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A community evaluation of Parent-Child Interaction Therapy for children with prenatal substance exposure

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ABSTRACT

Children with prenatal substance exposure (PSE) often have behavior problems, but few studies have demonstrated that behavior therapy can be effective for these children. The current study evaluated the efficacy of Parent-Child Interaction Therapy (PCIT) for improving behavior problems in a sample of 116 children with PSE using archival data from a Midwestern PCIT clinic. Analyses included mean comparisons of pre- and post-treatment measures of child and parent behavior, prediction of drop-out from treatment, and evaluation of the potential complicating effects of PSE on treatment response. Results indicate that treatment effects of PCIT for children with PSE appear similar to the outcomes observed elsewhere in the PCIT literature. There was no indication that maternal polysubstance use alters child response to treatment. Attrition was high, but similar to other community trials of PCIT. The current study lends support to the use of PCIT for children with PSE who have behavior problems.

1. Introduction

Children with prenatal substance exposure (PSE) are at risk for a variety of neurological, developmental, medical, and behavioral problems (Glass & Mattson, 2016; Parris, 2016; Singer, Min, Lang, & Minnes, 2016). Interventions have been established for child behavior problems (Kaminski & Claussen, 2017), but there has been insufficient evaluation of these interventions for children with PSE. Parent-Child Interaction Therapy (PCIT) is one such intervention that shows promise for children with PSE. The current study represents the first attempt to evaluate PCIT in its standard format for children with PSE, in the service of supporting good treatment decisions for providers working with this population.

1.1. Risks of prenatal substance exposure

Prenatal substance exposure is an increasingly significant public health concern, resulting in secondary disabilities and cascading pathways of influence in affected families. It is estimated that 15% of infants are affected by PSE ("Infants with Prenatal Substance Exposure," n.d.), with common drugs being nicotine, alcohol, marijuana, opiates, cocaine, and methamphetamines. In addition to the numerous medical issues of infants with PSE (e.g., low birthweight, congenital abnormalities, withdrawal symptoms), many infants show delays in movement, learning/memory, orienting, visual/motor skills, language, and other domains (Behnke & Smith, 2013). As they mature, these children can develop psychological and behavioral problems, particularly of the externalizing type (Fryer, McGee, Matt, Riley, & Mattson, 2007; Bada et al., 2007; Mattson, Crocker, & Nguyen, 2011). These problems may include irritability, attention problems, hyperactivity, impulsivity, school/academic difficulties, criminal behavior, and substance use (Behnke & Smith, 2013), and many of these problems persist into adulthood (Streissguth, Barr, Kogan, & Bookstein, 1996).

Research on the contributions to secondary emotional/behavioral difficulties in children with PSE points to both biological and environmental variables. At the biological level, PSE results in structural deficiencies in brain areas associated with self-control (Fisher, Kim, Bruce, & Pears, 2012; Fisher et al., 2011). Similarly, PSE contributes to neurobehavioral disinhibition (Chapman & Tarter, 2007; Kirisci, Tarter, Reynolds, & Vanyukov, 2006) which is a pattern of executive functioning deficits that affects a child's ability to respond appropriately to reward and stress (Lester & Padbury, 2009) and inhibit impulsive responses (Konijenberg & Melinder, 2015). At the environmental level, parental substance use is associated with poverty/homelessness (Grant et al., 2011), parental history of maltreatment (Appleyard, Berlin, Rosanbalm, & Dodge, 2011), parental psychopathology (Hans,

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Bernstein, & Henson, 1999; Suchman, McMahon, Slade, & Luthar, 2005), poor social support (Dawe, Harnett, Newman, & Krabman, 2008; Luthar & Suchman, 2000), exposure to violence (Najavits, Sonn, Walsh, & Weiss, 2004; Cohen et al., 2003), and placement instability (Hans, 2002). Meanwhile, parent who use substances have higher stress levels (Nair, Schuler, Black, Kettinger, & Harrington, 2003), more critical attitudes of their children (Griffith, Azuma, & Chasnoff, 1994; Paley, O'Connor, Frankel, & Marquardt, 2006), lower sensitivity/responsiveness (Hatzis, Dawe, Harnett, & Barlow, 2017), patterns of harsh and/or permissive discipline (Mayes & Truman, 2002; Suchman & Luthar, 2000), and greater incidence of abuse/neglect (Chaffin, Kelleher, & Hollenberg, 1996; Mayes & Bornstein, 1996). These caregiving deficits may also lead to insecure attachment status in the child (Suchman, Mayes, Conti, Slade, & Rounsaville, 2004; Mirick & Steenrod, 2016), which confers its own long-term risks for psychological maladjustment (Egeland, Weinfield, Bosquet, & Cheng, 2000; Sroufe, Carlson, Levy, & Egeland, 1999). Studies examining the relative contributions of these risk factors suggest that environmental variables contribute significant variance to child outcomes above and beyond what is accounted for by PSE physiological factors alone (Nair et al., 2003; Kandel, 1990; Johnson, Nusbaum, Bejarano, & Rosen, 1999; Johnson, 2001; Abar et al., 2013). Furthermore, children with PSE who benefited from more supportive and stable home environments (e.g., less stressed parents, more opportunities for stimulation, better parental responsiveness, consistent daily routine) have shown reduced behavioral symptoms later (Eiden, Godleski, Schuetze, & Colder, 2015; Dinehart, Dice, Dobbins, Claussen, & Bono, 2006; O'Connor & Paley, 2005; Twomey et al., 2013).

1.2. Interventions for difficulties associated with prenatal substance exposure

The buffering power of a supportive environment against the externalizing behaviors associated with PSE highlights the potential for psychosocial interventions for this population, but there is limited research examining such interventions. Most literature reviews of psychosocial interventions for children with PSE focus on Fetal Alcohol Spectrum Disorder (FASD; Peadon, Rhys-Jones, Bower, & Elliot, 2009; Premji, Benzies, Serrett, & Hayden, 2006; Reid, Dawe, Shelton, Harnett, & Warner, 2015), and each of them emphasizes the relative paucity and low quality of evidence for interventions with this population. Additionally, findings about these interventions might not generalize to all children exposed to alcohol, since users of alcohol routinely use additional substances (Petry, 2001; Staines, Magura, Foote, Deluca, & Kosanke, 2001). One recognized intervention for FASD features "cognitive skills training" that targets impulse-control and attention regulation deficits in FASD, with reported improvements in executive functioning tasks and teacher-rated behaviors in small samples (Bertrand, 2009; Riley et al., 2003). Other interventions for FASD have targeted social skills, with reported improvements in child knowledge of prosocial behavior and parent-reported behavior problems (O'Connor et al., 2006, 2012). A limited number of interventions promoting parent management of externalizing behaviors in FASD have reported improvements in parent self-efficacy, knowledge of behavior principles, and child behavior problems (Bertrand, 2009; Kable, Coles, & Taddeo, 2007; Kable, Coles, Strickland, & Taddeo, 2012). Because of inconsistent results with skill-specific interventions, a review by Reid et al. (2015) suggested that the best types of interventions targeted the child's environment and not just an individual neurological deficit in FASD.

Research support for psychosocial interventions for children with PSE but not FASD is even more scant. Bick, Bernard, and Dozier (2013) reported that Attachment and Bio-behavioral Catch-up (ABC) resulted in more secure attachment and less cortisol reactivity relative to a home-based control intervention called Developmental Education for Families, which targets cognitive and language development. Another attachment-based intervention, Mothering from the Inside Out (MIO), has been shown to increase sensitive and responsive parenting (Suchman et al., 2017; Suchman, DeCoste, Castgilioni, Legow, & Mayes, 2008). Several group-based parenting workshops have been shown to improve caregiver knowledge about PSE and healthy child development (D'Angiulli & Sullivan, 2010; Burry & Noble, 2001; Mickel, 1993) and one workshop produced increases in family meetings and maintenance of household rules (Catalano, Gainey, Fleming, Haggerty, & Johnson, 1999). However, none of these studies evaluated externalizing behaviors, and most of them were small pilot studies with heterogeneous samples (e.g., wide age ranges of the children). One home-based parenting intervention, Parents Under Pressure (Dawe & Harnett, 2007), focused more on parent management of externalizing behaviors, with findings of reductions in child externalizing behaviors and increases in child prosocial behaviors.

Considering the paucity of data for this population, it may be tempting to simply select an existing well-supported evidence-based treatment for externalizing behaviors (Eyberg, Nelson, & Boggs, 2008; Kaminski & Claussen, 2017), but this may be premature if the unique needs of children with PSE lead to a poor fit with the intervention (see Eyberg, 2005 for discussion of transporting treatments to new populations). For example, many well-established interventions for externalizing problems involve adjusting patterns of rewards and consequences and increasing the child's ability to inhibit impulsive actions, which may be more difficult for children with neurobehavioral disinhibition. Additionally, some researchers have argued that traditional externalizing behavior treatments do not address attachment disruptions (e.g., Suchman et al., 2004) and focus too much on limit-setting and control, which could already be adequate among parents of PSE children (Peisch et al., 2018). On the other hand, there is evidence that the mechanisms underlying negative behavior in children with PSE are similar to the mechanisms underlying negative behavior in general (Kurtz, Chin, Rush, & Dixon, 2008; McConnel et al., 2002; Heller, Sobel, & Tanaka-Matsumi, 1996), and thus might respond well to existing interventions.

1.3. Parent-Child Interaction Therapy

Parent-Child Interaction Therapy (Niec, 2018) is an ecologically sensitive and flexible intervention that holds promise for treating the externalizing problems endemic to children with PSE. It is already a well-established treatment for externalizing problems (Kaminski & Claussen, 2017) and uses an assessment-based approach to tailor treatment to the unique needs of each family (McNeil, Filcheck, Greco, Ware, & Bernard, 2001). Families progress through two phases of treatment, with the first phase focusing on positive parenting skills and relationship enhancement and the second phase focusing on consistent and effective discipline practices (Eyberg & Funderburk, 2011). Parents receive live coaching while they practice the new skills with the aid of bug-in-ear communication, a unique feature which differentiates PCIT from other parenting interventions. The primary target of intervention is not a specific skill deficit of the child or parent, but rather the reciprocal patterns of parent–child interaction that are known to lead to difficult behaviors over time (e.g., Patterson, 2016). For children with PSE, supporting warmth, responsiveness, structure, and consistency of the home environment through PCIT may be one of the best ways to safeguard against behavioral problems.

The current PCIT literature suggests potential effectiveness for this population, but some extrapolation is necessary. PCIT has been shown to be effective for children with other developmental disabilities, including autism spectrum disorder (Solomon, Ono, Timmer, & Goodlin-Jones, 2008) and intellectual disability (Bagner & Eyberg, 2007), which is encouraging for other children with atypical development. PCIT is also effective in child welfare settings, with children in foster care (Timmer, Urquiza, & Zebell, 2006) and parents found to be abusive (Chaffin et al., 2004), which often include children with PSE. With PSE

specifically, there is a small PCIT study summarized within a broader review by Bertrand (2009) in which a group of 46 children with Fetal Alcohol Spectrum Disorder (FASD) showed significant mother-rated behavior improvements after a 14-week PCIT group parenting program. However, the sample was limited to prenatal alcohol exposure (a common limitation) and the group-based format represents a modification of the typical PCIT delivery format.

In addition to the question of clinical efficacy for children with PSE, treatment attrition is a potential concern for this population. Factors associated with attrition in PCIT include caregiver stress, caregiver lack of praise or excessive criticism at intake, single-parent household, low socio-economic status, young child age, difficulties obtaining childcare, lack of transportation, and prior abuse/neglect (Lieneman, Brabson, Highlander, Wallace, & McNeil, 2017; Chaffin et al., 2004). Families of children with PSE often have more of these risk factors than other families. Additionally, when PCIT is implemented in novel settings with novel populations, attrition is sometimes significantly higher (Pearl et al., 2012; Lyon & Budd, 2010).

1.4. Purpose and scope of the current study

The current study made use of archival records containing treatment data from PCIT sessions to add to the existing literature about PCIT for children with PSE. Specifically, researchers sought to (a) provide efficacy data for this population, (b) examine attrition rate and potential predictors of attrition in this population, and (c) evaluate the possibility that PSE may interfere with a child's response to PCIT. Because of the post-hoc nature of the analysis and the limited data about the nature of the substance exposures, it should be emphasized that this study presents an initial evaluation of PCIT for a heterogeneous community sample of substance-exposed children. PCIT is already standard of care for children with externalizing behaviors, but a systematic evaluation of the effects of PCIT on this particular high-risk population will allow providers and clients to choose treatments with greater confidence in a climate of increasing opioid and amphetamine abuse (Haight, Ko, Tong, Bohm, & Callaghan, 2016; Winkelman et al., 2018).

2. Method

2.1. Participants

Archival data from 2005 to 2016 from an urban Midwestern outpatient therapy clinic was used to identify 123 families who met criteria for the study. To meet criteria, families (a) reported that prenatal substance exposure occurred for their child, (b) were deemed appropriate for PCIT by their clinician (e.g., externalizing problems, ages 2.5–7), and (c) had granted informed consent to share their data for the purposes of IRB-approved research. Prenatal substance exposure included nicotine, alcohol, marijuana, cocaine/crack, heroin/methadone, methamphetamines, inhalants, opioids, LSD, PCP, and ecstasy, though the data was not collected in a way that allowed for reporting descriptives of each exposure. Of the 123 eligible families, 116 had outcome data. Most children in the sample were Caucasian (56.9%), and the average child age was 4.98 years (SD = 1.51 years). Data were collected on the caregiver who participated in the greatest number of therapy sessions per family, mostly mother figures (87.9%). For analytic simplicity, all female caregivers were designated as mother figures, and all male caregivers were designated as father figures. However, it should be noted that there may be reasons to expect different risk factors for children in their biological parents' care vs. other types of caregivers (see introduction and discussion). Biological caregivers were more common than other kinds of caregivers (e.g., adoptive, foster). Demographic information is displayed in Table 1.

All 116 participants' outcome data was drawn from the PCIT Behavioral Clinic, and a subset of fifty participants were referred by a specialty clinic that provides assessments for children with PSE. The PCIT Behavioral Clinic is a generalized outpatient clinic for children with externalizing or internalizing concerns that receives referrals from the community and local medical providers. The PSE specialty clinic is the only multidisciplinary clinic in the state whose primary mission is to provide developmental evaluations and treatment for children with PSE from birth to age six. Children's cognitive, motor, and speech development are assessed as well as behavioral and emotional functioning. Most referrals to the PSE specialty clinic are from child welfare agencies across the state. Children reported to have behavioral problems are referred for the PCIT Behavioral Clinic. Both clinics are housed in the same outpatient facility. Included in the chart review were all families with (a) behavioral or family concerns warranting PCIT referral; (b) a child in the PCIT age range with receptive vocabulary at or above 24 month level; (c) English speaking caregivers, and (d) a sufficiently close home address to attend treatment regularly. Participants received no payment for participating in the study, and payments made by participants for clinical services varied based on their insurance coverage.

Table 1
Demographic Information.

Variable	Percentage of Sample
Child gender	
Male	83.3%
Female	16.7%
Child Ethnicity	
Caucasian	56.9%
African American	18.1%
Hispanic	5.2%
Multiracial	15.5%
Unknown	4.3%
Insurance type	
Medicaid	72.4%
Other	27.6%
History of Abuse/Neglect	
Reported	25.9%
Not Reported	74.1%
Primary Caregiver type	
Mother	87.9%
Father	11.2%
Mother's relationship to child	
Biological mother	50.0%
Biological grandmother	14.7%
Foster mother	7.8%
Adoptive mother	19.0%
Stepmother	0.9%
Other	7.8%
Father's relationship to child	
Biological father	68.8%
Biological grandfather	18.8%
Adoptive father	12.5%

2.2. Treatment

PCIT is a family therapy for children with behavior problems that proceeds through two phases: Child Directed Interaction (CDI) and Parent-Directed Interaction (PDI). In CDI, parents learn to use positive parenting skills with their children, including positive attention and selective ignoring. The goal is to increase warmth in the parent–child relationship and promote positive mutual responding. To move from the CDI phase to the PDI phase, the caregiver must master the "PRIDE" skills. These include specific Praise for prosocial behaviors, Reflection of the child's appropriate talk, Imitation of the child's play, Descriptions of the child's ongoing appropriate behavior, and creating an atmosphere of Enjoyment. Additionally, in CDI parents are taught to avoid

verbalizations that tend to lead the play interaction, namely, Questions, Commands, and Criticisms. In PDI, parents learn to use effective discipline strategies, including effective commands, consistent limit-setting, and appropriate use of time-out. The goal is to increase child compliance without the use of harsh punishment. In both phases, a single didactic session reviews all of the specific skills of that phase, followed by in-session practice of these skills with the parent and child in a play situation and daily brief practice sessions at home. In session, clinicians observe and coach the parents from behind a one-way mirror to promote skill use and correct mistakes. Treatment completion typically requires mastery of each phase's skillset, which is determined through clinician observation with the DPICS (see measures) and predetermined standards for mastery specified in the treatment protocol (for a longer description of PCIT, see Niec, 2018).

Because the archival data did not contain a variable for whether families dropped out of treatment before completion, a novel way of estimating attrition was devised for an attrition analysis. The protocol text in the PCIT Treatment Manual (Eyberg & Funderburk, 2011) specifies that the third session of Parent-Direct Interaction (PDI) can be the last treatment session before families graduate from treatment. This is because sessions subsequent to the third session of PDI introduce skills that are not needed by some families, so additional sessions are held for those families only if other graduation criteria have not been met yet. The archival data *did* contain variables about the phase of treatment and session number, so families with PDI session 3 data were classified as "treatment completers" and families without PDI session 3 data were classified as "dropouts." This does not reflect the *true* completion rate for the sample, as some families may have continued past PDI session 3 and stopped treatment before reaching the other graduation criteria. However, this was considered the best approach with limited information without resorting to an arbitrary session-number cutoff (for example, some studies use an "adequate dose" criterion to gauge attrition, using previous studies of child therapy as an estimate for how many sessions constitute an adequate dose; see Silverman et al., 2008). The arbitrary cutoff is not ideal in PCIT clinic reviews where progress through the content of the CDI and PDI phases is based on skills mastery rather than number of completed sessions. Most PCIT research that has examined a set number of sessions has prescribed the number of sessions for progression through the phases of treatment (e.g., Chaffin et al., 2004; Bertrand, 2009; Thomas & Zimmer-Gembeck, 2007).

2.3. Measures

2.3.1. Eyberg Child Behavior Inventory (ECBI)

The ECBI is a 36-item parent-report measure of child externalizing behaviors (Eyberg & Pincus, 1999). It has two scales: the intensity scale (IS) and the problem scale (PS). The IS lists problematic behaviors and respondents indicate their frequency on a scale ranging from 1 (*never*) to 7 (*always*). On the PS, respondents indicate whether this particular frequency of the behavior is considered to be a problem (*yes* or *no*). The IS has been shown to discriminate between non-diagnosed children and children diagnosed with externalizing behavior disorders (Rich & Eyberg, 2001), and has good internal consistency (Eyberg & Pincus, 1999) and test–retest reliability (Funderburk, Eyberg, Rich, & Behar, 2003). For the current study, the ECBI was used as a measure of treatment progress, and thus was the primary outcome measure available from the clinical archival data. In some cases, the ECBI scores were not recorded; these cases were still included if they had observational data (see below).

2.3.2. Dyadic Parent-Child Interaction Coding System-IV (DPICS-IV)

The DPICS-IV is a behavioral observation coding system that is used to track changes in parent skill use and child behaviors throughout PCIT (Eyberg, Nelson, Ginn, Bhuiyan, & Boggs, 2013). Extensive rules based on semantics, syntax, and timing of speech content are used to classify units of verbal behavior exhibited by both child and parent during play interactions. Some of these units are tracked throughout treatment (e.g., labeled praise, reflection, criticism) as indicators that parents are learning the skills emphasized in PCIT. Interrater reliability for the DPICS categories varies (Kappas ranging from 0.59 to 0.85), but the reliability for categories targeted for treatment is strong (Eyberg et al., 2013). For the current study, changes in the DPICS skills were used as PCIT treatment outcomes (i.e., evidence of adequate change in parenting techniques). In some cases, the DPICS scores were not recorded; these cases were still included if they had ECBI data (see above). All DPICS data were collected by the treating clinician, so no video recordings were used and no reliability data is available for the current sample. Additionally, it should be noted that the version of the DPICS changed from third to fourth edition during the study's duration, since DPICS-IV was published in 2013. However, definitions of the parenting skills between third and fourth edition were not significantly different (see "Evolution of the Categories," Eyberg et al., 2013), and the use of composites in the current study for "Do Skills" and "Don't Skills" decreases the magnitude of any possible frequency count disparities.

2.3.3. Demographic variables

Information about the families was collected during clinical interviews with the families during service provision and coded as covariates for the treatment interaction and attrition analyses. These covariates included ethnicity, history of abuse/neglect, child age, child gender, and insurance information (Medicaid vs. other). A subset of cases (n = 41) had information about the specific substances to which the child was exposed prenatally. For each case, a substance was considered "confirmed" if one informant (e.g., foster/adoptive caregiver, biological family member, family physician, referring medical provider, caseworker, etc.) reported knowing about the biological mother's substance use during pregnancy. The informants' knowledge came from a variety of sources, such as direct observation of maternal substance use, indirect evidence of substance use (e.g., social media posts during pregnancy), and/or knowledge of drug tests (e.g., urine during pregnancy, meconium of the child after birth).

2.4. Data analysis

Multiple paired t-tests were used to determine treatment effects, using a conservative intention-to-treat design to impute missing outcome data (Higgins & Green, 2011). If the family did not complete treatment, their most recent score was carried forward and used as the outcome score. Hypothesis testing for the paired t-tests used the Bonferroni correction to avoid spurious positive results for multiple statistical tests; in this case, significance was set to an alpha level of less than 0.00625. Observed skew and kurtosis of the distributions of all outcome measures were adequate for the selected analyses. The reliable change index (RCI; Jacobson & Truax, 1991) was used to determine the proportion of the current sample that reported clinically significant changes in behavior ratings at post-treatment. Additionally, two other analyses were conducted in support of the goals of the current study: an attrition analysis and a treatment interaction analysis. To evaluate predictors of attrition in the current PCIT sample, a step-wise logistic regression was conducted using a selection of attrition predictors from PCIT research and the broader literature on therapy attrition (e.g., caregiver praise and criticism at intake, young child age, minority status, and prior abuse/neglect). To evaluate whether PSE may interact with the effectiveness of PCIT for this population, a mixed linear model was used for the subset of data that had information about maternal substance use. No alpha correction was used for the latter two analyses.

3. Results

3.1. Treatment effects

Descriptives and comparisons of all pre- and post-treatment scores

Table 2
Mean Scores for All Outcome Measures at Pre- and Post-Treatment.

	Pre-Treatment				Post-Treatment[c]					
Measure	*n*	*M*	%[b]	*SD*	*n*	*M*	%[b]	*SD*	*p*	*d*[a]
Eyberg Child Behavior Inventory										
Intensity – Mother	108	158.14	81	30.98	108	122.78	38	39.22	< 0.001	1.01
Problem – Mother	107	18.54	71	8.00	107	12.74	43	9.40	< 0.001	0.69
Intensity – Father	44	156.86	84	27.10	44	127.34	41	38.82	< 0.001	0.82
Problem – Father	44	19.98	77	8.02	44	14.00	40	10.27	< 0.001	0.82
Dyadic Parent Child Interaction Coding System										
Do Skill Composite – Mother	97	4.98	–	4.53	97	22.04	–	13.25	< 0.001	1.28
Don't Skill Composite – Mother	97	18.75	–	13.71	97	6.46	–	9.25	< 0.001	0.82
Do Skill Composite – Father	36	5.67	–	5.90	36	17.69	–	10.38	< 0.001	1.18
Don't Skill Composite – Father	36	19.92	–	15.71	36	9.50	–	13.03	< 0.001	0.90

Note: Raw scores are reported.
[a] Cohen's d = effect size between pre- and post-treatment.
[b] Percent of Eyberg Child Behavior Inventory scores in the clinical range.
[c] Post-treatment includes both completers and dropouts with the last observation carried forward.

are shown in Table 2. Both mothers and fathers reported significant reductions in the frequency and perception of specific externalizing behaviors as problematic for them. For both of the ECBI scales and for both mothers and fathers (ECBI-Intensity and ECBI-Problem), scores were significantly lower at post-treatment compared to pre-treatment. Effect sizes for these changes ranged from medium ($d = 0.69$ for mother ECBI-Problem) to large ($d = 1.01$ for mother ECBI-Intensity) based on the effect size guidelines from Cohen (1988).

Similarly, both mothers and fathers were observed using significantly more positive parenting skills and fewer negative parenting skills. Mothers and fathers showed a significant increase in Do-Skills from pre- to post-treatment, and a significant decrease in Don't-Skills from pre- to post-treatment. Effect sizes for these changes were all large ($d = 0.82$–1.28).

The reliable change index (RCI; Jacobson & Truax, 1991) was used for ECBI-Intensity and ECBI-Problem scores for both mothers and fathers to ascertain the rate of clinically significant changes in behavior ratings in the current sample. RCI is calculated using a formula that incorporates (a) the reliability of the scale, (b) the standard deviation of the current sample of scores, and (c) a constant (1.96), with the result of the formula being a change value that would occur less than 5% of the time due to measurement error alone. The criteria for clinically significant change suggested by Jacobson and Truax (1991) for a given case is (a) a change in score from pre- to post-treatment that exceeds the RCI value, and (b) a post-treatment score that is below the clinical cut-off specified by the original measure. In this study, mothers reported clinically significant change 46.3% of the time for the ECBI-Intensity scale and 12.15% of the time for the ECBI-Problem scale. Fathers reported significant change 11.36% of the time for the ECBI-Intensity scale and 38.64% of the time for the ECBI-Problem scale. When only families who completed the minimum necessary treatment content were considered (based on the content-based completion criteria), mothers ($n = 52$) reported clinically significant change 71.15% of the time for the ECBI-Intensity scale and 21.15% of the time for the ECBI-Problem scale. Completing fathers ($n = 16$) reported significant change 25% of the time for the ECBI-Intensity scale and 75% of the time for the ECBI-Problem scale.

3.2. Attrition

Using the content-based completion rate for PCIT (see methods), the attrition rate for the current archival data was 51.72%. This means that 48.28% of the sample had at least one participant who completed the third session of the second phase of PCIT. Six potential predictors of attrition were considered from the available data for a logistic regression analysis. These variables included minority status, Medicaid status, history of abuse/neglect, total primary caregiver praise at intake, total primary caregiver criticism at intake, and age of child at intake. An examination of correlations between predictors revealed that Medicaid was significantly correlated with primary caregiver criticism, and was thus removed from the analysis to minimize collinearity. The remaining five variables were entered in four steps, determined by their estimated importance from the attrition literature: (1) minority status, (2) history of abuse/neglect, (3) primary caregiver praise and criticism at pre-treatment, and (4) child age. Caregiver praise and criticism were included in a single step because they are similar variables (e.g., skill counts) representing the range of parent positive and negative responses whose significance in predicting attrition was determined by the same previous study (Fernandez & Eyberg, 2009). A total of 88 participants had data for all of these variables and were included in the regression analysis.

Results from the logistic regression are displayed in Table 3. In each step of the model, minority status was a marginally significant predictor of attrition ($p < .10$). In the final model, minority status increased one's log odds of attrition by 0.92 ($p = .049$). At each new step in the model, none of the entered variables (child age, praise/criticism, and abuse/neglect) explained significant variance in attrition beyond what was accounted for by the previous model. Additionally, none of these variables were significant predictors of attrition in the final model when controlling for minority status.

Table 3
Log Odds for Predicting Attrition Status in Step-wise Logistic Regression.

	Step			
Effects	1	2	3	4
Step 1				
Minority Status	0.81	0.80	0.87	0.92*
Step 2				
Abuse/neglect		−0.60	−0.60	−0.55
Step 3				
Praise			0.02	0.01
Criticism			0.12	0.08
Step 4				
Child age				−0.20
Nagelkerke R^2	0.05	0.07	0.08	0.10
Chi-square value	3.34	4.84	5.42	6.74
df	1	2	4	5

Note. $n = 88$. For Minority Status, all reported log odds trended toward significance in each step ($p < .10$), except for step 4.
* $p < .05$.

Table 4
Linear Growth Model with Medicaid and Polysubstance use Predicting Change in Behavior.

Label	Estimate	Standard Error	*t*-Value	P value	Random SD
Intercept	210.79	22.72	9.28	< 0.001	34.18
Time	−59.39	14.34	−4.14	< 0.001	21.49
Medicaid	7.80	20.34	0.38	0.703	NA
Polysubstance	−6.98	5.98	−1.17	0.250	NA
Time × Medicaid	−5.07	12.83	−0.4	0.695	NA
Time × Polysubstance	7.18	3.78	1.9	0.064	NA
Residual	NA	NA	NA	NA	19.71

3.3. Treatment Interaction

One question for the current study was whether the nature of PSE would interfere with a child's response to PCIT; a linear growth model was used to answer this question for a subset of the data with substance use data ($n = 41$). These 41 participants were all referred to the PCIT Behavioral Clinic by the aforementioned specialty assessment clinic. The results of the linear growth model are displayed in Table 4. A linear growth model was fit to test the treatment effect on primary caregiver-rated child behavior problems (ECBI-Intensity score) changing across pre- and post-treatment with two time-invariant covariates: Medicaid status and polysubstance use (the number of unique substances used by the mother during the gestation period). Medicaid status was included in the model due to its significant correlation with polysubstance use, and thus its possibility as a confounder for the relationship between treatment effect and polysubstance use. The main focus of level one was how individual scores of the ECBI changed linearly over time. Level two estimated the average coefficients between individuals for a specific measurement time. The analysis was performed by the statistical software R (3.5.1) package *nlme*. The α of two-tailed level of significance was 0.05. A series of models was specified, and the model deemed to be the best fit was chosen using the smallest criteria values from $-2LL$. The model comparison details are displayed in Table 5.

The Level 1 model equation presents as follows:

$$ECBI_{ti} = b_{1i} + b_{2i} \times (TIME) + u_{ti} \quad (1)$$

where b_{1i} is the intercept; b_{2i} represents the estimated slope for individual changes and u_{ti} is the residual score.

The Level 2 equations are

$$b_{1i} = \beta_{01} + \beta_{11} \times Medicaid_{1i} + \beta_{12} \times Polysubstance_{2i} + d_{1i} \quad (2)$$

$$b_{2i} = \beta_{02} + \beta_{12} \times Medicaid_{1i} + \beta_{22} \times Polysubstance_{2i} + d_{2i} \quad (3)$$

where β_{01} and β_{02} show the average intercept and slope respectively for measurement t between individual i. β_{11} and β_{21} show the relationship between *Medicaid*, *Polysubstance* and individual-level intercept. β_{12} and β_{22} show the relationship between *Medicaid*, *Polysubstance* and individual-level slope. d_{1i} and d_{2i} show the residual term that between-individual differences in the intercept and slope not explained by the covariates.

Families' average rate of change on the ECBI-Intensity was −59.39 between pre- and post-treatment. Families using Medicaid were predicted to have higher ECBI-Intensity scores, though this was not significant ($\beta_{11} = 7.80$, $p = .703$). Their average rate of change in ECBI-Intensity was lower but not significantly different from zero ($\beta_{12} = -5.07$, $p = .695$). Furthermore, the count of reported substances use was not associated with ECBI-Intensity scores at baseline ($\beta_{21} = -6.98$, $p = .25$). However, the level of substance use was marginally related to the rate of change in ECBI-Intensity scores between pre- and post-treatment ($\beta_{21} = 7.18$, $p = .064$).

4. Discussion

This study provides initial information about the efficacy and appropriateness for PCIT for children with prenatal substance exposure (PSE), and may be one of the only studies to document observed parenting behavior change for this population (see Peisch et al., 2018 for review). Regarding efficacy, PCIT resulted in (a) statistically and clinically significant reductions in caregiver-rated externalizing behaviors, (b) significant increases in positive parenting skills, and (c) significant decreases in negative parenting skills. The current study documented large effect sizes in the reduction of caregiver-rated behavior problems that are similar to effect sizes reported in other single-group PCIT studies (mother report $d = 1.31$ and father report $d = 0.83$; Thomas & Zimmer-Gembeck, 2007). Similarly, changes in positive parenting skills are close to the range of changes reported in single-group PCIT studies (ranging from $d = 0.68$ to $d = 3.11$; Thomas & Zimmer-Gembeck, 2007). The relatively smaller effect sizes found for father outcomes are common to other PCIT studies (Thomas & Zimmer-Gembeck, 2007), and may be attributable to differences in engagement between mothers and fathers in parenting programs (Niec, Barnett, Gering, Triemstra, & Solomon, 2015). In the current sample, 16 out of 44 fathers (36.37%) completed the minimum necessary treatment content compared to 52 out of 108 mothers (48.15%) and primary caregivers were mostly mothers (87.9%), so it may be that fathers would demonstrate better outcomes with better participation in treatment. It is perhaps noteworthy that the current sample was from a working outpatient clinic rather than a research unit, and no extraordinary efforts (e.g., travel reimbursement, child-care on-site, weekend hours) were made to reduce barriers or boost engagement. It is likely that extra efforts such as extended clinic hours or childcare for siblings may be needed to increase participation of both caregivers in two-parent households, and specifically to include more fathers.

Attrition was shown to be a challenge for the current study, but this outcome may not have been specific to children with PSE per se. The overall attrition rate (51.72%) is higher than what is commonly reported in clinical trials of PCIT (18–35%; Thomas & Zimmer-Gembeck, 2007), but it may be more similar to community implementations of PCIT. For example, Lyon and Budd (2010) evaluated PCIT in a community mental health clinic with underserved youth and reported an attrition rate of 75%, even though families that did not complete treatment showed some evidence of increased positive parenting behaviors and reduced behavior problems. Similarly, Pearl et al. (2012) evaluated PCIT in a community mental health clinic with high-risk families and reported an attrition rate of 67%, citing a number of complicating factors that were related to premature termination (e.g., family loss, substance use, etc.). However, these studies had more stringent definitions of attrition, so caution should be utilized when making these direct comparisons. The current study was conducted in

Table 5
Linear Growth Model Comparisons.

	Model	AIC	BIC	$-2LL$	*df*	χ^2	*p* value
1	Time + Medicaid + random intercept + random slope	915.52	935.7	449.76	8	4.92	0.099
2	Time + Polysubstance + random intercept + random slope	911.08	931.25	447.54	8	0.17	0.917
3	Time + Medicaid + Polysubstance + random intercept + random slope	914.9	940.12	447.45	10		

Note. χ^2 is the likelihood ratio test between model 1 and 3; or between model 2 and 3.

the context of routine mental health care and also featured a population of children that may be considered high-risk, so a relatively higher attrition rate may be expected. However, it is worth noting that recent PCIT research has documented significant improvements in behavior even in cases of premature termination (Lieneman, Quetsch, Theodorou, Newton, & McNeil, 2019).

The attrition rate may have attenuated the level of clinical significance attained for the full sample, but there may be other factors involved. For example, it would seem that the 46.3% clinical significance rate for mother-rated frequency of behavior problems mirrors the 48.15% treatment completion rate for mothers, but when only treatment completers were considered, only 71.15% reported clinically significant change. Thus, while most families needed to complete treatment to report significant improvements in child behavior, some reported this change despite not finishing, and some did not report a large *enough* change despite meeting the minimum completion definition. Nevertheless, the proportion of clinically significant change for those who completed treatment was generally high for the frequency of behaviors for mothers. The number of perceived problem behaviors, however, did not change as consistently (only 21.15% clinically significant change for mothers who completed treatment). It may be that children with PSE have developmental deficits that are perceived by their caregivers to be lifelong and thus still problematic after treatment, despite a reduction in the frequency of these behaviors. It may also be that problem behaviors in children with PSE change in perceived frequency after PCIT but not perceived severity. It is worth noting that the average ECBI-problem score changed from being above-cutoff to below-cutoff, but did not achieve reliable change using the RCI parameters. Perhaps the RCI statistic may be too stringent for a measure like the ECBI-problem scale, given its relatively restricted range of scores. Treatment fidelity data may be helpful for future research in order to determine whether clinical significance findings are due to a lack of fidelity (e.g., terminating treatment before behavior problems were sufficiently low in frequency) or other factors (e.g., treatment response difficulties for this particular population).

The treatment interaction analysis raised the possibility that increased substance use leads to a reduced treatment response, but more data are needed to explore this relationship. The relationship between polysubstance use and the change in ECBI score was only marginally significant in the subset of specialty clinic data, and there are multiple competing explanations for this effect that were not taken into account by the present correlational analysis. For example, individuals who use additional substances may also have exposure to additional stressors, including violence, malnutrition, poverty, and comorbid mental and physical illnesses (Conway et al., 2013). Many of these factors carry their own risk pathways for the developing brain, and may be responsible for any treatment interaction effects observed in the current limited analysis. Additionally, there was no information available about dosage of any of the substances, which might also complicate the relationship between polysubstance use and treatment response.

4.1. Limitations

There were several limitations for this study. First, many instances of incomplete or limited data, while typical of data from a clinical setting, make it difficult to interpret some of the results. For example, the attrition analysis used a post-hoc decision process to differentiate completers from non-completers, which may not represent the “true” attrition rate accurately. Second, children in the sample were mostly male (83.3%), which may threaten the generalizability of the findings. This ratio is in line with findings that boys are over-represented in referrals for disruptive behavior, but may be surprising given that all children are equally at risk for PSE.

There were several research design limitations that may be addressed with future research. Due to the nature of the archival data, there were insufficient non-clinical assessment scores to construct a control or comparison group. Limited outcome measures were available for the cases analyzed, although these measures did include a well-validated parent-report measure of child behavior with strong psychometrics (ECBI) and a behavior observation measure (DPICS) to supplement parent ratings. Lack of systematic treatment fidelity data limits the certainty of uniform treatment standards, which could attenuate clinical effectiveness results. However, clinic staff hold regular reliability checks for DPICS coding skills and senior clinicians monitor cases for fidelity to the treatment model through regular supervision. Additionally, all analyses were conducted post-hoc, although efforts were made to reduce Type I error (e.g., Bonferroni correction, conservative model selection, limited number of post-hoc analyses, etc.). Finally, information about the specific drugs used by polysubstance users was unavailable. Given the rising incidence of polysubstance abuse for certain substances (Haight et al., 2016; Winkelman et al., 2018), it is urgent that future research continues to evaluate strong interventions like PCIT using more rigorous designs (e.g., randomized controlled trials) for this deeply at-risk population.

4.2. Conclusion

The current study represents the first evaluation of standard PCIT for children with PSE in a community treatment context, with promising results. Children with PSE show large improvements in challenging behaviors when they participate in PCIT with their caregivers, and caregivers show large improvements in parenting behaviors. These improvements are comparable to other diagnostic groups reported in the PCIT literature in general, and while the attrition rate is problematic, it does not appear to be significantly different from what is commonly observed in community-based PCIT studies. Very little can be said of the complicating effects of PSE on treatment response at this time; if anything, there is reason to be hopeful about PCIT’s generalizability to a population in need of evidence-based treatments. Providers serving families of children with PSE who present with externalizing behavior problems have preliminary evidence that PCIT can be an effective treatment for these clients.

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CRediT authorship contribution statement

Ryan Egan: Conceptualization, Methodology, Formal analysis, Data curation, Writing - original draft, Writing - review & editing. **Carisa Wilsie:** Conceptualization, Methodology, Formal analysis, Data curation, Writing - review & editing, Supervision, Project administration. **Yutian Thompson:** Methodology, Formal analysis, Writing - original draft, Writing - review & editing, Visualization. **Beverly Funderburk:** Conceptualization, Methodology, Writing - review & editing, Supervision, Project administration. **Elizabeth Bard:** Data curation, Writing - review & editing, Supervision, Project administration.

Declaration of Competing Interest

The first two authors and the last two authors are PCIT therapists/trainers. The 4th author receives royalties for PCIT treatment protocols

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