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A Pilot Randomized-Control Trial of a Parent-Child Intervention targeting Emotion Dysregulation in Children with ASD

A Dissertation Submitted in Partial Satisfaction of the Requirements for the Degree Doctor of Philosophy in Counseling, Clinical, and School Psychology

By

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Publications

1. Gonzalez, J.C., **Klein, C. C,** Barnett, M. L., Schatz, N. K., Garoosi, T., Chacko, A., Fabiano, G. A., (2023) Intervention and Implementation Characteristics to Enhance Father Engagement: A Systematic Review of Parenting Interventions. *Clinical Child and Family Psychology Review*.

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Abstract

A Pilot Randomized-Control Trial of a Parent-Child Intervention targeting Emotion Dysregulation in Children with ASD

By

Corinna C. Klein

Background: Children with autism spectrum disorder (ASD) experience high rates of comorbid diagnoses, including both externalizing and internalizing disorders. Emotion regulation has been posited as a possible mechanism underlying many emotional disorders, and children with ASD have higher rates of emotion regulation challenges than their typically developing peers. It has been recommended that treatments addressing both emotion dysregulation and comorbidities in children with ASD be developed. Additionally, considering the needs and preferences of caregivers when developing novel interventions is critical.

Objective: This feasibility pilot randomized control trial investigated initial feasibility, acceptability, and preliminary clinical outcomes of a novel adaptation of Parent-Child Interaction Therapy (PCIT) delivered daily over two weeks via telehealth, in which the second phase of treatment is replaced with an emotion-focused module.

Method: Participants included 22 young children aged 2 through 7 (M = 4.64, 72.7% male) and their caregiver(s). Families were randomized to receive either an intensive, telehealth version of PCIT's standard modules, Child Directed Interaction (CDI; relationship enhancing) and Parent-Directed Interaction (PDI; discipline and limit-setting), or an emotion-

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focused module (ED) instead of PDI. Child and caregiver measures were collected at pre, mid, post, and 1-month follow-up.

Results: Recruitment, retention, assessment collection, and caregiver satisfaction were adequate for the study. CDI+PDI was superior to CDI+ED on improvements in child disruptive behaviors and child dysphoria. CDI+PDI resulted in large effects on multiple child outcomes (dysphoria, reactivity, and disruptive behaviors) and on caregiver stress. CDI+ED resulted in improvements in caregiver cognitive reappraisal, one emotion regulation strategy. **Conclusion:** Internet-delivered intensive PCIT may be a helpful intervention for young children with autism, that is acceptable to caregivers, however PDI is likely a necessary treatment component for quick treatment gains, which cannot be substituted with emotionfocused content. Feasibility of the pilot study was demonstrated and can inform a larger trial.

A Pilot Randomized-Control Trial of a Parent-Child Intervention targeting Emotion Dysregulation in Children with ASD

Purpose

One in 54 children in the United States are estimated to have autism spectrum disorder (ASD) (Maenner et al., 2020). ASD is prevalent across race, ethnicity, and socioeconomic status, despite different prevalence estimates between groups and varying rates of early diagnosis (Maenner et al., 2020). Ninety-two percent of children with ASD meet criteria for another diagnosis, including attention deficit hyperactivity disorder, oppositional defiant disorder, anxiety, and other mood disorders (Brookman-Frazee et al., 2018). Many of those who do not meet full diagnostic criteria for a mood disorder still present some internalizing symptoms that complicate their clinical presentations (Brookman-Frazee et al., 2018). Identifying treatments that address these comorbidities in ASD populations at an early age is important to precluding deleterious trajectories and supporting children with ASD and their families (Leyfer et al., 2006).

Community therapists have lamented their lack of training about how to treat complex clinical presentations in children with ASD, who often present with disruptive behaviors, anxieties, and challenges with emotion regulation, among other symptoms (Brookman-Frazee et al., 2012). Currently, most ASD treatments address core features of the diagnosis (deficits in social communication, cognitive inflexibility, repetitive behaviors), without simultaneously addressing symptoms common to comorbid presentations (Brookman-Frazee et al., 2018). Additionally, currently-available treatments have limited approval by caregivers of children with ASD, who have expressed desires for greater access to services, more family-involvement in interventions, and more help supporting their

children in identifying emotional triggers (Tschida, et al., 2021). Developing treatments that address common co-occurring symptoms and complex clinical presentations has been recommended (Brookman-Frazee et al., 2018), and involving caregivers in such treatments may help overcome the limited acceptability of many currently available interventions. Deficits in emotion regulation (ER) has emerged in psychopathology research as a proposed common factor underlying many mood disorders. Given greater challenges in ER among children with ASD, and the need for treatments that address high rates of comorbidity in children with ASD, treatments targeting ER may be ideal interventions for this population. Since ER can develop and be inadvertently sustained in the context of family systems, and caregivers of children with ASD have expressed a desire for family-involved services, such treatments should involve caregivers.

Parent-Child Interaction Therapy (PCIT), which includes caregivers and improves ER (Rothenberg et al., 2019) may be an optimal treatment. PCIT is a widely disseminated evidence-based treatment with over 40 years of research demonstrating its effectiveness in addressing child conduct problems and improving parenting practices (Lieneman et al., 2017). PCIT is a behavioral, attachment-based treatment targeting parenting strategies and child conduct problems (Lieneman et al., 2017), which has been found to be helpful for children both with and without ASD (Parladé et al., 2020; Zlomke & Jeter, 2020). The effectiveness of PCIT is due in part to its unique format, in which the interaction between caregiver and child is the primary point of intervention. Additionally, didactic training is combined with in-vivo coaching, providing therapists an opportunity to coregulate parents as parents coregulate their children. PCIT teaches two sets of parenting skills in two phases. The first phase, Child-Directed Interaction (CDI), focuses on building a secure attachment

through positive parenting strategies while the second phase, Parent Directed Interactions (PDI), focuses on consistent and developmentally appropriate discipline techniques. Parents of young children with ASD have rated PCIT as highly acceptable (Zlomke & Jeter, 2020).

PCIT has been adapted for accessibility and clinical presentation. To increase accessibility and convenience, PCIT has been delivered and evaluated via telehealth (Comer et al., 2017) and in an intensive, time-limited format (Graziano et al., 2020). It has been adapted for a variety of clinical presentations including mood and anxiety disorders (Carpenter et al., 2014; Puliafico et al., 2012), separation anxiety (Pincus et al., 2008), early childhood depression (J. L. Luby et al., 2018), and selective mutism (Cotter et al., 2018), among others. Emotion-focused modules have been incorporated in some of these modifications to specifically teach caregivers to support the development of ER and emotional competence in their children (Chronis-Tuscano et al., 2016; Luby et al., 2018).

Past studies have affirmed the efficacy of PCIT in multiple mediums (i.e. telehealth) and in different formats (i.e. intensive and time-limited), and have demonstrated that standard PCIT improves child emotion dysregulation in addition to disruptive behaviors (Rothenberg et al., 2019). The addition of emotion-focused content has been found to uniquely contribute to treatment (Luby et al., 2020), and standard PCIT has been found to be effective for children with ASD (Parlade et al., 2019; Zlomke & Jeter, 2020). A preliminary study of intensive, telehealth PCIT found it to effectively decrease problem behaviors and improve parenting strategies in three families of children with ASD (Jimenez-Munoz et al., in preparation). The current study builds on this literature by evaluating the feasibility, acceptability, and preliminary efficacy of a telehealth-delivered, intensive (daily) time-

limited, modified emotion-focused version of PCIT for young children with ASD. The proposed research study presents the following aims:

- Evaluate the feasibility of a randomized clinical control trial comparing intensive telehealth standard PCIT (CDI+PDI) with intensive telehealth emotion-focused PCIT (CDI+ED), focusing on the feasibility of recruitment, randomization, retention, and assessments, and the feasibility and acceptability of both versions of the intensive, telehealth intervention to caregivers.
- Conduct preliminary efficacy analyses of child clinical outcomes (emotion regulation and disruptive behaviors) and caregiver outcomes (stress, emotion regulation, emotion socialization strategies, and distress tolerance) across treatment types.

Literature Review

Emotion Regulation

Researchers who study psychopathology have begun to focus on transdiagnostic mechanisms underlying a spectrum of mental health problems, including mood and externalizing disorders (Aldao et al., 2016; Sloan et al., 2017). Emotion regulation (ER) has emerged as a possible common underlying factor in the most prevalent childhood disorders, including depression, anxiety, and behavioral difficulties (Aldao, et al., 2016), and therefore as an important treatment target. ER is a set of strategies used to modulate emotion, which includes awareness, comprehension, and acceptance of emotions, the capacity to regulate behavior in the face of intense emotion, ability to flexibly apply emotion modulation strategies, and a willingness to experience negative emotion (Gratz & Roemer, 2004; Gross, 2004; Sloan et al., 2017). The failure to regulate one's emotions in conducive and functional ways results in emotion dysregulation, which is an inflexible approach to environmental circumstances and stimuli. Treating a transdiagnostic mechanism such as ER has been proposed as a way to address high rates of comorbidity, by offering treatment that may alleviate symptoms of multiple disorders and make treatments more effective and efficient (Sloan et al., 2017). Adaptive ER includes reappraising the environment and accepting one's emotional state, while maladaptive ER strategies include rumination, avoidance, and suppression (Aldao et al., 2016). Treatments emphasizing ER aim to enhance adaptive ER strategies such that children can better tolerate and respond to their intense emotional states. Transdiagnostic treatments for children have been developed that target ER as a feature common to emotion disorders (Kennedy et al., 2019).

Emotion Regulation and Caregivers

The ways in which children respond to and regulate their strong emotions is closely related to the emotional responding of their caregivers (Bariola et al., 2011; Eisenberg et al., 1998). ER capacities develop within the context of relationships with caregivers (Calkins & Hill, 2007; Morris et al., 2007) through ongoing patterns of reciprocal interactions (Kiel & Kalomiris, 2015). It has been suggested that positive emotion socialization behaviors by parents, which include facilitating emotional expression, modeling emotions, and coaching children through their strong emotions, help improve children's capacity to regulate their own emotions, in contrast to unsupportive responses such as minimization, criticism, or punishment (Kiel & Kalomiris, 2015). Many treatments for child mood and behavioral disorders provide psychoeducation to caregivers, which may indirectly result in different forms of emotional responding. Few studies have evaluated whether changes in caregiver response to child emotions or caregivers' own ER abilities mediate treatment gains. That is, if ER has been posited as a transdiagnostic mechanism underlying many forms of psychopathology, and it is deeply interwoven with caregiver ER and emotion responding, changes in one are likely tied to changes in the other.

A recent study by Tonarely et al. (2021) investigated how a transdiagnostic treatment for youth mood disorders impacted parent emotional responding and whether changes in parent emotional responding predicted youth symptoms after treatment. They found that changes in parent distress tolerance predicted changes in youth anxiety and depression symptoms at posttreatment, and that parent unsupportive emotional responses decreased through treatment, while certain adaptive ER strategies, such as cognitive reappraisal, increased. Parent participation in child therapy seems to strengthen treatment, as it confers ER benefits

to multiple members of the family system. In fact, a study evaluating an emotion-focused cognitive behavioral treatment for children ages eight to twelve with ASD, in which parents attended and were involved in each session, found improved parent ER after treatment, and found that changes in parent ER was associated with more improvement in internalizing symptoms in children (Maughan & Weiss, 2017).

Parenting interventions are increasingly incorporating emotion-focused components, which focus on four primary domains: 1) emotional experiences in parent family of origin, 2) parental emotional awareness and regulation, 3) parental responses to child emotion, and 4) skills to help parents be emotion coaches for their children (Havighurst et al., 2020). Understanding how caregivers are involved in socializing their children to emotions has motivated more clinicians and researchers to approach treatment through an emotion-focused lens. Emotion-focused interventions have been studied as an alternative to behavioral interventions to accommodate parent and therapist preferences. A study comparing an emotion- and behavior- focused parenting program found that both were equally effective in treatment conduct problems in 4- to 9-year-olds (Duncombe et al., 2016). David and colleagues (2014) similarly affirmed the importance of incorporating emotion-focused parent modules into treatment in a study comparing standard CBT to an enhanced CBT focused on teaching ER strategies to parents. The study of 130 children aged 4 to 12 and their caregivers found that both treatments were associated with improvements in externalizing symptoms, with the enhanced version resulting in greater improvements at one month follow-up (David et al., 2014).

Emotion Regulation and ASD

Children with ASD have been found to demonstrate grater emotional dysregulation than their typically developing peers (Conner et al., 2021; Samson et al., 2014). Given high rates of psychiatric comorbidities and increased recognition of the role emotion dysregulation plays in psychopathology, it has been recommended that research and treatment focus more on the intersection of emotion dysregulation in populations with ASD (Mazefsky, 2015). Children with ASD rely on more maladaptive ER strategies, such as crying, yelling, and avoidance, than adaptive strategies, such as problem solving or seeking support (Conner et al., 2021; Samson et al., 2014). A study by Samson and colleagues (2014) found that all core features of autism (social communication deficits, restricted behaviors, sensory sensitivities) are significantly related to emotion dysregulation. Additionally, emotion dysregulation has been found to weaken the association between social motivation and social skill in children with ASD, suggesting that it may impede their desire or capacity to engage socially (Neuhaus et al., 2019). ER impairments have been found to be associated with higher use of emergency and hospitalization services in youth with ASD (Conner et al., 2021), and to predict increased behavioral and social challenges over time if left untreated in youth with ASD (Berkovits et al., 2017). It has been suggested that therapy for children with ASD may be more effective if it targets emotion dysregulation, and that new interventions should be developed that do so (Samson et al., 2014). Additionally, a recent literature review of ER in young children with ASD suggested that treatments involving caregivers and children resulted in improved child ER (Cibralic et al., 2019).

Treatments for ASD

Currently available treatments for ASD focus primarily on the core features of ASD, rather than addressing emotion dysregulation. Treatments address social communication deficits and repetitive behaviors (Mohammadzaheri et al., 2014), with some also addressing additional behavioral challenges common to children with ASD, including aggression, impulsivity, and oppositionality (Brentani et al., 2013; Tschida et al., 2021). Few treatments address emotional dysregulation in ASD populations, although researchers have begun evaluating CBT for children with ASD (Maughan & Weiss, 2017; Reaven et al., 2012; Scarpa & Reyes, 2011). These studies have primarily focused on children over age five. In a pilot study of a novel ER-focused CBT intervention (Secret Agent Society: Operation Regulation) for 8 to 12-year-olds with ASD and their parents, children and their parents received psychoeducation on emotion identification, relaxation strategies, and techniques for coping with intense emotion. Child lability, as measured by the Emotion Regulation Checklist, improved through treatment, though ER did not. (Thomson et al., 2015).

Caregivers of children with ASD have expressed limited approval of currently available interventions. Caregivers expressed a desire for more availability and more services delivered in their communities, and have lamented limited access to services (Tschida et al., 2021). A study of 5,122 caregivers of children with ASD also found various barriers to treatment for ASD, with 44.8% of families reporting at least one barrier to treatment. In nonurban areas, 32% of caregivers reported that treatments were simply not accessible where they lived (Monz et al., 2019). In addition to facing barriers to access, caregivers reported wanting more family involvement in interventions, and more help in coping with triggers

rather than identifying and avoiding them, communicating, and understanding the child's perspective (Tschida et al., 2021).

It is important to develop treatments that are appealing to caregivers, and that are accessible to families living both in and outside of metropolitan areas. Telehealth-delivered interventions have been recommended as a format for expanding access for families of children with ASD and have demonstrated preliminary effectiveness for parent training (Vismara et al., 2012) and greater cost-effectiveness with this population (Lindgren et al., 2016). Additionally, developing treatments that address emotion dysregulation in ASD has been highlighted as a critical need (Mazefsky et al., 2013; Mazefsky & White, 2014).

Parent-Child Interaction Therapy

PCIT is a highly effective parent training program that can be successfully delivered over telehealth and has been modified to include ER content. It is divided into two phases, Child Directed Interaction (CDI) and Parent Directed Interaction (PDI). PCIT is manualized and contains structured sessions within both treatment stages. During each phase, caregivers are taught a set of parenting skills in both didactic format and then through in-vivo coaching. During CDI, caregivers learn a series of positive parenting skills, including how to provide labeled praises, reflect, imitate, describe, and express enjoyment of their child's play (referred to by the acronym PRIDE). During the second phase of treatment, they learn how to implement predictable, safe, and developmentally appropriate limit setting, which includes a time-out procedure for non-compliance and aggression. Treatment sessions are highly structured, and include a check-in, time for progress monitoring, evaluating caregiver skill level, and parent coaching. During each session, therapists assess caregiver proficiency with each skill and base subsequent coaching on targeted skills that require more practice.

Progress in treatment is also skills-criteria based, such that moving from one phase to the next and completing treatment are based on caregivers demonstrating proficiency in each set of skills, as measured through a standardized behavioral observation in each session (Eyberg & Funderburk, 2011).

PCIT has been modified to increase accessibility and convenience, making it an ideal intervention for widescale dissemination. Internet-delivered PCIT has been proposed as a treatment medium that may transcend many barriers to care (Comer et al., 2015), and has been found to have comparable results to clinic-based PCIT, with fewer barriers reported by parents, in an initial randomized-control trial (Comer et al., 2017). Modified versions of PCIT, tailored to treat anxiety disorders in young children, have also been successfully delivered via telehealth (Comer et al., 2021; Cooper-Vince et al., 2016). For example, iCALM, a telehealth-delivered adaptations of PCIT for child anxiety demonstrated preliminary efficacy in a control waitlist trial in which families who received the intervention showed greater child anxiety symptom improvement than families who did not (Comer et al., 2021). In this version of PCIT, CDI is delivered in 5 sessions, and is followed by 8 sessions of exposure-based treatment targeting specific anxieties. PDI is not included in this treatment, so rather than teaching disciplinary practices parents are taught how to model and encourage brave approach behavior to their children to target a range of anxious presentations.

Although PCIT is manualized and protocol-based, these modifications and different delivery formats evince its ability to address a range of presenting problems and be responsive to family needs. Remote delivery may increase accessibility for families for whom getting to a clinic is challenging. Additionally, PCIT has been evaluated in an

intensive format, in which families attend daily sessions over a shorter period. Offering intensive and time-limited child therapies has been recommended as an expeditious way to treat behavioral problems quickly while capitalizing on family motivation early in treatment and decreasing the likelihood of attrition (Graziano et al., 2020). Intensive PCIT offers treatment in a condensed, daily format, and showed comparable treatment gains to timelimited PCIT in a randomized trial (Graziano et al., 2020). Moderation analyses in this trial found that for parents with higher stress levels, intensive PCIT compared to standard timelimited PCIT was significantly associated with lower child behavioral challenges at posttreatment. It is possible that for highly stressed families, intensive, daily treatments are particularly helpful. In a cost-effectiveness assessment comparing standard, intensive, and group-based PCIT, the intensive format was found to be the most cost-effective in reducing child disruptive behaviors (Hare & Graziano, 2020). Intensive, telehealth-based delivery of PCIT may be a practical and cost-effective medium for improving access to services and supporting highly-stressed caregivers. In fact, a single study design evaluated the preliminary feasibility and effectiveness of a two-week time-limited daily telehealth PCIT for families of young children with autism (Jimenez-Munoz, in preparation). This study found improved parenting skills and decreased child disruptive behavior across the three participants, and caregivers in the study reported high satisfaction with the treatment. Given high stress levels among caregivers of children with ASD (Huang et al., 2014; Keenan et al., 2016; Schieve et al., 2007), this treatment format may be particularly relevant for the ASD population.

PCIT and ASD

PCIT has been evaluated for use with young children with ASD, with a particular emphasis on treating disruptive behaviors (Owen et al., 2018). In a randomized-controlled

trial of PCIT versus wait-list for 23 children with ASD, PCIT was found to predict reductions in disruptive behaviors (Scudder et al., 2019). A study comparing responses to PCIT in 16 children with and 16 children without ASD also found comparable significant improvements in both groups in disruptive behaviors, parenting skills, and parenting stress levels (Parlade et al., 2019). Contrary to researcher hypotheses that children with ASD would require a longer length of treatment, number of sessions did not differ significantly between the two groups. Similarly, in a retrospective study comparing 28 children with and without ASD, families completed the protocol in approximately 16 sessions without significant differences in length of treatment between the two groups. Parents of children both with and without ASD in this study rated PCIT as highly acceptable and reported similar improvements in child disruptive behaviors (Zlomke & Jeter, 2020).

The CDI phase of PCIT has also been delivered to the families of children with ASD without the subsequent PDI phase. In this format, families received 8 sessions of CDI in a brief, time-limited intervention intended to be more accessible to families. The CDI-only therapy was evaluated by Ginn and colleagues (2017) in a randomized controlled study of 30 mother-child dyads, of which 19 received the intervention. The authors note that the 5% treatment dropout rate was significantly lower than attrition rates in other PCIT studies, which may be due in part to the relative brevity of the intervention. Child disruptive behaviors in the intervention condition decreased significantly compared to the waitlist group, and child social awareness, as measured by the Social Responsiveness Scale, increased significantly in the intervention group compared to waitlist. Treatment gains were maintained at 6-week follow-up. This study suggests that the CDI component alone results in positive outcomes for children with ASD (Ginn et al., 2017).

While these studies indicate that PCIT is a promising intervention for young children with ASD, they have focused on improvements in disruptive behaviors and externalizing symptoms rather than emotion dysregulation or caregiver emotional responding. A single study design with three children with ASD and their mothers found improvements in maternal anxiety, depression, and stress after participation in PCIT, suggesting that in addition to positively impacting child behaviors, treatment may support parent wellbeing in families of children with ASD (Agazzi et al., 2017). No studies to date have evaluated the impact of PCIT on emotion dysregulation in children with ASD specifically.

PCIT and Emotion Regulation

Although the impact of PCIT on ER for children with ASD has not been assessed to date, researchers have begun to investigate how ER may change through PCIT in neurotypical children, given the increasing recognition of child ER capacity as a significant factor underlying many forms of psychopathology. It has been suggested that PCIT teaches caregivers to model ER by helping them model remaining calm in the face of child disruptive behavior (Lieneman et al., 2020). In fact, both caregiver and child ER have been found to improve over the course of standard PCIT (Lieneman et al., 2020). In a study of 66 caregiver-child dyads receiving community-based PCIT, Lieneman and colleagues found significant decreases in caregiver emotion dysregulation from both pre- to mid-treatment and mid- to post-treatment. Additionally, they found that child ER improved from pre- to mid- and mid- to post-treatment.

Zimmer-Gembeck and colleagues (2019) similarly evaluated changes from pre- to post-PCIT in the ER of 139 children and the ER and reflective functioning of their caregivers.

They found improvements in parental ER as measured by the Difficulties in Emotion Regulation Scale and increased parent use of a positive ER strategy, cognitive reappraisal, as measured by the ERQ. They did not find changes in parent use of suppression, a maladaptive ER strategy. They also found improvements in one facet of reflective functioning, prementalizing, or a caregiver's capacity to consider or comprehend their offspring's perspectives and emotions. In this study, greater improvements in caregiver ER and cognitive reappraisal were associated with greater improvements in child externalizing symptoms, while greater improvements in parental prementalizing were associated with greater improvements in child internalizing symptoms (Zimmer-Gembeck et al., 2019). In another study of 86 2- to 8-year-olds, Rothenberg and colleagues (2018) found that child ER improved from pre- to post-PCIT treatment, with 80% of children with clinically-elevated emotion regulation challenges falling into the normative range after completion of treatment (Rothenberg et al., 2019).

Emotion Regulation Adaptations to PCIT

While researchers have found that both child and parent ER can improve through standard PCIT, PCIT has also been adapted to specifically teach parenting strategies related to child emotions. Specifically, an adaptation of PCIT intending to treat early-onset mood disorders includes an Emotion Development module (PCIT-ED), which trains parents to act as emotion coaches for their children (Luby et al., 2018). PCIT-ED has proven efficacious in decreasing rates of depression in young children as well as comorbid disorders such as anxiety disorder and oppositional defiant disorder, compared to a waitlist condition. PCIT-ED also resulted in decreased caregiver-reported child emotional lability and increased ER,

as well as improving parental stress, emotional reflectiveness, and depression (Luby et al., 2018).

PCIT-ED was originally conceptualized as a full course of time-limited PCIT (CDI + PDI) with an additional Emotion Development (ED) module. The ED module includes 8 sessions. In the first session, which includes caregivers only, parent emotional development history is reviewed and psychoeducation about emotion is provided. Initial emotion-focused parenting skills are introduced (Support Steps, which include prepare, observe, connect, calm, work together, reassure). In the second session, strategies for responding to child emotion are further discussed and taught. The third session focuses on teaching the child emotion and feeling tools to help them recognize and label emotions (their own and those of other people). The fourth session includes a scenario intended to induce anger or frustration in the child while the parent practices and is coached in implementing their ED skills. The fifth session provides coaching of ED skills and introduces psychoeducation on guilt. The sixth session evaluates and coaches caregivers in their use of ED skills during a guilt inducing task for the child. The seventh session provides coaching of ED skills and teaches increasing positive affect. The eighth and final session provides coaching of ED skills and skills to increase positive affect. Homework between sessions includes emotion development journals (Luby et al., 2020; Luby, Pautsch et al., 2018).

The ED module alone has been found to offer unique contributions distinct from those offered in the first two phases of treatment (Luby et al., 2020). A study of differential contributions of the different phases of PCIT treatment (CDI, PDI, and ED) found that the ED phase offered unique changes, particularly in child neural response to reward and to parental reactions to child emotions. It has been suggested that the modules be offered in

different order or in equivalent session numbers (rather than with additional ED sessions) to clarify these differential contributions. Offering PCIT-ED as a modular approach, in which specific modules are offered depending on child clinical presentation, has been recommended as a possible way of tailoring treatment to particular children and families (Luby et al., 2018). Additionally, it has been suggested that treatment should be streamlined due to parent stress level and time-limitations; finding briefer versions of behavioral parent trainings that directly address emotion regulation is important to ensure therapy fit and feasibility (Butler et al., 2019). As such, the current study will evaluate a modified form of PCIT-ED, which offers ED, the component of treatment targeting mood disorders, rather than PDI, the component of treatment specifically targeting disruptive behaviors. In a preliminary study, children receiving a version of PCIT in which the PDI treatment phase is replaced with a module more specifically targeting specific symptoms (in that case, anxiety) demonstrated clinically meaningful improvements in their symptoms (Comer et al., 2012). The current modification will similarly offer CDI and the ED module, while eliminating PDI, in order to maintain the aim of providing brief and feasible treatments for families who already experience higher levels of stress and are often participating in multiple services.

PCIT-ED has also been delivered in an abbreviated format, with content tailored for children with attention-deficit hyperactivity disorder (ADHD). In this adaptation, called PCIT-ECo (Emotion-Coaching), the focus remains on teaching parents to be emotion coaches for their children by teaching and coaching them in the use of emotion regulation techniques (identifying and labeling emotions and triggers, tolerating the discomfort, and using relaxation skills). However, the ED module was shortened to five rather than eight sessions, with material not directly relevant to ADHD removed, such as portions about guilt, which

they found was not a common complaint within these families (Chronis-Tuscano et al., 2016).

The current ED module is similarly modified for relevance to the ASD population. It has been abbreviated for brevity and accessibility and will be delivered in 5 sessions. Sections less pertinent for families of children with ASD have been removed or shortened. For example, parent family of origin and emotion history has been shortened, and, as in PCIT-ECo, the guilt session has been removed. Psychoeducational material related to emotion dysregulation and ASD has been added. Length of treatment will include a total of 10 sessions. Because coaching parents in-vivo is likely a more potent mechanism of change in PCIT than didactic instruction (Shanley & Niec, 2010), the teach session has been condensed to a single session in which parents are taught all emotion coaching skills. PCIT-ED's Support Steps (for moments of heightened emotionality) and GUIDE steps (for discussing emotions after the fact) have been condensed into CALM steps, which provide a procedure the caregiver can use to calm themselves, label their child's emotion, and model a self-soothing strategy. This also matches the format of PDI more accurately. Four coaching sessions will follow. In each one, parents will be coached through discussing an emotion, how it expressed, emotion identification, and self-regulation strategies with their child. In each session, the parent will create a scenario that elicits a strong emotion (sadness, anger, fear, and happiness) and then coached to use the CALM skills while the child experiences the emotion (See Figure 2). Although PCIT has demonstrated efficacy for children with ASD (Parlade et al., 2020), PCIT-ED has not been evaluated for children with ASD. Given the relationship of emotion dysregulation and ASD symptomatology (Samson et al., 2014), and parental expressed desire to learn how to help children with ASD identify emotional triggers

(Tschida et al., 2021), this abbreviated PCIT-ED may offer a novel and useful way of treating comorbidities in children with ASD.

The Current Study

The proposed pilot randomized-control trial aims to evaluate the feasibility of a larger clinical trial comparing intensive time-limited PCIT with modified PCIT-ED. Pilot investigations have been recommended as a first step in evaluating the feasibility and acceptability of an intervention, and in planning for a larger randomized clinical trial (Leon et al., 2011). The current pilot RCT will assess feasibility and acceptability of the treatment protocol, and conduct preliminary analyses of comparative efficacy of the two interventions on child and parent outcomes. PCIT-ED is expected to result in greater improvements in child and parent emotion regulation, and both treatments are expected to similarly improve other outcomes. We expect PCIT-ED to be preferable to caregivers, given concerns some caregivers have about time-out (Canning et al., 2021) and controversy surrounding its use (Morawska & Sanders, 2011). Both interventions will be offered via telehealth to increase accessibility (Comer & Barlow, 2014) in an intensive time-limited format that addresses the need for expeditious and brief treatments for stressed and busy caregivers (Butler et al., 2019; Graziano et al., 2020).

Methods

Design

This study is a feasibility pilot randomized control trial with the goal of recruiting and randomizing 24 families into one of two treatment conditions intensive, standard PCIT (CDI+PDI) or intensive, emotion focused PCIT (CDI+ED). The study aimed to include 12

parent-child dyads (or child and two caregivers) per group, based on previous recommendations regarding sample size for pilot studies (Julious, 2005). All families received an intensive (daily), time-limited, telehealth-delivered version of PCIT. Measures were collected at pre-, mid-, post-treatment, and one-month follow-up. Figure 1 provides an overview of the study design.

Figure 1

Overview	of	`Study	Design
	~	~	0

			Child Direct	ed Interaction	Parent Directed Interaction			
CIT	Intake (1.5 hours)	CDI Teach Session (1)	CDI Coach Sessions (4)	Mid- Intervention Data Collection	PDI Teach Session (1)	PDI Coach Sessions (4)	Post- Intervention Data Collection	1-month follow-up
CONTROL: P	Clinical Interview, Baseline Assessment	Clinicians teach parents CDI skills (positive parenting skills)	Clinicians measure parent skills and provide in-vivo coaching of CDI skills	Abbreviated Standardized measures (EDI, ECBI)	Clinicians provide didactic instruction of PDI skills (time-out procedure)	Clinicians measure parent skills and provide in- vivo coaching of PDI skills	Standardized Measures, Open-ended surveys	Behavioral Observation, Standardized Measures
			Child Directed Interaction			Emotion De	evelopment	
PCIT-ED	Intake (1.5 hours)	CDI Teach Session (1)	CDI Coach Sessions (4)	Mid- Intervention Data Collection	ED Teach Sessions (1)	ED Coach Sessions (4)	Post- Intervention Data Collection	1-month follow-up
NTAL:	Clinical Interview, Baseline	Clinicians teach parents	Clinicians measure parent	Abbreviated Standardized measures	Clinicians provide didactic	Clinicians measure parent skills and	Standardized Measures, Open-ended	Behavioral Observation, Standardized

Participants

Participants were twenty-two families (child and one or two caregivers). The children were ages 2-7 (M = 4.64, SD = 1.50) and had pre-established autism diagnoses. The majority of them were male (72.7%, N = 16). Two children were Hispanic or Latinx (9.1%), and three were multiracial (13.6%). The remainder were non-Hispanic white. Most families had more

than one child (N = 13, 59%). Twenty children (N = 90.9%) were receiving additional weekly services, with the most common being occupational therapy (N = 14, 63.4%), speech and language (N = 11; 50%), and ABA or another behavioral treatment (N = 8, 36.4%). The primary participating caregivers were primarily female-identified (N = 20, 19.9%). Twelve (54.5%) were employed full-time, and 15 (68.2%) households reported annual household incomes over \$100,000. Two primary participating caregivers were Hispanic or Latinx, and three (13.6%) were Asian. Additional demographic data can be found in Table 1.

Table 1

	Total Sample ($N = 22$)		
-	М	SD	Rang
Child age, years	4.64	1.497	2-7
Caregiver age, years	40.82	6.57	31-59
	%	Ν	
Sex of child			
Male	72.7	16	
Female	27.3	6	
Child ethnicity			
Hispanic or Latinx	9.1	2	
Not Hispanic or Latinx	90.9	20	
Child race			
White	86.4	19	
Multiracial	13.6	3	
Receiving Other current services			
Speech/Language	50	11	
ABA/Behavioral Treatment	36.4	8	
Occupational Therapy	63.4	14	
Parenting Intervention	31.8	7	
Music/Art Therapy	9.1	2	
Counseling/Psychotherapy	13.6	3	
Other	18.2	4	
Annual household income			
<\$50,000	9.1	2	
\$50,000-\$100,000	18.2	4	
>\$100,000	68.2	15	
Caregiver gender identity			
Male	9.1	2	

Demographics of Study Participants

Female	90.9	20
Caregiver ethnicity		
Hispanic/Latinx	9.1	2
Not Hispanic/Latinx	90.9	20
Caregiver race		
Asian	13.6	3
White	86.4	19
Caregiver employment		
Part-Time	13.6	3
Full-time	54.5	12
Unemployed	31.8	7
Caregiver education		
Some college	13.6	3
Associates	9.1	2
Bachelors	36.4	8
Masters	27.3	6
Doctorate/Professional	13.6	3
Caregiver Marital status		
Single	9.1	2
Married/Partnered	90.9	20

Procedure

Recruitment

Recruitment efforts took place through email announcements, social media posts, classified advertisement websites and referrals from other professional agencies. Recruitment was conducted via postings to relevant websites (therapy4thepeople.com), Facebook autism parent groups, Koegel Autism Center Facebook posts, sending emails to an autism listserv, reaching out to local pediatricians, and sending our recruitment flyer to local school psychologists, school mental health staff, and PCIT clinicians to disseminate. Those interested first completed a consent to be screened and then a screener questionnaire through RedCap, a secure online survey platform and data management system (Harris et al., 2009). Individuals who did not qualify had the option to receive alternate referrals. Participant inclusion criteria were as follows: (a) child between the ages of 2 -7, (b) participating caregiver(s) was/were primary caregiver and/or legal guardian of the child, (c) child had previously been diagnosed with ASD by a licensed professional, (d) caregiver and child had access to a computer, smartphone, webcam, high-speed internet, and wired or wireless headphones, (e) child expressed self in at least simple 3-4 word phrases, (f) caregiver consented to sessions being recorded, and (g) caregiver could complete measures in English. Exclusion criteria were as followed: a) children younger than 2 or older than 7, b) nonprimary caregivers, c) no official autism spectrum diagnosis, d) caregivers who did not possess access to a computer, smartphone, webcam, internet, or headphones, (f) caregivers who did not consent to sessions being recorded, and (g) child communicated primarily in a nonverbal way or using one word utterance. Participant families were compensated \$40 for their time for the pre- and follow-up assessments (\$10 for intake only, \$20 for intake and mid-intervention, \$30 for intake, mid, and post-intervention, and \$40 for all four, including follow-up).

Randomization

RedCap's randomization function was used to randomize participants to either CDI+PDI or CDI+ED. Participants were matched by age and sex at birth for randomization.

Intake Data Collection

After completing the informed consent process, participants completed online pretreatment assessments to collect baseline measures. Assessments included online administration of measures of parenting stress (PSI), child emotional regulation (EDI), child disruptive behaviors (ECBI), child emotional and behavioral symptoms (BASC-3), autism symptoms (SRS), parent efficacy (PES), family quality of life (FQOL), and parent emotional responding measures (CCNES, DTS, ERQ). Questionnaires were administered through

RedCap. The intake session consisted of a clinical interview and behavioral observation (Dyadic Parent Child Interaction Coding System; DPICS).

Intervention

All participants received one of two possible time-limited, intensive, internet-based PCIT treatments delivered by clinical psychology doctoral students with training and experience providing PCIT under the supervision of a licensed psychologist and a Board-Certified Behavior Analyst, with the consultation of a certified PCIT trainer. Ten clinicians with previous experience providing PCIT and experience working with children with ASD provided the intervention. All clinicians had experience delivering standard PCIT via telehealth. Therapists were trained in the ED model through two-hours of live didactic instruction and then conducted co-therapy with the lead author on one ED case, before implementing the model independently. Two therapists, in addition to the lead author, were fully trained to deliver the ED model.

Internet-based PCIT (Comer et al., 2015) follows traditional clinic-based PCIT but offers treatment through tele-conference platform (Zoom) to enable therapists to deliver treatments remotely to families in their homes. Families use a webcam to broadcast their home-based interactions to therapists who provide remote coaching to parents through Bluetooth or wired earpiece. Sessions were recorded through Zoom for Telehealth and uploaded to a designated encrypted Box folder.

Intensive PCIT Intervention Group (CDI+PDI). Two phases of PCIT, childdirected interaction (CDI) and parent-directed interaction (PDI) were conducted via 50minute sessions taking place 5 times per week, following PCIT session protocol (Eyberg & Funderburk, 2011). During this study, families in the CDI+PDI group received five sessions

of CDI (one teach session and four coaching sessions) and five sessions of PDI (one teach session and four coaching sessions). CDI sessions included teaching caregivers positive parenting skills (the PRIDE skills) and selective attention, and coaching them in these skills in play sessions with their child. PDI session content included teaching caregivers how to give effective commands and how to respond to noncompliance consistently with a predictable and safe time-out procedure. Caregivers were then coached to deliver effective commands and to implement time-out, using increasingly challenging commands (i.e. beginning with play-based commands and then working up to clean-up and real-life commands). Length of treatment included a total of 10 sessions.

Intensive ED Intervention Group. Participants received a modified version of intensive PCIT, in which CDI was followed by an Emotion Development (ED) module rather than PDI. The ED module was informed by the Emotion Development Treatment Manual (Luby et al., 2018), and PCIT-ECo, a modified version of PCIT-ED for children with ADHD (Chronis-Tuscano et al., 2016). It was also modified for telehealth delivery, and psychoeducational material related to emotion dysregulation and ASD was added. The ED module teaches parents to be emotion coaches for their children, such that they validate, recognize, and label the child's emotions and teach their child ways to more adaptively regulate and respond to intense emotions rather than attempting to avoid them. In the ED model, caregivers receive psychoeducation about emotion development and explore their own familial histories related to emotion development and emotion socialization. They then are coached to talk with their child about four different emotions (anger, sadness, fear, and happiness), including how to express and recognize these emotions in themselves and others.

They are coached to then discuss coping strategies with their child and to model these coping strategies, using a set of skills called the CALM skills.

Figure 2

Comparison of Interventions – Session Content

	PCIT	PCIT-ED		
	CDI	CDI		
1	CDI Teach	CDI Teach		
2	CDI Coach 1	CDI Coach 1		
3	CDI Coach 2	CDI Coach 2		
4	CDI Coach 3	CDI Coach 3		
5	CDI Coach 4	CDI Coach 4		
	PDI	ED		
6	PDI Teach: time-out procedure	ED Teach: Emotional development history, emotion psychoeducation, CALM steps		
7	PDI Coach 1: Teach time-out procedure to child through play (i.e., Mr. Bear), Play commands	ED Coach 1: Child emotion coaching (sadness)		
8	PDI Coach 2: Play & real-life commands	ED Coach 2: Child emotion coaching (anger)		
9	PDI Coach 3: Clean-up commands	ED Coach 3: Child emotion coaching (fear)		
10	PDI Coach 4: House Rules	ED Coach 4: Child emotion coaching (joy/happiness)		

Mid Intervention Data Collection

After the CDI phase (first five sessions), caregivers completed parent-reported measures of child emotional regulation (EDI) and child disruptive behaviors (ECBI).

Post Intervention Data Collection

At the end of the 10 sessions, caregivers completed parent-reported measures of parenting stress (PSI), child emotional regulation (EDI), child disruptive behaviors (ECBI), autism symptoms (SRS), parent efficacy (PES), family quality of life (FQOL), parent emotional responding measures (CCNES, DTS, ERQ), and a treatment perception measure (TAI). Caregivers had the option of responding to open-ended survey items addressing their perceptions of treatment.

Follow-Up Data Collection

One month following the tenth session of treatment, caregivers attended a 50-minute follow-up session, which included a behavioral observation measure (DPICS). They again completed parent-reported measures of parenting stress (PSI), child emotional regulation (EDI), child disruptive behaviors (ECBI), autism symptoms (SRS), parent efficacy (PES), family quality of life (FQOL), and parent emotional responding measures (CCNES, DTS, ERQ).

Measures

Feasibility of RCT

Feasibility of the RCT was assessed in terms of recruitment, retention, assessments, and randomization.

Recruitment was evaluated based on the study's ability to recruit and enroll the target number (n = 24) of families within the intended timeframe of 24 months (12 families per year), the time to enroll target number, and representation of racial and ethnic minority families among study participants (diversity of study sample).

Retention was measured by percentage of families who completed treatment and percentage of families who attended follow-up.

Assessment feasibility was assessed by percentage of families who completed assessments at each timepoint, and average number of days after treatment completion when each assessment timepoint was completed.

Randomization was assessed based on demographic differences between groups and differences in variables of interest at intake (PSI, EDI, ECBI).

Feasibility of Intervention

Feasibility of the intensive telehealth intervention was assessed based on time-tocompletion of the intensive intervention, dosage of treatment received (how many out of 10 sessions), and therapist reports of challenges to delivery described in progress notes and reported in clinic meetings and consultations.

Acceptability of Intervention

Attrition served as a measure of treatment acceptability.

The Therapy Attitude Inventory (TAI) - modified. (Eyberg, 1974) The TAI is a 10-item caregiver-report measure that assesses parent satisfaction with treatment. Caregivers complete items that address their perceptions of treatment outcomes (i.e. regarding techniques for teaching my child new skills, I feel I have learned) on a 5 point scale (1 = nothing to 5 = very many useful techniques). An adapted version of the TAI addressing both emotions and behaviors was administered at the postintervention assessment. The TAI has demonstrated excellent reliability ($\alpha = 0.91$) and stability across a 4-month period ($\alpha = 0.85$) (Brestan et al., 1999).
Open-ended survey questions. Caregivers were asked a series of open-ended questions following completion of treatment to gather qualitative data regarding their perspectives on treatment. Questions included: What were the most helpful/challenging parts of CDI/ED/PDI? What do you feel that you learned in PCIT? What else would have been helpful? What was it like for your family to receive services over telehealth? What was it like for you and your family to attend PCIT daily over two weeks?

Child Measures

The Emotion Dysregulation Inventory (EDI). (Mazefsky et al., 2018) The EDI is a 30-item caregiver report measure of difficulties with emotion regulation. It was normed on children with ASD 5 and older, and has been studied with samples that include 4 year old children. There is no currently available measure of emotion dysregulation for younger children with ASD, and the oft-used Emotion Regulation Checklist was normed on children 6-12 without ASD. The EDI is the most developmentally appropriate measure given the paucity of measures for early childhood and for children with ASD. The EDI yields two scores: one for Reactivity (24 items) and one for Dysphoria (6 items). Caregivers rate items on a five-point scale based on their child's behavior over the past 7 days from "0 = not at all" to "4 = very severe." Reactivity provides a measure of intense, rapidly escalating, and poorly regulated emotional responses (characterized by anger/irritability) while Dysphoria, provides a measure of sadness, unease, low motivation, and anhedonia. The EDI has been found to have good reliability in samples of individuals across the spectrum of ASD ($\alpha = 0.94$; Conner et al., 2018)

Eyberg-Child Behavior Inventory (ECBI). (Eyberg & Pincus, 1999) The ECBI is a 36- item caregiver report measure of child behavior problems, used to track treatment

progress in PCIT. The ECBI assesses the frequency and severity of disruptive behaviors. It yields two scores: an Intensity score, calculated based on responses to 36 items about the frequency of specific disruptive behaviors on a 7-point scale (from 1 = never to 7 = always) and a Problem score, calculated based on 36 yes-or-no questions, inquiring how problematic child behaviors are for the caregiver. The ECBI has high reliability and validity across ages and is used as an indicator of treatment progress in PCIT.

Parent measures

Parenting Stress Index, Fourth Edition Short Form (PSI-4-SF). (Abidin, 2012) The PSI is a 36-item measure evaluating three domains of parenting stress: Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child. The three domains are totaled into a Total Stress scale. Responses are based on a 5-point Likert scale (1 = strongly agree to 5 = strongly disagree), and higher scores indicate higher levels of parenting stress. Parenting stress has been shown to be a predictor of treatment outcomes and engagement. Internal consistency for the PSI-4-SF is 0.91 and test-retest reliability is 0.96.

Coping With Children's Negative Emotions (CCNES). (Fabes et al., 1990) CCNES is a valid and reliable self-report measure that assesses how parents perceive themselves to cope with and respond to children's negative affect in distressing scenarios (i.e. anger, sadness, fear). It provides 12 short scenarios and asks parents to rate how likely they are to respond in one of 6 ways (1 = very unlikely to 7 = very likely). It comprises six subscales, which each represent a type of caregiver response to child negative affect: distress reactions (caregiver experiences of their own distress), punitive reactions (punishing in order to avoid child distress), expressive encouragement (encouraging and validating child negative affect), emotion-focused reactions (strategies to help child feel better), problem-

focused reactions (attempts to help child solve problem), minimization reactions (minimizing situation or devaluing child affect). This measure has been used to evaluate caregiver response to PCIT-ED in the past, since it measures two maladaptive caregiver strategies that the treatment targets: emotion minimization of emotions and negative affect avoidance (Luby et al., 2020). As in previous literature, these subscales were combined into a positive (expressive encouragement, emotion-focused, problem-focused subscales) and a negative (minimization, distress, punitive subscales) emotion socialization scales (Rothenberg et al., 2019; Tonarely et al., 2021)

Distress Tolerance Scale (DTS). (Simons & Gaher, 2005) The DTS is a 15-item selfreport measure assessing tolerance of negative emotions (i.e feeling distressed or upset). Caregivers are asked how much a statement describes their beliefs about feeling distressed on a 5 point scale (1 = strongly agree to 5 = strongly disagree). Items will be summed to yield a total DT score, with higher scores indicating greater ability to tolerate distress. The DTS has demonstrated good internal consistency (α = .89) and adequate test-retest reliability (r = .61) (Simons & Gaher, 2005) as well as Chronbach alphas of 0.88 (Gaher et al., 2013) and 0.92 (Simons et al., 2018) in adult samples.

Emotion Regulation Questionnaire (ERQ). (Gross & John, 2003) The ERQ is a 10item self-report measure that assesses two dimensions of emotion regulation: cognitive reappraisal (6 items) and expressive suppression (4 items). Caregivers will be asked to indicate how much they agree with statements about how they handle their own emotions (i.e. I keep my emotions to myself; I control my emotions by changing the way I think about the situation I'm in) on a 7-point Likert scale (1 = strongly disagree to 7 = strongly agree). The ERQ reappraisal and suppression subscales have adequate internal consistency

(reappraisal averaged $\alpha = .79$; suppression averaged $\alpha = .73$), and 3-month test-retest reliability of r = 0.69 for both subscales.

Data-Analysis Plan

Aim 1: Evaluate the feasibility of a randomized clinical control trial comparing intensive PCIT with intensive modified emotion-focused PCIT, focusing on the feasibility of recruitment, randomization, retention, assessments, and the feasibility and acceptability of both versions of the intensive, telehealth intervention to caregivers.

Recruitment. Number of months to recruit the intended sample size was calculated. Descriptive statistics of race and ethnicity variables were evaluated to indicate diversity of sample; percentage of non-white children and caregivers was calculated.

Retention. Percentage of families who completed treatment and who attended follow-up was calculated.

Assessments. Percentage of participants who completed assessments at each timepoint was calculated. Means and standard deviations were calculated for number of days following treatment completion after which post- and follow-up assessments were each completed.

Randomization. To assess randomization, Fisher's Exact tests for categorical demographic variables, and t-tests for continuous variables evaluated baseline differences across conditions.

Feasibility of Intervention. Mean and standard deviation was calculated for number of days to complete treatment, and percentage of families who received the full 10 session

protocol was calculated. Progress notes were reviewed for challenges reported by clinicians to delivering intervention.

Acceptability of Intervention to Caregivers. Attrition served as a measure of acceptability by comparing rates of drop out between the two conditions. Caregiver levels of satisfaction were assessed by comparing TAI scores between groups using between-group ttests. Open-ended responses collected via surveys were analyzed through a rapid coding and analysis process used in implementation research. Qualitative data analysis followed recommendations for rapid qualitative methods in implementation and mental health services research, which has been found to result in comparable findings to in-depth qualitative analyses (Gale et al., 2019; Hamilton & Finley, 2019; Nevedal et al., 2021). The lead author developed a matrix with relevant constructs divided into challenges and benefits. Themes were identified based on concordance between multiple participants, discussed with the research team, and then reviewed by another member of the research team to check for consensus. Qualitative data was used to triangulate and expand upon quantitative findings. Aim 2: Conduct preliminary efficacy analyses of child clinical outcomes (emotion regulation and disruptive behaviors) and caregiver outcomes (stress, emotion regulation, emotion socialization strategies, and distress tolerance) across treatment types.

Between Group Differences. Analyses were conducted comparing pre- to follow-up data to best investigate maintenance of treatment outcomes after the intensive treatments and to maximize the sample size as the majority of participants had post- or follow-up data. Missing data was evaluated for randomness using Little's (1988) MCAR test. According to Little's (1988) MCAR test, data were missing completely at random ($\chi 2 = 84.461$, df = 111, *p* = 0.971). Missing data was carried forward from post- to follow-up for those participants

who had not completed follow-up measures for the ANCOVA, as has been recommended in cases of missing data (Kang, 2013).

Outcome measures were evaluated for normalcy and to ensure that they met assumptions. First, to evaluate if there were between group differences in outcome variables between conditions at follow-up, analysis of covariance (ANCOVA) was used to assess differences, controlling for baseline scores. ANCOVA has been recommended for randomized controlled trials with multiple timepoints (N'zi et al., 2017; Rausch et al., 2010). Estimates of effect size are reported using partial eta squared ($\eta 2$) where 0.01 is a small effect, 0.06 is a medium effect, and 0.14 is a large effect.

Within Group Differences. Post-hoc analyses were then conducted to assess pre- to post- and pre- to follow-up changes for each condition. Paired sample t-tests were run for each condition separately for each outcome measure. Estimates of effect size are reported using Cohen's D (1988), where .10 is interpreted as a small effect, .50 is a medium effect, and .80 is a large effect.

Clinical Change Trajectory. Because the ECBI is the most commonly used measure in PCIT studies and as a progress measure during treatment, ECBI scores were examined as an indicator of clinical change. Jacobson and colleagues (1984) recommend evaluating clinically significant change by calculating a Reliable Change Index (RCI) in addition to whether a participant moves from the clinical range to the subclinical range over the course of treatment. If a participant moves from clinical to subclinical and their RCI (post score – pre score divided by the standard error) is calculated at greater than 1.96, their change is considered clinically significant (Jacobson et al., 1999).

Results

Aim 1: Evaluate the feasibility and acceptability of a randomized clinical control trial comparing intensive PCIT with intensive modified emotion-focused PCIT, focusing on the feasibility of recruitment, randomization, retention, assessments, and the acceptability of both versions of the intensive, telehealth intervention to caregivers.

Recruitment: It took 9 months to recruit 22 families (September, 2021 – June 2022). Recruitment began in September 2021, with the first intake conducted on December 7th, 2021 and the first treatment session on December 13th, 2021. Given the goal of recruiting 12 families per year, the recruitment goal was reached. A flowchart diagram and timeline are provided in Figure 3. Sixty-one families consented to be screened, with 49 actually completing the screening process. Of those who completed the screener (n = 49), 44.9% (n =22) were randomized. Families were excluded (n = 19) due to limited verbal language (n = 19)9), location outside of the US (n = 1), age (n = 3), not having an autism diagnosis (n = 4), and caregiver not able to complete measures in English (n = 1). Eight families who met inclusion criteria declined to participate; four families reported that the time commitment was not feasible, and four families did not provide a reason. In terms of recruiting an ethnoracially diverse sample, only three participants (13.6%) identified their child as multiracial and the 19 other families identified their child's race as white. Two caregivers (9.1%) identified as Hispanic/Latino and two (9.1%) identified as Asian. The remainder identified as non-Hispanic white.

Retention. Twenty of the 22 randomized families completed treatment, with one family lost to follow-up after intake and before completing treatment, making the retention

rate 95.24%. Of the 20 families who have completed treatment, 19 attended their one-month follow-up appointments (95%).

Randomization. To assess randomization, baseline participant characteristics were compared using t-tests for continuous variables and Fisher's Exact tests for categorical variables. Characteristics and differences are summarized in table 2, with no significant differences found between baseline variables of interest (ECBI, EDI, or PSI), or between demographic variables (child age, caregiver age, child sex at birth, child ethnicity, or child race). Due to age and sex-matching in randomization, and the randomization matrix in RedCap, the first family of each age and sex was randomized to PDI, resulting in a larger PDI sample. Participants were manually assigned to the ED group after 11 participants had been completed CDI+PDI.

Table 2

			Condition						
	Total Sa	mple	CDI + P	DI	CDI + F	ED			
	(N = 22)) (D	(n = 13)	CD	(n =9)	CD			Manu lif
	M	SD	М	SD	М	SD	l	р	Mean alj
Child age, years	4.64	1.497	4.54	1.51	5.11	1.62	.85	.405	57
Caregiver age, vears	40.82	6.57	40.77	7.20	40.88	5.97	04	.968	12
ECBI Intensity	127.59	35.95	129.92	25.58	124.22	48.89	.36	.724	5.70
EDI Reactivity	39.41	20.18	41.77	17.95	36.00	23.76	.65	.523	5.77
EDI Dysphoria	3.45	3.23	3.38	2.81	3.56	3.94	12	.906	17
PSI Total Stress	111.50	17.31	112.00	17.97	110.78	17.36	.16	.875	1.22
-							Fisher	's Exact	Test
	%	N	%	N	%	N	Signifi	icance	
Sex of child									1.000
Male	72.7	16	69.2	9	77.8	7			
Female	27.3	6	30.8	4	22.2	2			
Child ethnicity									1.000
Hispanic or Latinx	9.1	2	7.7	1	11.1	1			
Not Hispanic or Latinx	90.9	20	92.3	12	88.8	8			

Pre-trial between group demographic and measure comparisons

Child race							.240
White	86.4	19	77.0	10	100	9	
Multiracial	13.6	3	23.1	3	0	0	

Assessments. All participants who completed treatment (n = 20, 100%) completed mid-treatment assessments. Sixteen participants (80%) completed post-treatment assessments, and 1 completed some post-treatment assessments. Post measures were completed M = 2.71, SD = 2.05 days after treatment ended (Range = 0 - 8 days). Fifteen participants (75%) completed follow-up assessments, and two completed some follow-up assessments. Follow-up measures were completed M = 36.53, SD = 9.49 days after treatment ended (Range = 26 - 58 days). Nineteen (95%) participants completed either or both post and follow-up and assessments, with only one participant completing neither.

Feasibility of Intervention. Feasibility of the intensive model was measured as average length of time for the intervention and assessed through review of therapist progress notes and videos. Participants received the 10-session intervention in an average of 14.45 days (SD = 2.94, Range = 12 - 24). Of the families who did not drop out of treatment (n = 20), 100% received 10 sessions of treatment. Therapist notes and video review indicated challenges to delivering the novel ED protocol, due to difficulty getting children to engage with the screen or to pay attention to caregiver's discussion of coping strategies or emotions.





Acceptability of Intervention to Caregivers. Dropout served as an indication of intervention acceptability: only one family assigned to the CDI+PDI condition dropped out of treatment. However, dropout occurred during the CDI phase, so it did not appear to be related to the condition they were assigned to. Additionally, the TAI served as a measure of satisfaction: Overall, treatment satisfaction was high (across both conditions ($M_{CDI+PDI} = 42$, SD = 5.87 vs $M_{CDI+ED} = 40.25$, SD = 5.01), with no significant difference in scores (t = .670, p = .513).

Open-ended responses were thematically analyzed to assess for acceptability of the intervention, with caregivers describing many benefits and challenges to each treatment group, to telehealth delivery, and to the intensive format (summarized and presented with illustrative quotes in Table 3) and discussed below. Themes will be discussed first related to standard characteristics of PCIT (e.g., coaching, the CDI phase), then the adaptations to format (telehealth, intensive), and finally the differences and similarities between acceptability of the PDI and ED phase.

Overall, caregivers in this study described appreciating certain characteristics of the PCIT model, such as the live coaching and in-the moment support. One caregiver explained that "having the opportunity to actually practice and implement the PRIDE skills with live feedback helped us feel more confident and better equipped to work with our son. We were never in a situation where we felt helpless or didn't know what to do." In general, caregivers valued the skills taught in CDI, stating that the most helpful part of this treatment phase was "learning the PRIDE skills." One stated: "I learned how to use the PRIDE skills. Those skills really helped with making playtime fun and [child] really started talking a lot more." Of the multiple PRIDE skills, caregivers repeatedly expressed appreciation for "increasing specific

praise." In addition to the skills taught and coached in CDI, caregivers valued the emphasis on play and following their child's lead. One caregiver expressed her appreciation for "learning to go with the flow with my child during play. My mom (his grandma), is really good at getting down on the ground and playing with him but I was not the best at it. Seeing him open up and have so much fun while he led the play was really helpful for me to see how much that influences his positive development. I feel like, 'duh, why didn't I do this before?'" While caregivers valued this new set of skills, they also endorsed that learning to stop asking questions and to use selective inattention was challenging. One reported struggling with "not asking questions or giving commands" and another struggled with "not asking questions during special time [and] ignoring misbehavior."

Regarding the telehealth format, most caregivers gave positive feedback, with some articulating surprise at its effectiveness: "I was worried about how my child would respond/not respond [to telehealth], but it was great!." Most stated that telehealth was "easy," "good," and "worked well." One family struggled due to their child's age and behaviors: "it was hard because [child] got very defensive when he knew the phones or computers were on. He also tried to take out the air pods many times. Because he's older and doesn't like telehealth, it was a challenge. But it really helped show you what we struggle with at home." Multiple families also described technical challenges inherent to telehealth: "it worked out better than planned, but we always have technical difficulties."

Caregivers also provided feedback on the intensive, daily format of treatment. They appreciated receiving the skills quickly and efficiently, but struggling with the added stress of scheduling so many sessions in such a short period of time: "It was challenging because we had to commit every day. If I was not working from home, I'm not sure how we would have

done this. But I'm also glad we committed and got this beneficial therapy so quickly." Most families conveyed similar sentiments, relating that the treatment "was quite a time commitment, but definitely worth it," however a few families stated that they would have appreciated a longer course of treatment. One caregiver endorsed "wishing we could continue at least once a week for many months," while another desired a "longer duration and less compressed timeframe."

Regarding PDI, the second phase of conventional PCIT, caregivers valued "learning how to give clear directions and then being consistent with giving a timeout. Now [child] has an easy and clear understanding of what is expected." Although caregivers appreciated learning to set consistent limits and to follow through in predictable ways, they also reported struggling with the delivery of time-out, describing "we were hesitant to use physical means to bring our son to the time out square because we feared it would increase the frequency of his physical responses, but it has not." Notably, caregivers also reported improved confidence, calmness, and patience following PDI. One reported better ability to regulate their emotions: "I wish every parent could receive PCIT because I feel we would live in a world full of better people that know how to regulate their emotions in a more healthy way." Caregivers who received the ED module also described different ways of responding to emotion, stating that it was helpful "to remind ourselves of the tools and skills we have to work through all emotions." They valued learning the CALM skills, and the focus on "modeling coping skills," but they described difficulty due to "feeling like my son wasn't paying attention as we were presenting coping tools."

Table 3

Themes and Illustrative Quotes

	Benefits	Challenges
PCIT Generally	[I learned] How to be a better, happier, more effective parent and hoping for a happier, more regulated son. I have been searching for an effective parent training since my son's diagnosis and no therapist or book has come close to what this therapy has provided for me. I am motivated to make this our way of life and think it will be life-changing for me and my son.	It was tiring to hold back and constantly correct myself during the sessions. And listening to my child and the counselor at the same time was a lot of stimulation for me.
	Live coaching: The coaching was surprisingly wonderful. I think it was the best way to learn PCIT.	
	Supportive treatment: PCIT was an incredible experience for our entire family. Even our older neurotypical son started using the skills and we would find ourselves naturally incorporating strategies into our daily activities and conversations. We had meaningful feedback during and after each session and felt extremely encouraged throughout the entire process.	
Telehealth PCIT	Convenience: Telehealth was very convenient for our schedule.	Occasional technical glitches: It was a little tricky with the equipment from time to time
	In home support: I thought it was fantastic. I appreciated receiving support in my home where we face real-life situations and where my son is comfortable.	Managing elopement: Our son's behavior was very intense and having the session in our house allowed him to throw many items, elope, and it was very hard to manage.
Intensive Daily PCIT	helpful learning: [the intensive format] was helpful and really drove the learning home	Scheduling challenges : Daily sessions are tough to schedule but it was totally worth it.

	Very difficult emotionally because we have to work on the skills daily. But, it was the best way for all three of us to make a behavior change that I believe will last. I am surprised on how successful I believe Telehealth over two-weeks worked.	Added stress: Very challenging! It would have been easier for our family if the timeframe had been less compressed. There was only one hour during the day that worked for us to all be home together. We adjusted our routines to make that happen but that caused some stress in our already stressed household.
CDI	PRIDE Skills: Learning the PRIDE skills and having someone help us with communicating them the right way to our son.	Avoiding questions: It was difficult to refrain from asking questions.
	Play: Very fun to have a planned session to play with your kid and make them feel good about themselves. We loved this portion.[I learned]How to play with my child and enjoy their company in an intimate way that is enjoyable for both of us.	Selective inattention/ignoring: The most challenging part was allowing my son to work thru challenging behaviors and tantrums but we found early on that they only lasted for a brief time.
PDI	Emotion Regulation: I learned so much from this research study. I'm more confident playing with [child]. Patience and remaining calm were definitely issues we both had and now we know how to de- escalate.	Time out "Waiting out the time for [child] to calm down from being on the timeout chair or room was the toughest part." "I did not like giving my child a time-out or sending him to the time- out room. It made me uncomfortable to use physical force to get him in the room."
	Consistency and limit-setting: Learning a consistent strategy for discipline has taken the burden out of disciplining my child. My husband and I had tried to come up with a consistent disciplinary technique together but we always went back to our old ways. Now we are all on the same page and my son knows what to except. It really is freeing.	Felt manipulative to create opportunities for child to disobey. At the beginning there were times where a misunderstanding or slight delay on his part were treated as disobedience and a time out felt very unjust.
ED	CALM Skills and modeling coping strategies: CALM Skills. It made me realize how anxious I have been because of his aggressive behavior. I needed the reminder to calm myself down and stay calm when he was starting to show behaviors. And model my own behavior better for him. Handling Emotions: When it comes to	Coping Cards: Trying to get my child to respond more to the tool cards. They seemed a bit too abstract for her but with explanation I think she gets it. But the cards on their own for future use- I'm not sure.
	Emotion Development, I've experienced	

stro	ng emotions throughout my entire life	
and	I tend to get stuck in the negative,	
hear	vier emotions, which makes me want	
to a	void situations where my autistic son	
wou	ald experience such emotions. PCIT	
taug	ght us as we experience all emotions,	
we	can acknowledge them, remind our	
son	of his coping skills and strategies, and	
the	power of narrating and talking thru	
chal	llenging behaviors and circumstances.	

Aim 2: Conduct preliminary efficacy analyses of child clinical outcomes (emotion regulation and disruptive behaviors) and caregiver outcomes (stress, emotion regulation, emotion socialization strategies, and distress tolerance) across treatment types.

Between Group Differences. ANCOVA assumptions were checked with Shapiro-Wilk's test (normality), Levene's test (homogeneity of variance), correlations (correlation between covariates), and homogeneity of regression. Variables met most assumptions but did not all meet the homogeneity of regression assumption, so results are reported but should be interpreted with caution.

There was a significant effect of treatment group on child disruptive behaviors at follow up after controlling for pre-treatment score on child disruptive behaviors (ECBI Intensity Scale: F(1,16)=8.19, p = .011, $\eta 2 = .34$) with large effects. There was also a significant effect of treatment group on child dysphoria (EDI Dysphoria: F(1,16)=4.63 p = .047, $\eta 2 = .23$) with large effects. Differences between conditions were not detected in caregiver reports of other child symptoms or caregiver measures (see Table 4). As reported in Table 4 and Figures 4 and 5, caregivers reported lower levels of child behavior problems on the ECBI and dysphoria on the EDI in the PDI condition in comparison to the ED condition.

Table 4

Outcome	Condition	Pre		Follow-up		F	р	η2
		М	SD	М	SD			
Child Measures								
EDI Dysphoria	CDI+PDI	3.38	2.28	1.00	1.89			
	CDI+ED	3.56	3.94	3.67	4.69	F (1,16) = 4.63	.047	.23
EDI Reactivity	CDI+PDI	41.77	17.95	22.80	19.27			
	CDI+ED	36.00	23.76	32.00	22.29	F (1,16) = 2.47	.14	.13
ECBI Intensity	CDI+PDI	129.92	25.58	92.40	25.15			
Scale	CDI+ED	124.22	48.89	123.67	45.09	F (1,16) = 8.19	.011	.34
Caregiver Measures								
PSI Total Stress	CDI+PDI	112.00	17.97	95.60	22.21			
	CDI+EDI	110.78	17.36	105.13	23.48	F(1,15) = .42	.526	.03
CCNES Positive	CDI+PDI	5.75	.47	6.03	.47			
Strategies	CDI+ED	5.83	.64	5.95	.60	F(1,15) = .12	.733	.01
CCNES Negative	CDI+PDI	1.97	.45	1.77	.32			
Strategies	CDI+ED	2.60	.67	2.72	.84	F (1,15) = .47	.502	.03
DTS Total	CDI+PDI	55.23	9.61	61.60	8.72			
	CDI+ED	50.00	9.98	52.00	9.96	F (1,16) = 4.37	.053	.22
ERQ Cognitive	CDI+PDI	26.77	7.75	31.10	8.54			
Reappraisal	CDI+ED	23.67	6.14	28.89	4.54	F (1,15) = .22	.644	.02
ERQ Expressive	CDI+PDI	10.92	5.33	11.60	4.77			
Suppression	CDI+ED	9.87	4.32	10.00	4.41	F (1,15) = .68	.42	.04

Means, Standard Deviations, and differences between conditions at follow-up -treatment

Figure 4

Caregiver-reported child disruptive behaviors between groups at pre- and follow-up



Figure 5



Caregiver-reported child dysphoria between groups at pre- and follow-up

Within Group Differences. Outcome measures were evaluated for normality to meet paired t-test assumptions. Difference scores between pre and post and pre and follow-up on all outcome variables were created and analyzed for normality. All pre to follow-up variables met assumptions for normality, with acceptable skewness and kurtosis and non-significant Shapiro-Wilk's tests. For pre to post variables, several variables did not meet normality assumptions; in the PDI condition, one outlier was removed from the ECBI intake-to-post analysis, after which the means met normality assumptions and had non-significant Shapiro Wilk's tests. In the PDI condition, the PSI total score from intake to post did not meet normality assumptions and required the removal of multiple outliers, so this t-test was not run. Within the ED condition, the ECBI and CCNES negative strategies at intake-to-post also did not meet normality assumptions without requiring the removal of multiple outliers, so ttests were not included in the analysis. To assess pre to post and pre to follow-up changes for each condition, paired sample t-tests were run for each condition separately for each outcome measure. Results for pre to post comparisons can be found in Table X, and pre to follow-up comparisons can be found in Table X.

The CDI+PDI treatment group experienced large effect sizes across measures with significant pre to post changes (EDI Reactivity d = 1.17; ECBI Intensity d = 2.39, CCNES Negative Strategies: d = 1.10). The CDI+ED treatment group did not experience any significant changes on any pre-to-post measures. From pre-to-follow-up, the CDI+PDI group experienced large effect sizes on all measures with significant changes, including all child measures (EDI Dysphoria d = 1.23; EDI Reactivity d = .94; ECBI Intensity d = 1.03), and one caregiver measure of parent stress (PSI Total Stress d = 1.08). The CDI+ED group only experienced a large effect size on one caregiver measure of an emotion regulation strategy (ERQ Cognitive Reappraisal d = -1.02).

Table 5

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Outcome	Condition	Pre		Post		Cohen's D
		M	SD	M	SD	Effect Size
						pre to post
Child Measures						
EDI Dysphoria	CDI+PDI	2.75	1.83	.88	1.46	.710
	CDI+ED	4.00	3.94	4.88	4.52	371
EDI Reactivity	CDI+PDI	37.13	19.90	18.88	10.08	1.17*
	CDI+ED	38.38	24.23	39.13	24.25	058
ECBI Intensity Scale	CDI+PDI	131.75	22.82	97.13	18.33	2.39***
	CDI+ED	131.75	46.36	141.00	49.99	
Caregiver Measures						
PSI Parental Distress	CDI+PDI	36.69	7.90	32.88	12.65	
	CDI+ED	35.11	6.85	37.57	10.45	
PSI Parent-Child Dysfunctional	CDI+PDI	31.77	5.20	24.75	7.61	
Interaction	CDI+ED	34.44	6.33	33.00	5.60	
PSI Difficult Child	CDI+PDI	43.54	7.30	33.00	11.35	
	CDI+ED	41.22	8.23	40.71	9.79	
PSI Total Stress	CDI+PDI	108.13	21.16	90.63	28.22	
	CDI+EDI	112.71	16.18	111.29	23.46	.106
CCNES Positive Strategies	CDI+PDI	5.73	.60	5.82	.53	22
	CDI+ED	5.63	.57	5.60	.57	.043

Pre vs Post Outcomes Across Intensive PCIT and Int
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CCNES Negative Strategies	CDI+PDI	1.97	.47	1.60	.21	1.10*
	CDI+ED	2.68	.72	2.69	1.22	
DTS Total	CDI+PDI	54.75	9.61	60.75	11.21	50
	CDI+ED	51.00	10.18	51.88	10.83	169
ERQ Cognitive Reappraisal	CDI+PDI	26.00	7.39	29.63	7.82	46
	CDI+ED	25.43	4.89	29.14	3.53	870
ERQ Expressive Suppression	CDI+PDI	9.88	3.87	11.13	4.91	51
	CDI+ED	11.14	3.84	11.71	5.06	104

*p < .05, ** p < .01, *** p < .001

Table 6

Pre vs Follow up Outcomes Across Intensive PCIT and Intensive PCIT-ED conditions

Outcome	Condition	Pre		Post		Follow-	up	Cohen's D
								Effect Size
		М	SD	М	SD	М	SD	pre to follow-up
Child Measures								
EDI Dysphoria	CDI+PDI	3.38	2.28	.88	1.46	.89	1.96	1.23**
	CDI+ED	3.56	3.94	4.88	4.52	3.00	5.07	.177
EDI Reactivity	CDI+PDI	41.77	17.95	18.88	10.08	22.00	20.27	.94*
	CDI+ED	36.00	23.76	39.13	24.25	29.71	24.66	.428
ECBI Intensity	CDI+PDI	129.92	25.58	98.89	17.95	93.00	26.60	1.03*
Scale	CDI+ED	124.22	48.89	141.00	49.99	128.00	46.15	.000
Caregiver Measu	res							
PSI Parental	CDI+PDI	36.69	7.90	32.88	12.65	30.33	8.62	
Distress	CDI+ED	35.11	6.85	37.57	10.45	35.00	12.17	
PSI Parent-Child								
Dysfunctional	CDI+PDI	31.77	5.20	24.75	7.61	26.67	5.50	
Interaction	CDI+ED	34.44	6.33	33.00	5.60	33.50	6.47	
PSI Difficult	CDI+PDI	43.54	7.30	33.00	11.35	34.89	10.67	
Child	CDI+ED	41.22	8.23	40.71	9.79	37.00	9.90	
PSI Total Stress	CDI+PDI	112.00	17.97	90.63	28.22	91.89	20.00	1.08*
	CDI+EDI	110.78	17.36	111.29	23.46	105.50	26.88	.40
CCNES Positive	CDI+PDI	5.75	.47	5.82	.53	6.03	.50	43
Strategies	CDI+ED	5.83	.64	5.60	.57	6.01	.64	34
CCNES Negative	CDI+PDI	1.97	.45	1.60	.21	1.81	.32	.20
Strategies	CDI+ED	2.60	.67	2.69	1.22	2.67	1.17	04
DTS Total	CDI+PDI	55.23	9.61	60.75	11.21	60.56	8.56	73
	CDI+ED	50.00	9.98	51.88	10.83	51.67	11.38	.60
ERQ Cognitive	CDI+PDI	26.77	7.75	29.63	7.82	32.33	8.06	58
Reappraisal	CDI+ED	23.67	6.14	29.67	3.53	28.29	4.89	-1.02*
ERQ Expressive	CDI+PDI	10.92	5.33	11.13	4.91	11.44	5.02	23
Suppression	CDI+ED	9.87	4.32	11.71	5.06	10.0	4.76	.17

*p < .05, ** p < .01, *** p < .001

Clinical Change Trajectory. Descriptive statistics and change trajectories on the ECBI Intensity for each family within each condition were further inspected. Figure 6 shows average ECBI scores at each timepoint for each treatment condition. Figure 7 shows ECBI scores at each timepoint for CDI+PDI families, while Figure 8 shows ECBI scores at each timepoint for CDI+ED families. As shown in Table 7, in the PDI treatment, four families began treatment with ECBI scores above the clinical threshold (130). Three dropped below the clinical threshold at post-treatment, with all three (75%) experiencing clinically significant change at post-treatment. Within the ED condition, three families began treatment or follow-up. Of the nine families who completed the ED treatment, five families' (55%) scores worsened by post treatment. Only three remained worse at follow-up (30%). Of the 13 families who completed the PDI treatment, only one family (8%) exhibited an increase in ECBI scores at post or follow-up.

Figure 6



ECBI scores across timepoints in ED and PDI conditions.

Figure 7



ECBI scores across timepoints for individual participants in ED condition

Figure 8

ECBI scores across timepoints for individual participants in PDI condition



Table 7

Number of families showing clinically significant child behavior change in PDI and ED

		Number in clinical		Reliable Chang	ge*	Clinically Significant		
		Tange				Chan	ge	
Group	N	Pre	post	п	%	п	%	
PDI	13	4	1	3	75	3	75	
ED	9	3	3	0	0	0	0	

conditions on ECBI Intensity Scale.

*The reliable change index (RCI) was calculated by dividing the difference between post and pre score by the standard error of the sample difference scores, to ensure that change exceeded the margin of error. If the RCI was greater than 1.96, the change was considered statistically significant

**Change was considered clinically significant if pre score was clinical, post score was subclinical, and change was reliable as indicated by the RCI.

Discussion

Developing and identifying treatments that improve emotion regulation in young children with ASD, and which are acceptable and accessible to caregivers is important. The aim of this pilot study was to evaluate the feasibility of implementing a RCT and the acceptability and preliminary efficacy of a novel emotion-focused adaptation of PCIT for young children with autism. Implementing the RCT was demonstrated to be feasible, in terms of recruitment, randomization, retention, and assessment completion. Although the RCT was feasible, there were challenges in recruiting a diverse sample, obtaining assessments online at both post-treatment timepoints, randomization, and delivering the novel intervention. An adequate number of families who met inclusion criteria was recruited within the intended timeframe, but the study was not effective in recruiting an ethnoracially diverse sample. The lack of diversity in this sample is concerning, given ongoing calls to increase ethnoracial diversity in treatment studies and to consider the role of culture in parent training in particular (Lansford, 2022; Lau, 2006; Nielsen et al., 2017). There was limited socioeconomic diversity in the sample as well, given that nearly 70% of participating families reported annual household incomes above \$100,000. This is consistent with findings that studies conducted by university-based research clinics report higher income levels than samples recruited from community clinics (Southam-Gerow et al., 2003). Since this treatment necessitated adequate access to internet, screens, and headphones, it is possible that results would differ in families with lower SES and limited access to technology. In fact, SES has been identified as a predictor of teletherapy service delivery; clinicians in one study who reported higher proportions of low-SES clients reported decreased teletherapy provision after the covid-19 pandemic (Gangamma et al., 2022). Additional studies have identified differences in access to telehealth services by race and socioeconomic status, suggesting that factors contributing to disparate access to in-person healthcare are replicated in telehealth access (Darrat et al., 2021; Rivera et al., 2021). While recruitment was successful temporally and in quantity, it was not successful in obtaining an adequately diverse sample that would generalize to the larger population.

Beyond recruitment, the study's matched randomization structure was not effective as intended in creating equally-sized groups, resulting in manual assignment of families who enrolled in treatment later to the ED group. The randomization issue would likely be resolved in a larger study and longer recruitment period. Despite manual group assignment, families were split into comparable groups, with no significant differences on intake disruptive behaviors or demographic variables. With regards to study retention, nearly all families who enrolled in treatment remained in treatment. Although collecting measures at both posttreatment timepoints (post and follow-up) was challenging, almost all families completed at least one of these two time-points. Collecting post-treatment measures online was

demonstrated to be feasible, with multiple reminder emails, although collecting two measures so close in time may not be feasible for a future, larger study, and decreasing the number of measures at each timepoint may help with higher completion rates.

In terms of the feasibility and acceptability of the novel, emotion regulation intervention, initial findings demonstrated that therapists struggled to implement the novel intervention as planned to high fidelity, due to behavioral challenges impeding full delivery in some cases, however parental satisfaction was high for both treatment groups. Delivery of an intensive treatment over telehealth was found to be feasible, with each participant receiving 10 sessions in an average of 14.45 days. Although some parents described daily scheduling as an added stressor, many expressed appreciation for the intensive treatment and the ability to develop new parenting skills so quickly. The speed and intensity of the intervention may have contributed to high retainment in treatment and few dropouts. This could be a helpful antidote to high dropout rates that have been found in PCIT studies, which can range from 12-67% (Lieneman et al., 2019), ensuring that families have a higher likelihood of receiving an adequate dose of treatment, and capitalizing on their initial motivation to participate. Graziano (2020) similarly found very low attrition rates (3%) for the intensive version of PCIT, and found that the intensive form of PCIT was particularly helpful for families in which caregivers reported higher levels of stress. Families of children with autism have higher stress levels (Keenan et al., 2016) so this may be a particularly helpful form of intervention for them. This is the second study known to the authors applying the intensive model of PCIT to families of children with autism. The first was a feasibility study that similarly found high levels of parent satisfaction and decreases in disruptive behaviors in enrolled families (Jimenez Muñoz et al., in preparation). Since families with an

autistic child are often receiving multiple services simultaneously, the feasibility of delivering an intensive intervention is striking in this population. According to one study of families with children aged 2-7 with ASD, children received 13.17 hours of services weekly (McIntyre & Zemantic, 2017), which was still less than recommended guidelines on early intervention services. Adding five hours of services to an already busy schedule would seem likely to increase stress, however caregivers in the current study receiving the CDI+PDI intervention reported significantly decreased stress at follow-up. Those who received CDI+ED did not report significant changes in stress level.

In terms of receiving treatment over telehealth, parents reported increased convenience and accessibility, however families with more severely dysregulated children also described challenges with telehealth delivery, with struggles to manage their child's elopement or aggressive behaviors. It has been posited that internet-delivered PCIT may be particularly helpful for families with autistic children (Hong et al., 2019), and this study provides additional support for that supposition. Telehealth services for children with autism have also been found to be more cost effective than clinic-based or home-based services (Lindgren et al., 2016), and clinicians have reported benefits of telehealth provision of PCIT specifically, including decreased barriers to access and the ability to support families in their home environment (Barnett et al., 2021). It has also been suggested that telehealth is a particularly useful medium for family-based treatments, given that getting multiple family members to a clinic can be challenging (Crum & Comer, 2016). The current study did not evaluate whether the telehealth delivery medium increased the participation of multiple caregivers, but this would be an important future direction, given the importance of engaging

fathers in their children's care and low rates of father involvement in children's mental health services (Klein et al., 2022; Tully et al., 2017).

In addition to providing insight into the feasibility and acceptability of offering a telehealth and intensive version of PCIT to families with an autistic child, one of the strengths of this study was its comparison of PCIT with the standard module on effective commands and consequences with the adapted version of PCIT, in which the consequences module is replaced with emotion-focused content. The study aimed to identify a caregiverinvolved treatment that would enhance emotional learning for young children with ASD and improve ER, an underlying mechanism of many psychiatric comorbidities, in response to limited acceptability of currently available interventions, and a desire for treatments that teach children self-regulation techniques (Tschida, 2021). In terms of preliminary efficacy, contrary to our study hypothesis, PCIT-ED did not result in greater improvements in child or parent emotion regulation. In fact, families in this group did not improve on any child outcomes, with some reporting increased behavioral challenges following treatment. The small sample size precluded detection of anything other than large effect sizes according to a power calculator (G* Power 2), so it is possible that changes would be detectable in a larger sample, however in this study no significant changes were detected at post or follow-up for the ED group, other than in caregiver report of their use of cognitive reappraisal, which is one emotion regulation strategy. In contrast, caregivers who participated in PDI reported large effect sizes in child dysphoria, emotional reactivity, and disruptive behaviors, with caregivers reporting significantly less stress and less use of negative strategies to cope with children's negative emotions. It has been found previously that standard PCIT, without added emotion content, improves emotion regulation in addition to disruptive behaviors

(Rothenberg et al., 2019). This study offers preliminary evidence that these gains hold for children with ASD as well, and that the PDI phase, while ostensibly improving child compliance, simultaneously improves child ER. Comparable effect sizes for child disruptive behaviors have been found for PCIT with both phases delivered, with one meta-analysis of PCIT studies reporting an average Cohen's D's of 1.65 (Ward et al., 2016). Comparable effect sizes have also been found for intensive PCIT, in which a feasibility study reported effect sizes ranging from 1.67 to 2.50 for disruptive behaviors (Graziano et al., 2015).

It is possible that changes in family patterns of interaction respond more slowly to emotion-focused interventions, and much more quickly to behavioral disciplinary strategies. Shifts in cognitive reappraisal, for example, may result in eventual changes in response to displays of dysregulation in a child, and have longer term impacts on child emotion regulation. However, it is also possible that the PDI phase of treatment is simply a necessary component of treatment for children with autism, and may be a prerequisite to delivering emotion-focused content, as was previously done in the trial for childhood depression (Luby et al., 2012). This is an important finding at a time when many clinicians are not using timeout in behavioral parent training treatments (Brookman-Frazee et al., 2021), and clinicians are increasingly reporting negative beliefs about the effectiveness and utility of time-out (Woodfield et al., 2021). Many treatment studies are focused on integrating emotion-focused material into parenting interventions due to their increased popularity (Jugovac et al., 2022). One study comparing an emotion-focused parenting program with a behaviorally-focused one found similar follow-up ECBI scores, but results were mediated by child age, such that older children benefited significantly more from the emotion-focused content, while younger children benefited more from the behavioral program (Duncombe et al., 2016). This study

provides some preliminary evidence that behavioral parent training that includes teaching caregivers to use time-out may be more effective for young children with autism than a comparable intervention that replaces time-out with emotion-focused content.

Study Limitations

This study demonstrated that a significant amount of change in behaviors and ER can occur in a relatively short period of time in young children with autism, with appropriate treatment, however many children will likely need more treatment even following an intensive course of PCIT. It had several limitations, including a small sample size, minimal diversity, and deviations from normality within some outcomes rendering analyses less reliable. The current study did not confirm autism diagnoses, and relied on caregivers to report that their child had been diagnosed. Additionally, mean ECBI scores at intake were lower than community clinic averages for child disruptive behaviors at intake (Danko et al., 2016). Although ECBI was not the measure of the primary outcome in this study, it is an important outcome in PCIT. Finally, given challenges to telehealth for families with children who have severe aggression or a tendency to elope, positive results may not hold if the sample had more severe behaviors at intake.

Future Directions

Results of this pilot study may inform a larger future study. In future studies, emotion-focused content should be integrated after PDI, to increase the likelihood that children and caregivers can engage with the material in a meaningful way. Ease of recruitment, a very low attrition rate, and caregiver reported satisfaction on a standardized measure and in qualitative reports indicate how eager families are for this type of intensive in-home support. Offering varied treatment formats, such as intensive and internet-delivered,

may increase accessibility for families who face scheduling difficulties, have limited providers in their areas, or cannot get to clinics for other reasons. Additionally, the impact of behavioral training on child emotion regulation is an important finding to disseminate to clinicians who may hesitate to use time-out due to their own biases, beliefs, and anxieties. A larger study should follow to confirm the efficacy of the CDI+PDI delivered through an intensive, telehealth format for families of young children with autism.

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