

COVER LETTER

Full study title: Early Parenting Intervention Comparison (EPIC)

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Comparing Two Parent Programs for At-Risk Families

1. Abstract

Scientists and economists agree that the most cost-effective investments we can make as a society are those targeting children during the first 5 years of life, particularly for children living in urban poverty. Although poverty and its associated stressors are difficult to change, research shows that high quality parenting early in life can substantially buffer the negative effects of socioeconomic adversity on children's development. However, we do not know the most cost-effective ways to improve parenting quality among highly stressed, impoverished families of young children, a disproportionate number of whom are African American. This problem is further compounded by the fact that the evidence-based parenting programs typically used to help low-income families were originally developed and tested on White, middle-class parents. The purpose of this study is to test the equivalence of two evidence-based parent training (PT) programs, Parent-Child Interaction Therapy and the Chicago Parent Program for improving parenting quality and reducing behavior problems in young children (2-5 years old) living in urban poverty.

Parent-Child Interaction Therapy (PCIT) is a well-established PT program that uses individualized parent coaching to treat behavior problems in preschool children. In contrast, the Chicago Parent Program (CPP) is a novel group-based PT program developed with an advisory board of African American and Latino parents. Although both programs have been shown to be highly effective for reducing behavior problems in preschool children, when compared with Parent-Child Interaction Therapy, the group-based Chicago Parent Program may be cost-effective and yield greater program satisfaction and engagement among African American parents from low-income urban communities.

Using a randomized experimental design, 300 parents of 2-5 year old children (predominantly African American and economically disadvantaged) referred for behavior problems to the Family Center at Kennedy-Krieger Institute will be randomized to Parent-Child Interaction Therapy (PCIT; n=150) or Chicago Parent Program (CPP; n=150). Data on child behavior problems, parent discipline strategies, parenting self-efficacy, observed parent behavior, parent stress, and depression will be obtained from all participants at baseline and post-intervention assessments. Social risk will be assessed at intake. Parent satisfaction, attendance, and engagement in the intervention will be obtained at post-intervention. Clinical costs related to PT and non-PT treatment will be measured monthly. This innovative study will be the first to compare the effectiveness, cost, and social validity of a brief treatment designed with and for ethnic minority parents of young children against a well-established treatment considered to be the "gold standard." Determining whether a PT treatment can yield comparable effects for low-income, racial/ethnic minority parents of young children but at less cost, in less time, and with greater social validity is of significant public health importance.

2. Objectives: To compare the:

1. Effectiveness of PCIT and CPP for reducing behavior problems in a predominantly African American sample of children 2-5 years old from low-income communities. It is hypothesized that CPP will be equally as effective as PCIT for reducing child behavior problems based on parent report and observation.
2. Effectiveness of PCIT and CPP for improving parenting behavior and self-efficacy among a predominantly African American sample of parents of 2-5 year old children from low-income communities. It is hypothesized that CPP will be equally as effective as PCIT for improving parent discipline, self-efficacy, and observed parenting behavior.
3. Perceived social validity of PCIT and CPP based on parent satisfaction scores, treatment attendance, and parent engagement ratings (i.e., active parent participation in the intervention)

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- sessions). It is hypothesized that parents in the CPP condition will (a) attend a higher percent of PT sessions, (b) be more engaged, and (c) report higher satisfaction than parents in PCIT.
4. Cost and consequences of PCIT versus CPP using a cost-consequence analysis as they relate to treatment effect size (improvement from baseline), clinical costs, and perceived social validity. CPP is hypothesized to yield comparable effects but at less cost and with greater satisfaction.
 5. Degree to which parent stress and depressive symptoms moderate intervention effectiveness for PCIT and CPP. It is hypothesized that there will be no difference between PCIT and CPP in the moderating effects of baseline parent stress and depressive symptoms on parent or child behavior.

In addition, **one exploratory aim will be tested:** Is PCIT more effective than CPP for some families? It is possible that PCIT is more effective for families with specific risk factors. We will examine differences in PT program effects based on baseline child behavior problems (severity of behavior problems; externalizing versus internalizing problems) and degree of family social risk.

3. Background:

Parent-Child Interaction Therapy: Description, Critique, and Justification. Parent-Child Interaction Therapy (PCIT) was developed in the early 1970's and its effectiveness supported by over 25 years of research. There are two phases to PCIT: child-directed interaction and parent-directed interaction. During child-directed interaction, parents are taught to follow the child's lead during play and coached to use skills such as praise, encouragement, descriptive commenting (i.e., describing aloud what the child is doing), and imitation to engage the child without controlling the interaction. This phase of treatment is intended to build the parent-child relationship and create a foundation of positive experiences for the child and parent. Once parents' skill levels meet a predetermined set of mastery criteria (based on clinician observation during the PCIT session), they begin the phase of parent-directed interaction which focuses on child behavior management. In this second phase, parents are taught to provide clear, direct commands, and to follow through on commands using consequences for compliance (e.g., praise) and noncompliance (e.g., logical consequence or time-out). Parents' progress is assessed at each session and treatment progression is guided by the rate at which parents master each set of new skills. According to published research, most families complete the full course of treatment in 10-20 weekly, 1-hour clinic-based sessions. However, clinicians using PCIT with ethnic minority, low-income families report longer courses of treatment that can extend up to 8 months if mastery attainments require more sessions.

A unique aspect of PCIT is the way parents are coached during the treatment sessions. During the sessions, parents wear a bug-in-the-ear hearing device and are guided on their use of the skills by a clinician who is observing the parent-child interaction from behind a one-way mirror. This strategy requires that clinical facilities have a one-way mirror and that the clinicians are highly trained to be active, directive, and assertive. A strength of PCIT is that parents directly practice these new techniques with the child under the tutelage of a trained clinician and new skills are not introduced until prior skills have been mastered.

Like other evidence-based PT programs, PCIT has led to substantial improvements in parent and child outcomes. However, among children with very high rates of behavior problems, researchers have reported the strongest effects with PCIT, with effect sizes ranging from .61 (parent reported child behavior problems) to 5.67 (observed parent behavior) when compared to untreated waiting-list controls. Studies have also shown that most children retain improvements 3 to 6 years post-treatment. Based on the strength of these data, PCIT is considered to be the "gold standard" among individually-delivered PT. It is also one of the most widely disseminated PT programs in the United States, with "PCIT laboratories" for training graduate students and clinicians offered at 8 major universities.

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Although impressive, these data only reflect outcomes for “completers,” parents who start PCIT and do not drop out before they have completed the program. In a recent study of attrition from PCIT, 36% of parents prematurely stopped attending PCIT and the most common reason cited by parents was “disagreement with the treatment approach.” In addition, like many other PT programs, the strongest predictor of premature termination was low socioeconomic status. These data suggest that PCIT may not be viewed as useful or relevant by many economically disadvantaged parents. In addition, since most PCIT studies include samples that are predominantly non-Latino White, it is unclear how effective this program is among low-income ethnic minority families. Although there have been some efforts to adapt PCIT to other populations, rigorous trials of these adaptations have not been conducted. In sum, like many treatments identified as “gold standards,” its validity for low income, ethnic minority populations has not been sufficiently evaluated.

The Chicago Parent Program: Description, Critique, and Justification. Funded by a grant from the NINR, the Chicago Parent Program (CPP) was developed in 2002 specifically to address the gap in evidence-based PT programs for ethnic minority parents. Created in collaboration with an advisory group of African American and Latino parents, the CPP was designed to improve parenting and reduce child behavior problems using strategies that are culturally and contextually relevant for ethnic minority parents of young children living in low-income urban neighborhoods.

The CPP is designed to be delivered in 12 weekly 2-hour parent group sessions and teach the same strategies taught in PCIT, with the first 4 weeks focused on building a positive relationship with the child and the second 4 weeks focused on child behavior management. The last 4 weeks center on stress management, problem-solving skills, and skill maintenance, concepts that are interwoven in PCIT individual sessions.

There are several unique features of the CPP. Because it was designed to be culturally and contextually relevant for ethnic minority parents from low-income urban neighborhoods, some parenting strategies common in all PT programs are described or managed differently in CPP. For example, parent-child play—a centerpiece of most PT programs—is not highlighted as an essential strategy for building a good relationship with their child. This is because advisory board parents considered parent-child play to be a somewhat frivolous activity valued by middle-class parents with leisure time. Instead, CPP describes the importance of “child-centered time,” defined as time parents spend with their children focused on their interests but which could occur in a variety of non-play situations (e.g., cooking together, grocery shopping, bedtime stories).

Another difference is how new parenting skills are taught. In contrast to PCIT, CPP uses a combination of video vignettes and parent group discussion to teach behavioral management techniques. These vignettes (n=160) were created with input from the advisory board and all families shown in the vignettes (59% African American, 25% Latino) were recruited from Chicago neighborhoods. Vignettes show parents interacting with their children and managing misbehavior at home, in a grocery store, and a Laundromat. Thus, the CPP is designed so parents can watch and critique parent-child models similar to themselves, engaged in situations they can relate to. This modeling helps parents visualize the behavior they are working towards or, in some cases, parent behavior that inadvertently reinforces children’s misbehavior. Role-play exercises are built into CPP sessions to give parents direct opportunities to rehearse new strategies with the group’s support. However, these exercises include only parents; unlike PCIT, children are not included in the group sessions. Weekly homework is assigned to increase practice opportunities, then discussed at the following PT session.

CPP groups are led by two trained group leaders using a standardized manual that lists specific discussion questions associated with each video vignette. Typically, 8-12 parents are enrolled in a 12-session CPP group (unlike PCIT, parents are encouraged to bring other family members to the CPP

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sessions for support). The vignettes are designed to stimulate discussion and problem-solving around each of the vignettes and the group leaders help parents tailor strategies to meet their childrearing goals. Although CPP group leaders are experts about the child behavior management strategies and program principles, they are trained to view parents as the experts about their own children. Thus, the parent groups are designed to help parents (a) clarify their childrearing goals and (b) select those strategies they believe will be most effective and most likely to advance their childrearing goals. This aspect of CPP lies in contrast to PCIT, where treatment progress is dependent on parents mastering each skill taught in the program before acquiring a new skill.

The CPP was rigorously evaluated in a randomized trial of 253 parents of 2-4 year old children in 7 childcare centers serving low-income families in Chicago (59% African American, 33% Latino). Parents in the CPP condition used less corporal punishment and had more positive observed interactions with their children at 1-year post-intervention when compared to control parents. In addition, their children exhibited significantly fewer behavior problems during observed parent-child interactions. Parents who attended at least half of the CPP sessions also reported higher parenting self-efficacy, more consistency in their discipline, and fewer behavior problems at home. In addition, teacher-ratings of children's behavior problems in child care showed significant improvements. Parent stress and depression did not moderate these outcomes. Moreover, consumer satisfaction was high; parents reported that they would highly recommend (85%) or recommend (15%) the program to other parents.

To date, the published research supporting the efficacy of the CPP has focused mainly on community samples where most children do not have high rates of behavior problems. However, among those children with very high baseline behavior problem scores (T scores >60; CBCL teacher version), 50%-86% of the CPP children improved to within normal limits at post-intervention compared to only 29%-36% in the control group. This suggests that CPP is effective for children with very high rates of behavior problems. In addition, this study used the more conservative intent-to-treat design. As a result, CPP effect sizes, though substantial for prevention studies (.24-.64), are smaller than those found in the PCIT treatment studies (.61-.5.6). Nonetheless, these results are the first to show sustained reductions in observed child behavior problems in a community sample of young, predominantly African American children from low-income urban neighborhoods following PT. Moreover, new research shows replication of these results. Together, these data provide strong evidence that the CPP is effective for this vulnerable population of families.

4. Study Procedures

- a. Design: This equivalence study will use an experimental design with randomization of parents seeking behavioral treatment for their 2-5 year old children at the Family Center (FC) in East Baltimore, MD. Equivalence studies are used to determine whether a novel treatment or health delivery model, that might be less costly or more acceptable to the treatment population, is at least as effective as another more well-established treatment. It is important to note that the participants in this study, who experience multiple adversities associated with urban poverty and mental health problems, may require more therapeutic services than just PT. As a result, parents and children may receive additional treatment (e.g., individual therapy, medication) other than PT. However, PT treatment (PCIT or CPP) will be randomly assigned and all additional therapies provided to the participating parent or child at the Family Center or other agencies during the course of this study (type, amount, and cost) will be accounted for in the study and included as co-variables in the analyses. In addition, the effect of parent depression and stress on PT outcomes will be evaluated. The strengths of this design include (a) the ability to determine whether families exposed to one PT program need more additional treatment than families exposed to the other PT program, (b) the ability to estimate the costs of additional therapy, (c)

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greater buy-in from clinicians who may be concerned that randomization will negatively affect treatment outcomes for their families, and (d) enhanced external validity of the study.

This study will use a block randomization procedure to facilitate the initiation of parent groups without lengthy waiting periods. Each block will consist of the next 19 eligible parents (estimated recruitment time=3-4 months). Following intake assessment by a FC clinician to determine study eligibility, parents who meet the inclusion criteria will be invited to participate in the study. Parents who state interest in participating and agree to have their name given to the Project Director will meet individually with the Project Director (to be hired) who will describe the study and obtain informed consent. Documentation of parent's agreement to be contacted by the Project Director will be placed in the child's medical record.

- b. Study duration and visits: Following consent, parents will be assigned to the appropriate block consisting of the next CPP group or the next available PCIT therapist. Participating parents and children will complete three assessment phases: baseline, 4 months post-baseline, and 9 months post-baseline. Each assessment phase includes parent-report surveys on child behavior problems, parenting self-efficacy, parent discipline strategies, stress, depressive symptoms, and attachment, and a 15- minute videotaped parent-child free play interaction (Dyadic Parent-Child Interaction Coding Systems; DPICS), followed by a clean-up session. Videotaped DPICS assessments will be coded by research colleagues at the University of Iowa (Sharon Tucker, Ph.D.) A Data Use Agreement will be obtained between Drs. Tucker, University of Iowa and Gross, Johns Hopkins School of Nursing. Assessments typically require 45-75 minutes at each phase. All measures are described in Table 1 below.

Table 1. Parent-Child Variables, Measures, Informant, Items, Assessment Time-points*, Reliability, Validity

| Variables | Measure(s) | Informant | # of Items | When Assessed | Reliability | Validity Evidence |
|---|--|-----------|------------|-----------------------|--------------------------------|-------------------|
| Child Behavior Problems (parent) | Child Behavior Checklist (CBCL/1½-5) (Externalizing Scale & Internalizing Scale) | Parent | 99 | T1, T2, T3 | .86-.89 | [40; 41] |
| Child Behavior Problems (observed) | Dyadic Parent-Child Interaction Coding System (DPICS) (non-compliance, destructives, physical negatives, smart talk, cry, whine, yell) | Observer | 7 | T1, T2, T3 | .73 | [22; 57; 58] |
| Parent Self-Efficacy | Toddler Care Questionnaire (TCQ) | Parent | 38 | T1, T2, T3 | >.93 | [22; 57; 59; 60] |
| Parent Discipline | Parenting Questionnaire (PQ) (Warmth, Following Through, Corporal Punishment subscales) | Parent | 50 | T1, T2, T3 | .68-.84 | [22; 61] |
| Parent Depression | Center for Epidemiologic Studies Depression Scale-Revised | Parent | 20 | T1, T2, T3 | >.85 | |
| Parent Attachment | Attachment Style Questionnaire | Parent | 40 | T1 | Test-retest .75-.80 | |
| Parent Behavior | DPICS (Praise, Commands, Physical Coerciveness, Critical Statements, Positive/ Negative Affect) | Observer | 10 | T1, T2, T3 | .88-.90 | [22; 57; 58] |
| Social Validity: parent satisfaction w/ PT | Parent Satisfaction at end of program | Parent | 4-12 | T2 –CPP T3-PCIT | NA (items analyzed separately) | [34; 55; 57] |
| Social Validity: Degree to which parent actively participated in PT | Parent Engagement Scale | Clinician | 7 | T2-CPP T3-PCIT | .87 | [35] |
| Social Validity: % of recommended PT sessions parent attends | % of 12 CPP sessions attended; % of clinician-recommended PCIT sessions attended | Clinician | 1 | After each PT session | NA | |
| Clinician Satisfaction | Perceived satisfaction with performance, PT match with parent needs, flexibility of PT model | Clinician | 3 | After each PT session | NA (items analyzed separately) | New measure |

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|--|---|-----------------------|----------------|-------------------|---------|------------------------|
| | | | | | | created for this study |
| **Assessment of parent psychosis/thought disorder | Clinician assessment and/or psychosis subscale from B-24 | Clinician | 5 | Intake assessment | 0.77 | |
| Parent Stress | Parenting Stress Index-Short Form (PSI) (parent distress, parent-child dysfunction, child difficulty) | Parent | 36 | T1, T2, T3 | .80-.91 | [64; 65] |
| **Family Social Risk | Summed composite of poverty, < HS education, single parent, depressed, > 4 people in the home, teen parent, unemployed, parent substance abuse hx | Parent with clinician | 8 yes/no items | Intake | .81 | [66] |
| **Medical, psychosocial, and mental health history and diagnoses | Diagnostic Interview and Psychosocial History | Clinician | | Intake | | |
| **Significant developmental delay+ | Ages & Stages Questionnaire, 3 rd ed. | Parent with clinician | | Intake | .94 | [50] |

* T1=baseline, T2=4 months post-baseline, T3=9 months post-baseline; + used to establish eligibility

** Standard clinical practice assessments.

Parents randomized to PCIT will be scheduled for weekly individual sessions with the target child led by trained PCIT therapists. Each treatment session is 1 hour. Parents randomized to CPP will be randomized to a weekly parent group led by trained CPP therapists. Each CPP session is 2 hours, scheduled on week-day evenings. Target children do not participate in CPP groups; therefore, childcare will be provided at no charge to facilitate parent attendance. Though PCIT and CPP each prescribe approximately 24 hours of treatment exposure, PCIT occurs over a longer period of time (usually 6-8 months versus CPP which occurs over 3 months). This is because (1) PCIT sessions are 1 hour shorter, and (2) PCIT treatments are delayed when parents cancel or do not show up for appointments whereas CPP group sessions continue even if some parents do not attend. All CPP sessions will be audio recorded and a random selection of CPP sessions will be reviewed for fidelity by Dr. Susan Breitenstein at Rush University. A random number of PCIT sessions will be videotaped and reviewed for fidelity by a research colleague certified in PCIT who works at the University of Maryland, Kelly O'Brien, PhD. A data use agreement will be obtained between Dr. Gross and Dr. O'Brien and Dr. Breitenstein.

- c. Blinding: parents and therapists cannot be blinded to treatment condition. Research assistants trained to code video recorded parent-child free play and clean-up sessions will be blind to treatment condition and hypotheses.
- d. Participants will have full access to routine care at the Family Center. If a PCIT therapist determines at the beginning of the session that the parent is in crisis (e.g., reports severe depression, domestic violence), or the parent requests using the session to discuss a non-child related crisis, they may decide to use that session for crisis intervention. This session will be documented as a non-PT session and accounted for in the analysis of total PT and non-PT treatment exposure. If the CPP therapist determines that a parent in the parent group is in crisis, or a parent requests to discuss a non-child related crisis, that therapist will meet with the parent after the CPP group to discuss scheduling a separate session.
- e. There is no control or placebo group. Participants in both conditions receive an evidence-based parenting program delivered by trained therapists.
- f. Definition of treatment failure or participant removal criteria: Participants will be removed from the study if they (a) lose custody of the target child during the course of treatment, (b) attend treatment sessions under the influence of drugs or alcohol, (c) become actively psychotic or aggressive during treatments, or (d) are uncooperative/noncompliant with the baseline research evaluation or with the

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Time 2 and Time 3 evaluations. Participants who are removed from the study for these reasons will still be eligible to receive all other treatments routinely available to them at the Family Center.

- g. Description of what happens to participants receiving therapy when study ends or if participation in the study ends prematurely: Participants will remain eligible to receive all other treatments normally available to them at the Family Center.

5. Inclusion/Exclusion Criteria

Parent Inclusion criteria are (a) “parent” is the biological or adoptive parent or the legal guardian for the target child being treated at the Kennedy Krieger Institute, (b) parent is English- speaking, (c) child is 2-5 years old, (d) child is brought to the Family Center by the parent/legal guardian because of externalizing or internalizing behavior problems, and (e) willing to be randomly assigned to PCIT or CPP. There will also be 13 clinicians participating in this study and we expect all of them to be female.

Therapist inclusion criteria are (1) employed by the Family Center, (2) graduate-prepared licensed social worker, psychologist, professional counselor or equivalent, and (3) completed necessary training to provide PCIT or CPP

Exclusion criteria are parent(s) who (a) has (have) severe mental illness that would interfere with their ability to participate in PT (measured by the Psychosis Subscale of the Basic-24 or diagnostic intake clinician assessment) and/or (b) is (are) actively using drugs or alcohol, based on clinician assessment at intake. Foster parents or relatives without legal status for the child are excluded since they may not be able to complete the study.. Children who are actively suicidal, psychotic, or who have significant developmental delay (i.e., fail developmental screening using Ages and Stages Questionnaire at intake), congenital, genetic, or sensory abnormalities that interfere with the child’s understanding, cooperation, and/or participation in PCIT or CPP will be excluded and referred for appropriate treatment services or hospitalization. Children diagnosed with autism or Pervasive Developmental Disorder will also be excluded since there is no evidence that CPP or PCIT is effective with these populations.

6. Drugs/ Substances/ Devices

- a. NA
- b. NA.
- c. NA

7. Study Statistics

- a. Primary outcome variables: Child behavior problems (parent report and observed from video recorded parent-child play/clean-up), parenting self-efficacy, parent discipline, parent behavior (observed from video recorded play/clean-up), parent satisfaction, parent engagement in the intervention, parent attendance in PT sessions.
- b. Secondary outcome variables: cost variables are those related to (1) time required to administer PT (including lost time for missed appointments) and additional non-PT therapy services used by parent or child (i.e., individual therapy, medications); (2) therapist time, (3) parent time, (4) childcare provided during CPP sessions; (5) space (including one-way mirror).
- c. Sample Size and Statistical Plan: Sample size in this equivalence study is designed to determine whether CPP is as effective as PCIT for the targeted clinical population (i.e., outcomes do not differ clinically or statistically). We used CBCL scores (child behavior problems) to estimate the sample size positing the null hypothesis that the absolute difference in the post intervention means between the CPP and PCIT groups will be > 0.5 standard deviations (i.e., > 5 point difference on the CBCL). The alternative hypothesis is that the absolute difference in the two means is less than or equal to 0.5

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standard deviations. We will use the more conservative two-sided test. Thus, with 300 participants (150/condition) we will have 99% power to detect this difference using a two-sample comparison of means with $\alpha=0.05$.

Hypothesis testing will mainly be conducted using repeated-measures MANOVA. Should the MANOVA be significant, univariate ANOVA will follow to identify the source of those differences. MANOVA was determined to be a more desirable approach than random regression models because MANOVA corrects for multiple tests of hypotheses. All baseline difference analyses and hypothesis testing will be conducted using 2-tailed tests and $\alpha=.05$ (except tests to examine baseline differences between conditions, which will use .01 to correct for the multiple tests of hypotheses).

d. Early stoppage rules. Interventions will be discontinued if (a) more than 50% of parent participants in either condition report dissatisfaction on consumer satisfaction surveys with their assigned intervention or (b) more than 50% of child participants' CBCL scores (in either condition) worsen from baseline by $> .5$ SD. In this event, the research team will immediately convene with the members of the DSM committee to carefully review the protocol, reasons for dissatisfaction, and recommendations for change. A data safety and monitoring committee will meet early in the first year of the study to make additional recommendations for stoppage rules.

8. Risks

- a. Medical risks. Parent-Child Interaction Therapy and the Chicago Parent Program are psychosocial parent training interventions that have shown no evidence of medical risk. The major risks of this study are disclosure of confidential information and discomfort with the personal nature of some of the survey questions. These risks are no greater than what parents would be exposed to in a mental health treatment setting.
- b. Efforts to minimize risk. Efforts have been taken to minimize risk through appropriate training of research and clinical staff and the use of random number subject identifiers. All therapists have licensed and experienced therapists and have completed the appropriate training (PCIT or CPP).
- c. Plan for reporting unanticipated problems/study deviations. A Data, Safety, and Monitoring Plan will be comprised of 6 members who will monitor (a) the conduct of the study, (b) recruitment/retention rates, (c) participant satisfaction, (d) the safety of participants, and (e) the validity and integrity of the data. The committee will include the PI (Gross) and the Co-PI (Belcher) and four additional members who are not members of the research team: an experienced child psychiatrist, a biostatistician, a clinical trial expert, and a community member. If an adverse event occurs, the event will be reported within 48 hours to the Johns Hopkins University School of Medicine IRB and the NIH Project Officer using the JHU IRB Protocol Event Report with supporting documentation.
- d. Confidentiality: The parent/child participants are all patients of the Family Center and will be provided with the same confidentiality afforded to all patients receiving care at the Family Center at Kennedy Krieger Institute. We will also apply for a Certificate of Confidentiality. Clinicians will not be required to provide personal information as a part of this study.
- e. Financial risks to the participants: Parent training is considered routine care and will be billed to the child's insurance. Childcare will be paid by a grant. There is no financial risk associated with parents' participation in this study.

9. Benefits

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All participants will receive treatment and both PT treatments offered in this study have been shown to be effective for improving parenting behavior and reducing behavior problems in young children. The potential benefits include: (1) improved child behavior, (2) parent use of more positive child management strategies, (3) improved quality of parent-child relationships, and (4) increased parenting self-efficacy. Since parents in the study will be able to access additional treatments as needed, it can be expected that parents and children who participate in this study will experience improved mental health and wellbeing. Therapists will receive confidential support and supervision for their work with the families.

10. Payment and Remuneration.

Parents who participate in this study will receive the following:

- \$30 gift cards for each fully completed set of assessments (\$90 total for all 3 assessment phases)
- A book for the target child after each completed assessment phase (value approximately \$5)
- If participants complete all 3 assessment phases, they will also receive a free copy of their video-recorded parent-child play sessions (collected as part of the assessment battery)
- Free childcare at the Family Center for children not involved in the study treatment sessions during the time their parent is attending the study treatment.
- If parent groups are scheduled during the dinner hour (between 5:30 and 8pm), parents and children in the CPP condition will receive free dinner during the study treatment sessions
- Taxi vouchers for participants to and from study treatment sessions

11. Costs

There are no costs associated with participation in this study.