCIT-ED ERP assessments and not during the baseline to post-standard PCIT ERP assessments, alterations in children's reward responding may have been occurring throughout the course of treatment. Again, randomization of modules would help to address this intriguing question. These limitations notwithstanding, the current study provides initial insights into the kinds of changes in parent and child behaviors evident during each module of PCIT-ED. These findings, pending confirmation with further study using designs that randomize order administration, may be useful to inform future use of PCIT and PCIT-ED in a modular fashion, an approach that there is increasing interest in to personalize and streamline this treatment.

Overall, study findings suggest that PCIT-ED, and in particular, the novel ED module, showed added utility for the treatment of depression in early childhood based on several measures. Notably, the CDI also positively impacted child depression as well. Also, of interest was that all other child outcomes with the exception of CBCL externalizing scores were also reduced significantly more in therapy compared to WL subjects during the ED module. Further, and of importance, was the significant improvement in caregiver stress evident only during ED compared to WL. Analyses of change on the ECBI, the standard measure of improvement in PCIT, that combined all treatment data (including the group who received treatment after the

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wait period) suggest that global improvement in child behavior is occurring in CDI, PDI, and ED modules.

Findings from this study have important clinical implications and suggest that the modified version of PCIT for depression, or PCIT-ED, may be needed for the most effective treatment of early childhood depression. Also notable was that CDI seems to be a key component of this treatment response even in the face of limited parental mastery of skills in the abbreviated module. Findings showed that neural response to reward, as well as several key aspects of parenting relevant to the management of early childhood depression and emotion management skills, are uniquely targeted by the ED module. These findings underscore the importance of the focus on emotion development in the treatment of early childhood depression. Findings also suggest the ED module is useful for improving overall functioning in keeping with the effects of CDI and PDI. Findings suggest that modular approaches where specific modules of the PCIT-ED are administered depending upon the child characteristics and forms of psychopathology may be most useful. Future studies that provide rigorous tests of the efficacy of each module of PCIT-ED are now needed to further clarify their utility in varying forms of child psychopathology to provide the most personalized and streamlined treatment approaches.

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Table 1. Subject Characteristics by Randomization Group

	Wait List (n=115)		Therapy (n=114)		Wait List vs. Therapy	
	%	N	%	N	χ^2	p
Completed assessment						
Baseline	100.0	115	100.0	114	--	--
Post-CDI	80.0	92	83.3	95	0.42	0.5146
Post-PDI	82.6	95	82.5	94	0.00	0.9757
Post-ED	79.1	91	87.7	100	3.05	0.0807
Gender						
Male	63.5	73	66.7	76	0.26	0.6129
Female	36.5	42	33.3	38		
Ethnicity						
Not Hispanic	91.3	105	86.8	99	1.17	0.2790
Hispanic	8.7	10	13.2	15		
Race						
Caucasian	71.3	82	82.5	94	F.E.	0.1033
African-American	14.8	17	7.9	9		
Asian	0.0	0	0.9	1		
More than one race	13.9	16	8.8	10		
	Mean	**SD**	**Mean**	**SD**	**t**	**p**
Age in years						
Baseline	5.28	1.13	5.14	0.97	1.00	0.3192
Post-CDI	5.40	1.16	5.30	0.96	0.68	0.4962
Post-PDI	5.58	1.15	5.40	0.99	1.14	0.2540
Post-ED	5.66	1.15	5.61	0.97	0.33	0.7431
Weeks between assessments						
Baseline to Post-CDI	8.37	1.71	8.55	1.97	-0.65	0.5150
Post-CDI to Post-PDI	5.74	1.55	5.89	1.44	-0.68	0.4952
Post-PDI to Post-ED	5.93	1.75	9.28	3.27	-8.76	<0.0001
Number of therapy sessions						
CDI (6 possible)	--	--	5.54	1.43	--	--
PDI (6 possible)	--	--	5.20	2.01	--	--
ED (8 possible)	--	--	6.67	2.89	--	--
Income-to-needs ratio						
Baseline	2.85	1.35	3.13	1.31	-1.55	0.1229
Post-ED	2.94	1.34	3.24	1.21	-1.59	0.1125

Note: CDI = child directed intervention; ED = emotion development; FE = Fisher's Exact Test; PDI = parent directed intervention.

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Table 2. Effect Sizes[a] for Change in Scores from Beginning to End of Each Module in Therapy Compared to Wait List Subjects

Measure (time frame for all measures last 2 weeks)	Baseline to Post-CDI	Post-CDI to Post-PDI	Post-PDI to Post-ED
PFC-Scale Score	0.55	0.23	0.47
CBCL Depression	0.15	0.23	0.62
CBCL Anxiety	0.06	0.16	0.36
CBCL Internalizing	0.25	0.37	0.44
CBCL Externalizing	0.26	0.80	0.35
BDI-II Total Score	0.12	-0.53	0.81
PSI Total Stress Score	0.31	0.11	0.49
CCNES Distress Reactions	-0.03	-0.09	0.84
CCNES Punitive Reactions	0.12	0.12	0.74
CCNES Expressive Encouragement	-0.09	0.11	-0.97
CCNES Emotion-Focused Reactions	0.03	0.22	0.42
CCNES Problem-Focused Reactions	-0.01	0.09	-0.20
CCNES Minimization Reactions	0.37	0.18	0.40

Note: BDI = Beck Depression Inventory; CDI = child directed intervention; CCNES = Coping with Children's Negative Emotions; ED = emotion development; PDI = parent directed intervention; PFC = Preschool Feelings Checklist and Scale; PSI = Parenting Stress Index.

[a]Effect sizes calculated as Cohen's d with positive numbers indicating greater decreases and negative numbers indicating greater increases in therapy compared to wait list

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Figure 1. Overview of Study Design
Note: Some sessions took place back to back (two sessions contiguously for a 90 min). BDI = Beck Depression Inventory; CBCL = Child Behavior Checklist; CCNES = Coping with Children's Negative Emotions; CDI = child directed intervention; C-GAS = Children's Global Assessment Scale; ED = Emotion Development; ERP = event related potentials; K-SADS = Kiddie Schedule for Affective Disorders and Schizophrenia; PDI = parent directed intervention; Obs = XX; PFC = Preschool Feelings Checklist and Scale

Figure 2. Estimated Trajectories from Multilevel Models of PFC-Scale Scores (A) and Child Behavior Checklist (CBCL) Depression (B), Anxiety (C), Internalizing (D), and Externalizing T-Scores (E) in Wait List and Therapy Subjects
Note: Solid lines indicate trajectories from baseline to post-emotion development (ED); Dashed lines indicate trajectories of post-hoc multilevel models during the child directed intervention (CDI), parent directed intervention (PDI), and ED modules for measures with a significant overall difference in group trajectory; asterisks identify post-hoc models with a significant time by group interaction after false discovery rate (FDR) correction for multiple comparisons.

Figure 3. Estimated Trajectories from Multilevel Models of Beck Depression Inventory (BDI-II) Total Score (A) and Parenting Stress Index (PSI) Total Stress Score (B) in Wait List and Therapy Subjects
Note: Solid lines indicate trajectories from baseline to post-emotion development (ED); Dashed lines indicate trajectories of post-hoc multilevel models during the child directed intervention (CDI), parent directed intervention (PDI), and ED modules for measures with a significant overall difference in group trajectory; asterisks identify post-hoc models with a significant time by group interaction after false discovery rate (FDR) correction for multiple comparisons.

Figure 4. Estimated Trajectories from Multilevel Models of Coping with Children's Negative Emotions (CCNES) Distress Reactions (A), Punitive Reactions (B), Expressive Encouragement (C), Emotion-Focused Reactions (D), Problem-Focused Reactions (E), and Minimization Reactions Scores (F) in Wait List and Therapy Subjects
Note: Solid lines indicate trajectories from baseline to post- emotion development (ED); Dashed lines indicate trajectories of post-hoc multilevel models during the child directed intervention (CDI), parent directed intervention (PDI), and ED modules for measures with a significant overall difference in group trajectory; asterisks identify post-hoc models with a significant time by group interaction after false discovery rate (FDR) correction for multiple comparisons.

Figure 5. Neural ERP Response to Win at Baseline, Post-Standard Parent Child Interaction Therapy (PCIT) and Post-PCIT-Emotion Development (ED)

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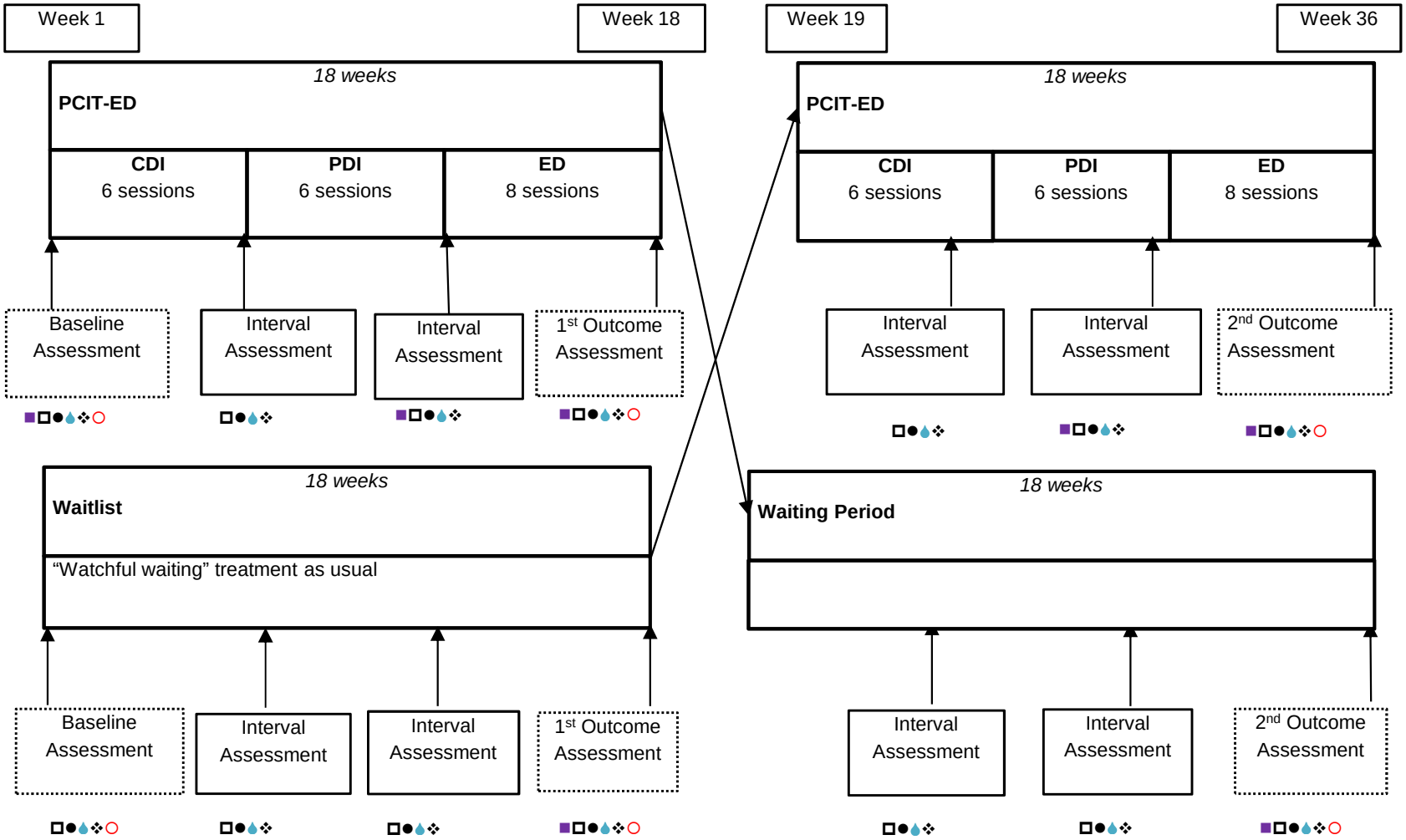
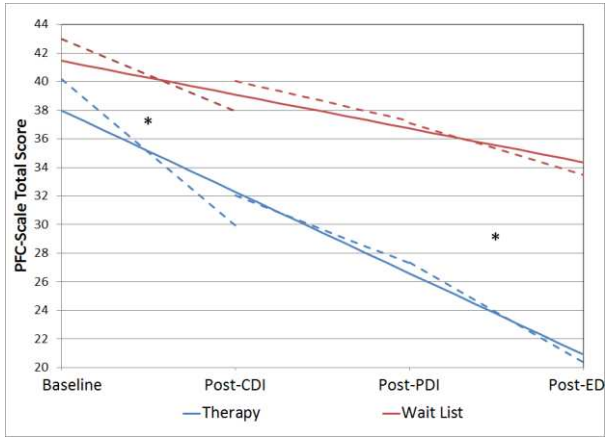
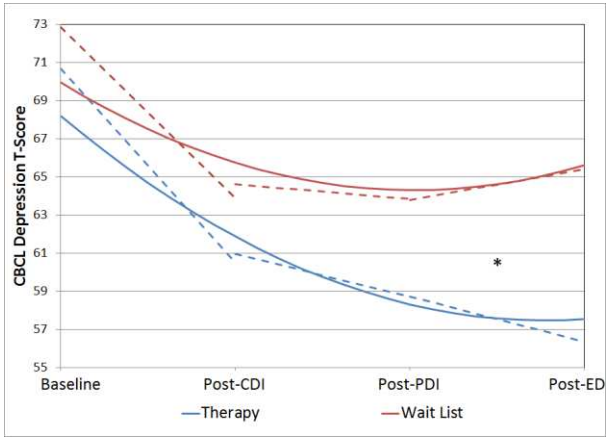


■ = ERPs during a reward task; ◘ = CBCL; ● = PFC; 💧 = BDI; ❖ = CCNES; ○ = comprehensive assessment (K-SADS, PFCAS, C-GAS, Obs measures)

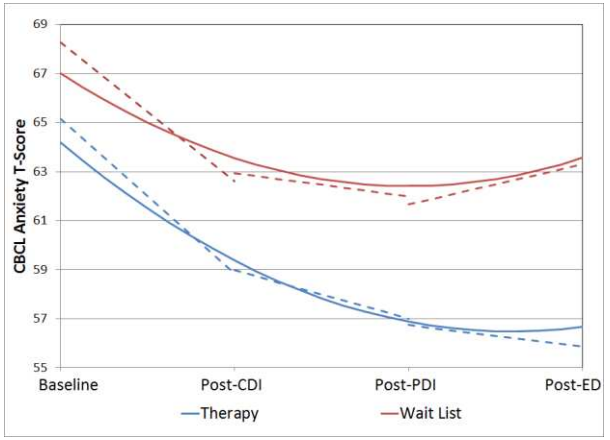
A


PFC-Scale Total Score
44
42
40
38
36
34
32
30
28
26
24
22
20
*
*
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

B


CBCL Depression T-Score
73
71
69
67
65
63
61
59
57
55
*
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

C


CBCL Anxiety T-Score
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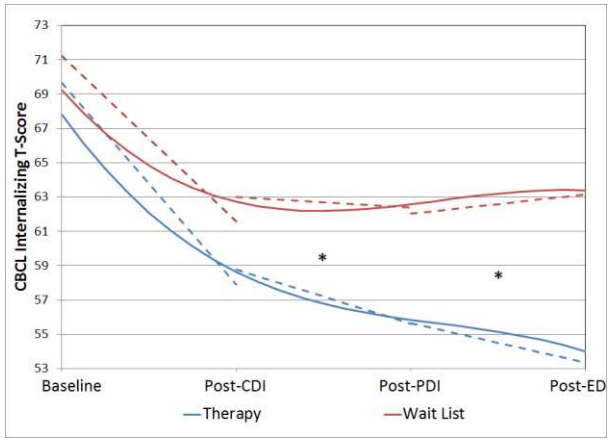
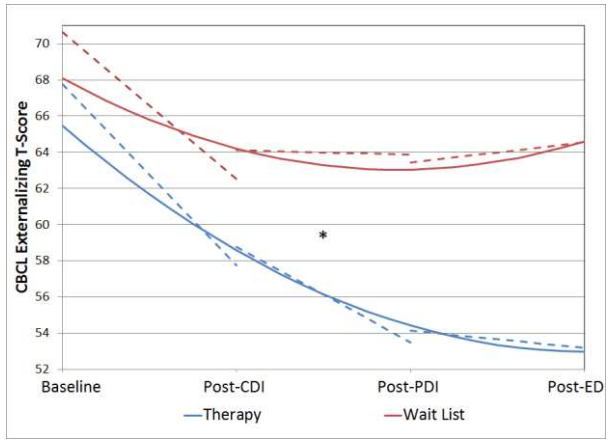
67
65
63
61
59
57
55
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

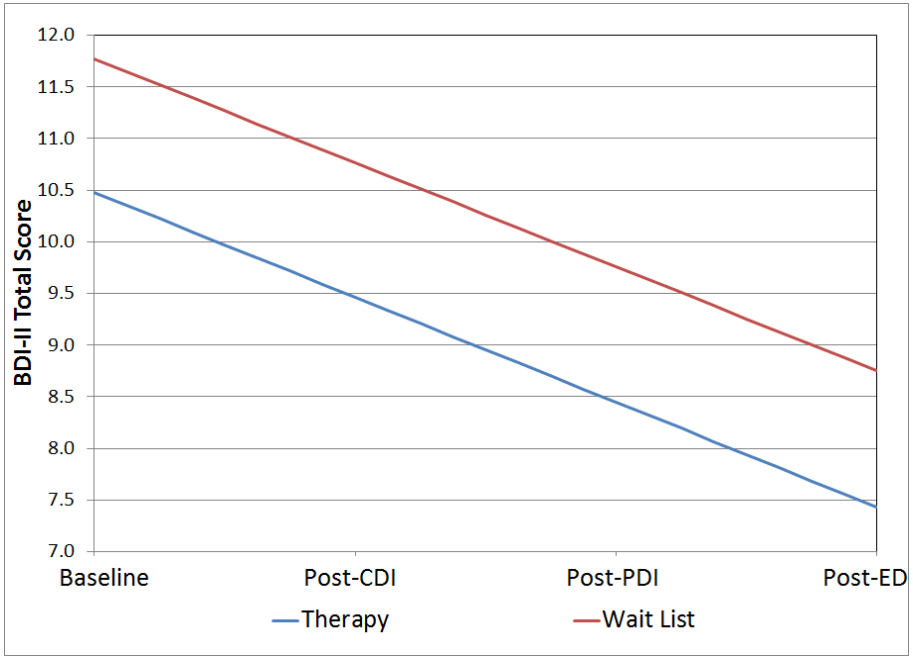
D


CBCL Internalizing T-Score
73
71
69
67
65
63
61
59
57
55
53
*
*
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

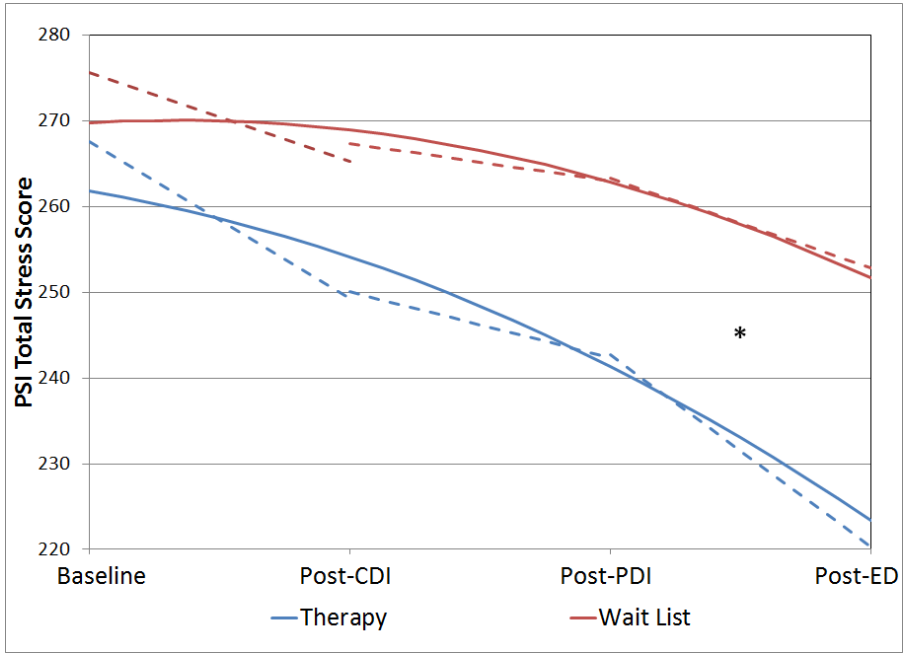
E


CBCL Externalizing T-Score
70
68
66
64
62
60
58
56
54
52
*
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

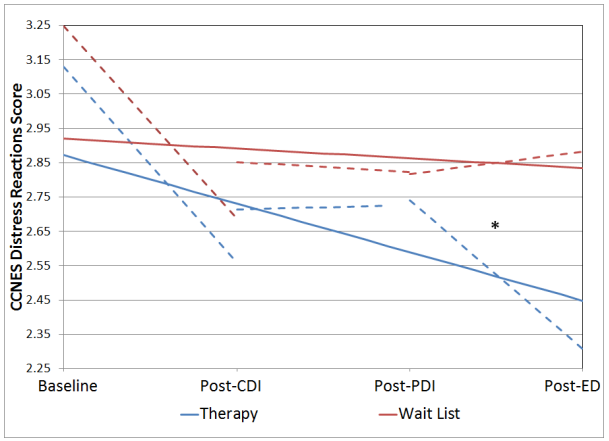
A


12.0
11.5
11.0
10.5
10.0
9.5
9.0
8.5
8.0
7.5
7.0
BDI-II Total Score
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

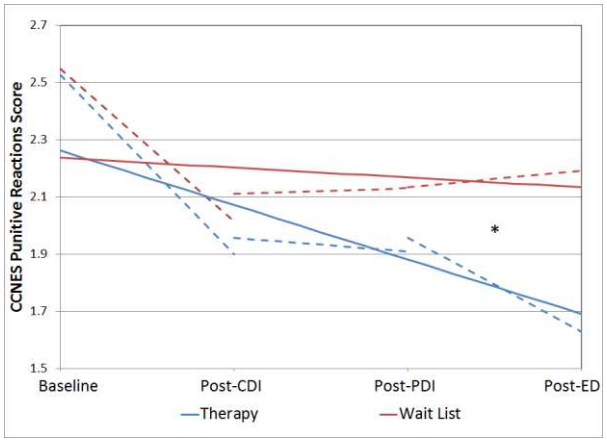
B


280
270
260
250
240
230
220
PSI Total Stress Score
*
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

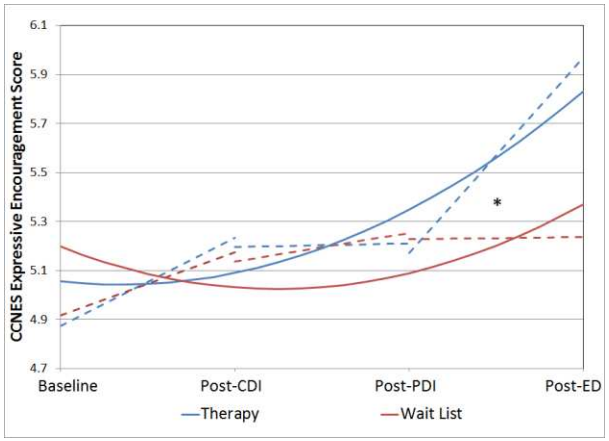
A


CCNES Distress Reactions Score
3.25
3.15
3.05
2.95
2.85
2.75
2.65
2.55
2.45
2.35
2.25
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List
*

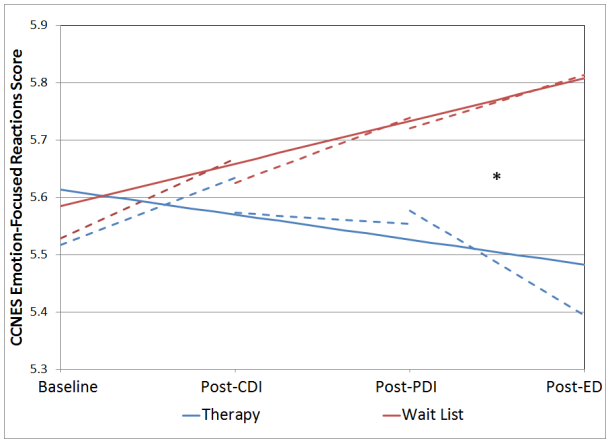
B


CCNES Punitive Reactions Score
2.7
2.5
2.3
2.1
1.9
1.7
1.5
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List
*

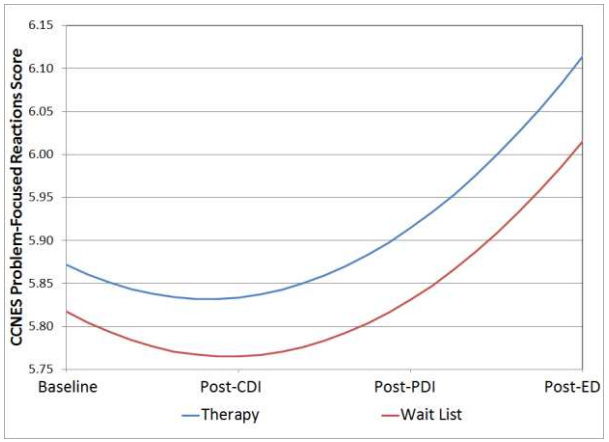
C


CCNES Expressive Encouragement Score
6.1
5.9
5.7
5.5
5.3
5.1
4.9
4.7
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List
*

D


CCNES Emotion-Focused Reactions Score
5.9
5.8
5.7
5.6
5.5
5.4
5.3
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List
*

E


CCNES Problem-Focused Reactions Score
6.15
6.10
6.05
6.00
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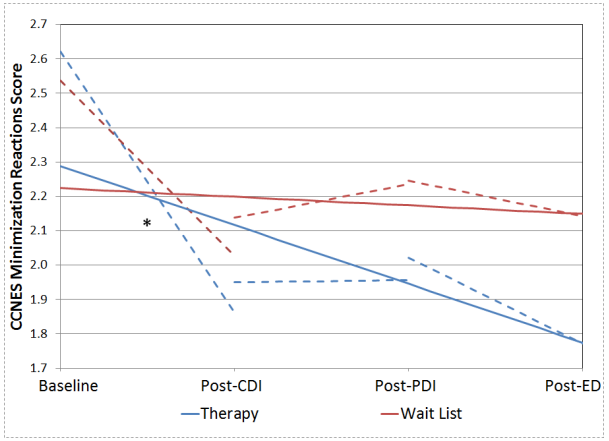
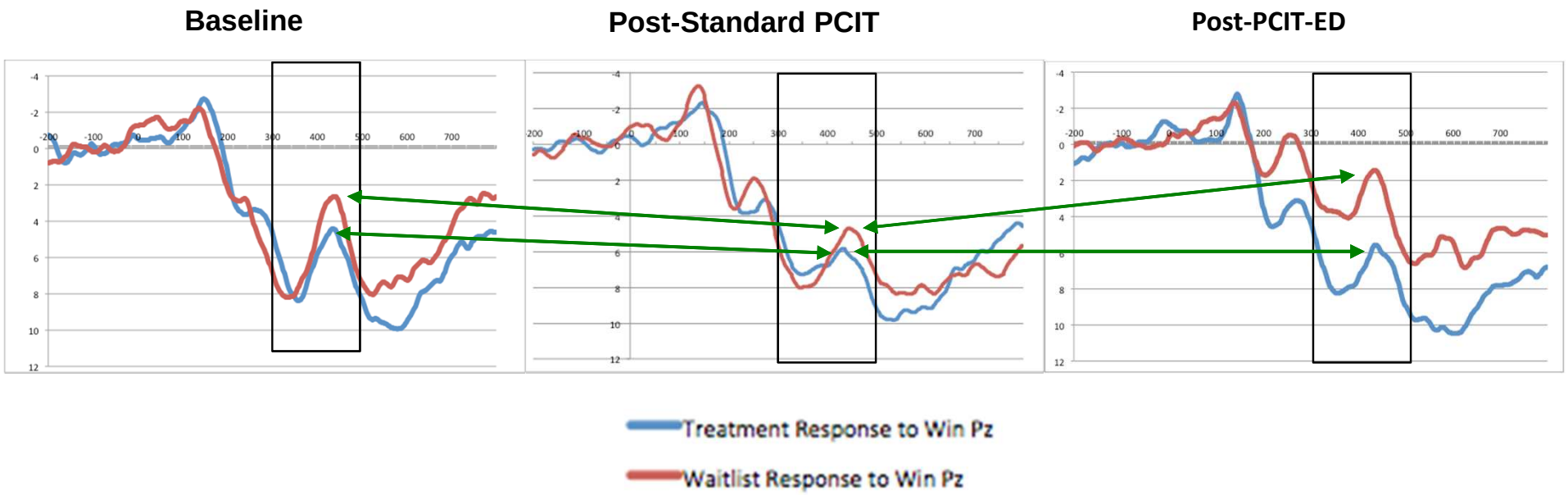
5.75
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List

F


CCNES Minimization Reactions Score
2.7
2.6
2.5
2.4
2.3
2.2
2.1
2.0
1.9
1.8
1.7
Baseline
Post-CDI
Post-PDI
Post-ED
Therapy
Wait List
*


Baseline
Post-Standard PCIT
Post-PCIT-ED
Treatment Response to Win Pz
Waitlist Response to Win Pz

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DISCLOSURES

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There are no additional funding sources or financial conflicts to disclose.

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