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Smart Start for Trauma: A Multiple Baseline Design

Sarah E. Dickinson

University of South Florida, sdickinson@mail.usf.edu

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Smart Start for Trauma: A Multiple Baseline Design

by

Sarah E. Dickinson

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
Department of Educational and Psychological Studies
College of Education
University of South Florida

Co-Major Professor: Linda Raffaele Mendez, Ph.D.

Co-Major Professor: Heather Agazzi, Ph.D.

Emily Shaffer-Hudkins, Ph.D.

John Ferron, Ph.D.

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Toddlers

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Dedication

This work is dedicated to Matthew (my “M.J.”). Your humor and lightheartedness have been so enriching. You have taught me to experience life without worry. You have given me resilience. Above all, you have loved me every step of the way. I am forever grateful for your presence. Thank you for being my balance.

“The Lord bless you and keep you;

The Lord make his face to shine upon you and be gracious to you;

The Lord lift up his countenance upon you and give you peace.”

Numbers 6:24-26 ESV

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Abstract

The purpose of this study was to address gaps in the trauma treatment literature related to the expense and inaccessibility of evidence-based interventions for children with disabilities who have experienced trauma. Another aim of this study was to provide additional support for a newly piloted intervention for children with disabilities who have experienced trauma. This intervention is known as Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma. A non-concurrent multiple baseline method was used to determine whether there was a functional relationship between the intervention and children's challenging behaviors for five caregiver-child dyads. In addition, three of five caregiver-child dyads were assessed for improvements in child PTSD symptomatology, positive parenting practices, parenting stress, and treatment acceptability. Results from visual analysis, masked visual analysis, and hierarchical linear modeling were mixed, but generally supported a statistically and clinically significant relationship between participation in Smart Start and improved caregiver ratings of children's challenging behaviors. Wilcoxon Signed-Rank test did not show statistically significant changes in interventionists' ratings of challenging behavior, but descriptively, four of five children were rated as improved. Reliable change index scores revealed statistically significant changes in trauma symptoms and parenting stress for two participants. Positive parenting practices improved significantly for all participants according to the reliable change index. The intervention was implemented with good fidelity. All caregivers

found Smart Start highly acceptable. Future research with larger samples is warranted based on the extremely promising results of the present study.

Chapter One:

Introduction

Problem Statement

Approximately 26% of children experience a potentially traumatic event by the age of 4 years (Briggs-Gowan, Ford, Fraleigh, McCarthy, & Carter, 2010) and about 16% of children ages 2 to 18 years meet full criteria for a DSM-5 (Diagnostic and Statistical Manual of Mental Disorders—Fifth Edition; American Psychiatric Association, 2013) diagnosis of posttraumatic stress disorder (PTSD; Alisic et al., 2014). Potentially traumatic events include abuse/neglect, interpersonal violence, natural disasters, large-scale transportation accidents, fires or burns, motor vehicle accidents, rape and sexual assault, stranger physical assault, witness to domestic violence, sex trafficking, war, witness to or confrontation with homicide or suicide, and life threatening medical conditions (Briere & Scott, 2014). Of these events, child maltreatment is one of the most common types of trauma among young children ages 0 to 3 years. Four maltreatment categories are reported each year by the U.S. Department of Health and Human Services: physical abuse, sexual abuse, psychological/emotional abuse, and neglect. According to the 2015 report, children ages 0 to 3 years had the highest rate of victimization (U.S. Department of Health and Human Services, 2017).

Children with disabilities experience higher rates of maltreatment compared to typically developing children (Jones et al., 2012; Sullivan & Knutson, 2000). Moreover, children with disabilities are more likely to be re-victimized and to experience more than one type of abuse compared to typically developing children (Sullivan & Knutson, 2000). On average, the first

incidence of maltreatment for children with disabilities occurs before the fifth birthday (Maclean et al., 2017). Thus, young children with disabilities face a unique risk with regard to maltreatment.

Trauma among young children mimics that of adults (De Young, Kenardy, & Cobham, 2011). Expressions of trauma typically take the form of challenging behaviors for young children and include intrusion, avoidance/numbing, and hyperarousal symptoms (De Young et al., 2011). Intrusion symptoms include distressing memories or dreams, dissociative reactions, psychological distress/physiological reactions when presented with reminders of the event, and tantrums (Gaensbauer, 1995; Scheeringa, Zeanah, Myers, & Putnam, 2003). Avoidance/numbing symptoms include escape behaviors and withdrawal from family or preferred activities (Coates & Gaensbauer, 2009). Hyperarousal symptoms include irritability, fussiness, defiance, tantrums, nightmares, anxiety, overactivity, and poor concentration (Lieberman & Knorr, 2007; Pynoos et al., 2009).

When left untreated, trauma exposure can result in a host of negative short-term and long-term outcomes, and outcomes are poorer when the trauma occurs between the ages of 1 and 3 years (Font & Berger, 2015). Researchers have found a dose-response effect of early adversity on physical and mental health over time such that increased traumatic experiences have been linked with earlier death (Felitti et al., 1998). In addition, early trauma is associated with the adoption of health-risk behaviors (Felitti et al., 1998). Not only are physical and mental health implicated, but also academic well-being is compromised following trauma exposure. Children who have experienced maltreatment have poorer school attendance compared to children with no history of maltreatment (Lansford et al., 2002). Children with disabilities who have experienced maltreatment have even worse attendance than typically developing peers who have been

maltreated (Sullivan & Knutson, 2000). In addition, children with disabilities who have a maltreatment history have poorer grades than typically developing children (Sullivan & Knutson, 2000). Finally, neurological development is significantly impacted by early childhood trauma through epigenetics, or environmentally facilitated changes in genetic expression (Orr & Kaufman, 2014). This may result in an impaired ability to regulate one's stress response (Briere & Scott, 2014).

Circumstances that place parents at-risk for child maltreatment include teen parenthood (Oliver, Kuhns, & Pomeranz, 2006), parental history of maltreatment, negative attitudes towards the child, substandard knowledge of child development, parental psychopathology, low household income and poverty, insufficient social support, single parenthood, and family/community violence (Goldman, Salus, Wolcott, & Kennedy, 2003). One major protective factor against maltreatment, however, is a strong parent-child attachment, which is often the basis for treatment of trauma among young children (DeYoung et al., 2011).

The evidence-based interventions that exist for young children who have experienced trauma include Attachment and Biobehavioral Catch-up (Dozier, Meade, & Bernard, 2014), Child-Parent Psychotherapy (Lieberman, Silverman, & Pawl, 2000), Parent-Child Interaction Therapy (Eyberg & Funderburk, 2011), and Trauma-Focused Cognitive Behavioral Therapy (Cohen, Mannarino, & Deblinger, 2012). Unfortunately, the evidence-based treatments available are limited in terms of their financial accessibility and feasibility for young children with disabilities. More specifically, no treatments have been created expressly for young children with disabilities who also have a history of maltreatment. This is particularly concerning, given that young children with disabilities are at high-risk for maltreatment (Jones et al., 2012; Maclean et al., 2017; Sullivan & Knutson, 2000). In addition, many of the children who experience

maltreatment are of low socioeconomic status and are less likely to have insurance coverage to pay for expensive treatments (Sullivan & Knutson, 2000). Moreover, the clinician trainings available for the evidence-based treatments are costly and often require at least a master's level degree, thus limiting the number of individuals who can provide trauma-informed treatment.

Purpose and Significance of the Study

The purpose of this study was to address the gaps in the trauma treatment literature with regard to 1) trauma-informed service-delivery for young children with disabilities and 2) financially ascertainable evidence-based interventions for both therapists and families. This was achieved through the implementation of a newly piloted parenting program. The treatment is known as Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma (Agazzi, Salloum, Shaffer-Hudkins, & Adams, 2016). The Smart Start intervention was founded on strategies from Parent-Child Interaction Therapy (PCIT; Eyberg & Funderburk, 2011) and from Helping Our Toddlers, Developing Our Children's Skills (HOT DOCS; Childress, Agazzi, & Armstrong, 2011) and was created for bachelor's level early interventionists to implement with young children who have an identified disability and maltreatment history. Both the training for Smart Start and the treatment are free or of low cost. Training includes a detailed manual for interventionists to use throughout treatment.

A second aim of this study was to further assess the efficacy of Smart Start. A recent pilot of Smart Start resulted in positive pre-intervention to post-intervention outcomes for children and families, which necessitated further validation of its effects (Agazzi et al., 2016). The current study extended the work of Agazzi et al. (2016) by employing a more rigorous single case methodology wherein children were randomized to receive treatment in staggered phases. In addition, this investigation compared Smart Start to early intervention as usual. Specifically,

children received treatment as usual for 3, 5, or 7 weeks, and then children began the Smart Start intervention. Targeted outcomes included children’s challenging behaviors, children’s PTSD symptomatology, parenting stress, and positive parenting practices.

This study contributed to the current knowledge of evidence-based treatments for young children with disabilities who have experienced trauma. More specifically, results of this study lent support to the use of a manualized approach for the treatment of trauma among young children with disabilities. Additionally, the results of this study supported Smart Start as a cost-effective intervention approach that is easily accessed by bachelor’s level early interventionists.

Terminology

The terms listed below were defined as such for the purposes of this study.

Child maltreatment. The Federal Child Abuse Prevention and Treatment Act has developed a widely used definition of child maltreatment that characterizes abuse and neglect as “...any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical^{SEP} or emotional harm, sexual abuse or exploitation, or an act or failure to act which presents an imminent risk of serious harm” (42 U.S.C.A. §5106g).

Disability. The United States Department of Education (2014) defines disability under the Individuals with Disabilities Education Act Part C as a child with a developmental delay in at least one of the following areas of development: cognitive, physical, communication, social or emotional, or adaptive. These delays prevent a child from progressing at the same rate as their typically developing peers in the first three years of life.

Trauma. The Substance Abuse and Mental Health Services Administration (2014) defines trauma as “...an event, series of events, or set of circumstances that is...physically or

emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being" (p. 7).

Posttraumatic stress disorder (PTSD). For children younger than 6 years, the American Psychiatric Association defines PTSD as direct experience of, witness to, or learning of "actual or threatened death, serious injury, or sexual violence." This exposure to trauma must be accompanied by at least one intrusion symptom, one avoidance symptom or negative cognitive alteration, and two arousal symptoms. In addition, the symptoms must persist beyond a period of one month and must cause relational distress (DSM-5).

Challenging behavior. Defined by Fox and Smith (2007), a challenging behavior is "any repeated pattern of behavior, or perception of behavior, that interferes with or is at risk of interfering with optimal learning or engagement in prosocial interactions with peers and adults" (p. 6).

Caregiver. A caregiver is the legal or court-appointed guardian of a child. This may include biological parents, biological or legal family members, or foster parents.

Parenting stress. Stress is a part of the typical parenting experience that may lead to "biochemical, physiological, cognitive, and behavioral changes" in an effort to "alter the stressful event or accommodate to its effects" (Patnaik, 2014).

Interventionist. An interventionist is an Early Steps provider or practicum student who was trained to use the Smart Start manual and implemented the Smart Start intervention. These interventionists were either non-licensed and held a bachelor's/master's degree or licensed and held a master's or doctoral degree.

Treatment integrity. The extent to which an interventionist engages in all the components of a treatment session as outlined by a treatment integrity checklist.

Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma. A 9-week manualized parenting intervention founded upon the principles of PCIT and HOT DOCS. The goal of this intervention is to improve caregiver and child well-being following trauma.

Research Questions

The research questions were as follows:

1. With what degree of integrity do Smart Start interventionists implement Smart Start?
2. Is there a functional relationship between participation in Smart Start and children's challenging behaviors?
3. Do interventionists report a decrease in the severity of the child's challenging behavior from pre-intervention to post-intervention?
4. Do caregivers report lower rates of PTSD symptomatology in their children from pre-intervention to post-intervention?
5. Do caregivers' positive parenting practices improve from pre-intervention to post-intervention?
 - a. Do caregivers increase the number of labeled praises used throughout play?
 - b. Do caregivers increase the number of reflections used throughout play?
 - c. Do caregivers increase the number of behavior/emotion descriptions used throughout play?
 - d. Do caregivers decrease the number of questions used throughout play?
 - e. Do caregivers decrease the number of commands used throughout play?
 - f. Do caregivers decrease the number of criticisms used throughout play?

6. Do caregivers self-report improved levels of parenting stress from pre-intervention to post-intervention?
7. How satisfied are caregivers with Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma?

Limitations

There were some limitations to be considered in relation to this study. First, the small sample of participants limited the generalizability of the findings. A second limitation to this study was the potential for “practice effects” in relation to the behavioral outcome measure (i.e., Eyberg Child Behavior Inventory). In addition, some of the measures that were used in this study (i.e., Young Child PTSD Checklist [YCPC]) have not been validated yet. Specifically, the YCPC has not been psychometrically validated for use as a reliable measure of PTSD symptomatology among very young children. A further limitation was that long-term follow-up data were not collected. A final limitation was the vast difference in the training backgrounds among interventionists. The differences among interventionists means it was difficult to ascertain a true understanding of “treatment as usual.” Therefore, “treatment as usual” for one child could have meant strong evidence-based behavioral supports, while “treatment as usual” for another child could have meant minimal evidence-based strategies.

Chapter Two:

Literature Review

This section includes a detailed review of the literature surrounding the tenets of this research project. Many topics are discussed, including the types of trauma children may experience, the broad prevalence of trauma, and the specific prevalence of maltreatment. The manifestations and outcomes associated with early childhood trauma are discussed along with the risk and protective factors associated with maltreatment. The evidence-based treatments available for trauma are reviewed and critiqued. A newly piloted parenting intervention, Smart Start, is introduced in response to the concerns associated with the current literature. This section concludes with the significance and purpose of this research endeavor.

Historical Context of Trauma Treatment among Young Children

Historically, young children aged birth to five have been neglected as a population in need of treatment for exposure to potentially traumatic events (Brandsetter, 2014). Young children with disabilities who have trauma exposures have been an especially understudied population (Brandsetter, 2014). A number of misconceptions have perpetuated the omission of these populations from study. Misconceptions that have been dispelled include that young children do not remember or understand trauma during and after it happens, that children with disabilities cannot feel pain, and that children with disabilities have little to no risk of being victimized by adults (Child Welfare Information Gateway, 2012). Thus, trauma treatment for young children has only been introduced within the last two decades with the inception of therapies such as Attachment and Biobehavioral Catch-up, Child-Parent Psychotherapy, Parent-

Child Interaction Therapy, and Trauma-Focused Cognitive Behavioral Therapy. Specific trauma treatments for young children with disabilities, however, have yet to be validated.

Trauma Types and Prevalence

By the age of 24 to 48 months, approximately 26% of children experience a potentially traumatic event (Briggs-Gowan et al., 2010), and overall, approximately 16% of children ages 2 to 18 years have a diagnosable posttraumatic stress disorder (PTSD; Alisic et al., 2014). There are a multitude of potentially traumatic events that young children may experience. These events include child abuse/neglect, interpersonal violence, natural disasters, large-scale transportation accidents, fires or burns, motor vehicle accidents, rape and sexual assault, stranger physical assault, witness to domestic violence, sex trafficking, war, witness to or confrontation with homicide or suicide, and life threatening medical conditions (Briere & Scott, 2014). One particularly common type of trauma that happens to young children is maltreatment. In 2015 alone, 4 million referrals were made to Child Protective Services (CPS), and 683,000 of the reports were substantiated. Furthermore, the number of substantiated cases of child abuse and neglect has risen by 3.8% since 2011, reflecting a growing concern for child welfare in the United States. Very young children are at especially high risk for child abuse and neglect compared to older populations (U.S. Department of Health and Human Services, 2017). The annual child maltreatment report from the U.S. Department of Health and Human Services revealed that the victimization rate was highest among children ages 0 to 3 years, with nearly 28% of victims falling into this age bracket.

Maltreatment among children with disabilities. Children with disabilities are a population that is especially vulnerable to maltreatment. Children with disabilities are 1.68 to 3.4 times more likely to be maltreated than children with no documented disability (Jones et al.,

2012; Maclean et al., 2017; Sullivan & Knutson, 2000; U.S. Department of Health and Human Services, 2006). Stated another way, 9% of children with no documented disability experience maltreatment in comparison to 31% of children with a disability (Sullivan & Knutson, 2000). Moreover, children with disabilities are significantly more likely to be re-victimized and to be subjected to multiple types of abuse compared to children with no disability (Sullivan & Knutson, 2000). Sullivan and Knutson (2000) also studied four specific types of disability categories and the age of first incidence. Disability categories included behavior disorders, communication disorders, health/orthopedic disabilities, and intellectual disabilities. Results indicated that young children ages 0 to 5 years in all disability categories except for behavior disorders were more susceptible to maltreatment compared to other age groups. Furthermore, Maclean et al. (2017) reported the average first incidence of maltreatment for children with disabilities occurs prior to the age of 5 years. Thus, very young children who also have a disability are in a unique position of vulnerability in relation to maltreatment compared to typically developing children.

Maltreatment categories. There are four major categories of maltreatment that are reported by the Department of Health and Human Services each year: neglect, physical abuse, sexual abuse, and emotional/psychological abuse. Neglect is the failure of a parent or caregiver to provide basic living necessities such that a child is subjected to danger or harm (Child Welfare Information Gateway, 2016). Neglect is the most frequent type of maltreatment, accounting for 75.3% of all cases in 2015 (U.S. Department of Health and Human Services, 2017).

Physical abuse can be defined as non-accidental injury to a child that results in physical impairment (Child Welfare Information Gateway, 2016). Physical abuse accounted for 17.2% of all substantiated cases in 2015 (U.S. Department of Health and Human Services, 2017).

Sexual abuse is broadly defined by the Child Abuse Prevention and Treatment Act as “the employment...of any child to engage in, or assist any other person to engage in, any sexually explicit conduct or simulation of such conduct for the purpose of producing a visual depiction of such conduct; or the rape, and in cases of caretaker or interfamilial relationships, statutory rape, molestation, prostitution, or other form of sexual exploitation of children, or incest with children” (42 U.S.C.A. §5106g). Sexual abuse accounted for 8.4% of all substantiated maltreatment cases in 2015 (U.S. Department of Health and Human Services, 2017).

Finally, emotional/psychological abuse can be defined as psychological or emotional injury that leads to a change in cognition or behavior and that possibly results in psychopathology (Child Welfare Information Gateway, 2016). Emotional abuse can be difficult to substantiate, but nevertheless, accounted for 6.2% of all maltreatment cases in 2015 (U.S. Department of Health and Human Services). Finally, 6.9% of reports included “other” types of maltreatment such as domestic violence or parental drug use (U.S. Department of Health and Human Services, 2017).

Manifestations and Outcomes Associated with Early Trauma and Maltreatment

The manifestations and outcomes associated with early childhood trauma are especially deleterious due to the rapid rate of neurological and physical development among infants and toddlers (De Young, Kenardy, & Cobham, 2011). Though young children were once considered to be resistant to trauma, research has shown that they are not only affected by maltreatment and trauma, but also they are more susceptible than other populations to the negative ramifications of trauma on physical, psychological, and neurological health (Anda et al., 2006; De Young et al., 2011; Felitti et al., 1998). The impact of trauma on developmental trajectories is outlined below.

Early childhood manifestations of trauma. In order for young children to develop posttraumatic stress symptoms, they must meet several cognitive and developmental criteria, including the ability to make implicit memories (this develops prenatally), have perceptual capabilities (this develops between 3 and 6 months of age), engage in affective expression (this develops between 6 and 8 months for the self and 18 and 21 months for others), engage in motoric behaviors to express trauma symptoms (this develops between 7 and 18 months), verbalize traumatic experiences (this develops between 18 and 29 months), and develop attachments to others (this develops between 7 and 18 months; Scheeringa & Gaensbauer, 2000). Thus, even infants and toddlers have the capacity to internalize and respond to potentially traumatic events such as maltreatment.

Posttraumatic stress among young children under the age of 6 years is defined by the DSM-5 as series of intrusion, avoidance and/or numbing, and hyperarousal symptoms. These posttraumatic stress symptoms mirror those of adults; however, young children typically display posttraumatic stress symptoms in a manner consistent with their cognitive and physical development (De Young et al., 2011). Taken together, posttraumatic stress symptoms among young children can be broadly categorized as a set of challenging behaviors.

Intrusion symptoms are most common among young children, with 35-80% of children showing signs of intrusion following a trauma (Meiser-Steadman, Smith, Glucksman, Yule, & Dalgleish, 2008). According to the DSM-5, intrusion symptoms include distressing memories or dreams, dissociative reactions, and psychological distress and physiological reactions when presented with reminders of the event. In a young child, this looks like engaging in posttraumatic play and drawing or talking about the trauma excessively (Gaensbauer, 1995). In addition,

children often respond to trauma reminders with emotionally and physically challenging behaviors such as tantrums and withdrawal (Scheeringa, Zeanah, Myers, & Putnam, 2003).

Approximately 18 to 62% of young children develop at least one avoidance or numbing symptom following a trauma (Meiser-Steadman et al., 2008). Avoidance among young children manifests as active escape behaviors (e.g., turning away, crying, eloping) when faced with trauma triggers (Coates & Gaensbauer, 2009). Numbing among young children exhibits as withdrawal from close adults and previously preferred activities (Pynoos et al., 2009).

Hyperarousal symptoms are displayed among 32 to 45% of young children who have experienced a trauma (Meiser-Steadman et al., 2008). These symptoms include extreme emotional lability such as irritability, fussiness, defiance, and tantrums (Pynoos et al., 2009). Hyperarousal among young children also includes nightmares (although, they are not always directly relevant to the trauma), increased anxiety (e.g., alertness to danger/separation from caregiver and exaggerated startle response), increased activity, and decreased concentration (Lieberman & Knorr, 2007). A final symptom that falls within an associated feature of the DSM-5 criteria for posttraumatic stress is regression of previously met developmental milestones.

Long-term outcomes of early adversity. Not only do trauma and maltreatment have short-term manifestations, but they also have long-term consequences if not treated appropriately (Felitti et al., 1998). In their seminal Adverse Childhood Experiences (ACE) study, Felitti and colleagues demonstrated the dose-response effect of early adversity, particularly abuse and household dysfunction, on development. Since then, researchers have corroborated and expanded upon these findings to show the destructiveness of early adversity across all domains of life.

Psychological and behavioral health. Individuals with four or more ACEs are 4.6 times as likely to experience at least two weeks of depressed mood throughout the year compared to

individuals with no ACEs (Felitti et al., 1998). In addition, individuals who have experienced four or more ACEs are 12.2 times as likely as those with no ACEs to make a non-fatal suicide attempt (Felitti et al., 1998). Compared to no ACEs, four or more ACEs was additionally associated with a 2.5 times greater likelihood of experiencing panic reactions, a 3.6 times greater likelihood of having depressed affect, a 2.4 times greater likelihood of experiencing anxiety, and a 2.7 times greater likelihood of having hallucinations (Anda et al., 2006). Other psychological concerns that have been associated with maltreatment in childhood include bipolar disorder, panic disorder, specific phobias, posttraumatic stress disorder, schizophrenia, reactive attachment disorder, eating disorders, and personality disorders (Heim, Shugart, Craighead, & Nemeroff, 2010). Further, individuals who have experienced maltreatment are more likely to be unresponsive to treatment for depression, even with treatment in adulthood (Yonkers, Zlotnick, Warshaw, Shea, & Keller, 1998).

In support of the association between earlier maltreatment and worse socio-emotional outcomes, Font and Berger (2015) found that children who had been maltreated between the ages of 1 and 3 years had poorer outcomes by age 9 years compared to children who had experienced maltreatment between the ages of 3 and 5 years. In addition, Font and Berger (2015) found relationships between the type of abuse experienced and psychological and behavioral outcomes. Specifically, children who were physically neglected had greater behavioral problems and worse cognitive abilities compared to other abuse categories. Children who experienced supervisory neglect at an earlier age had greater internalizing behaviors (i.e., anxiety, depression, and withdrawal) and aggression compared to other types of maltreatment over time. It is important to note, however, that early physical and emotional abuse were also associated with greater

internalizing and externalizing behavior problems from ages 3 to 9 years compared to later exposure to maltreatment.

Physical health. People who have experienced past trauma also are more likely to adopt significantly greater health-risk behaviors and have poorer overall health compared to those who have not experienced past trauma (Felitti et al., 1998). Those who report four or more ACEs are 2.2 times more likely to smoke, 1.6 times more likely to be obese, 1.3 times more likely to engage in no physical activities, 7.4 times more likely to consider oneself an alcoholic, 4.7 times more likely to have used an illicit drug, 3.2 times more likely to have more than 50 sexual partners, and 2.5 times more likely to have a sexually transmitted disease compared to individuals with no ACEs (Felitti et al., 1998). Not only do people with four or more ACEs have poor health behaviors, but also they have more diseases such as ischemic heart disease (2.2 times more likely), any cancer (1.9 times more likely), stroke (2.4 times more likely), chronic bronchitis or emphysema (3.9 times more likely), and diabetes (1.6 times more likely) compared to those with no ACEs (Felitti et al., 1998). Collectively, this early exposure to adversity coupled with adoption of health-risk behaviors leads to earlier death among those who have been exposed to early adversity compared to those who have had no experience with early adversity (Felitti et al., 1998).

Academic success. Early childhood maltreatment also is associated with a number of academic difficulties (Lansford et al., 2002). Risk factors associated with maltreatment account for lower grades and lower standardized test scores, while early childhood maltreatment itself accounts for increased absences compared to children with no history of maltreatment (Lansford et al., 2002). These outcomes are even more pronounced for children from minority backgrounds

(Lansford et al., 2002). All of the outcomes found by Lansford et al. (2002) were in addition to the internalizing and externalizing concerns reported in the previous section.

Children with disabilities who have been maltreated miss more school overall than other children, including typically developing children who have been maltreated (Sullivan & Knutson, 2000). In addition, children with disabilities who have been maltreated display the lowest academic achievement scores compared to peers, including typically developing children that have been maltreated (Sullivan & Knutson, 2000). This indicates that maltreatment is associated with especially poor academic outcomes for children with disabilities compared to those without disabilities.

The challenging behaviors exhibited by children who have experienced maltreatment also come with a number of risks. Children with challenging behavior are more likely than those with typical behavior to be placed in an exclusionary special education setting (Fox & Smith, 2007). In addition, they are more likely than their typical peers to have relational problems with teachers, caregivers, and peers (Fox & Smith, 2007). In the long-term, children with early-onset challenging behaviors also are less likely than their peers to graduate from high school and to find employment (Fox & Smith, 2007).

Neurological functioning. Brain development is significantly influenced by early childhood maltreatment. One pathway by which neurobiology is affected is through epigenetics, or environmentally facilitated changes in genetic expression that occur through methylation (Orr & Kaufman, 2014). Epigenetics can include early life exposure to toxic stress and teratogens that result in certain genes being turned “on” or “off” (Orr & Kaufman, 2014). Moreover, the early childhood toxic stress associated with maltreatment conditions neural pathways towards danger and hypervigilance, which in turn diminishes brain functioning (Shonkoff & Philips, 2000).

More specifically, the hypothalamic pituitary adrenal (HPA) axis secretes corticotropin releasing factor (CRF). CRF activates the pituitary gland, which releases adrenocorticotrophic hormones (ACTH). ACTH is then carried through the blood to the adrenal gland. The adrenal gland is ultimately responsible for releasing cortisol. In concert with neuropeptide Y, cortisol regulates the fight-or-flight, or sympathetic nervous system (SNS), response (Sherin & Nemeroff, 2011). After cortisol is released and the danger has passed, the HPA axis regulates the release of CRF to return the body to homeostasis (Briere & Scott, 2014).

When children are exposed to early-onset toxic stress like maltreatment, the HPA and SNS are over activated, and thus, damaged (Briere & Scott, 2014). As a result, the HPA axis secretes CRF with no uptick in cortisol (Raison & Miller, 2003). Therefore, the chemicals that are protective in dangerous situations (i.e., cortisol, neuropeptide Y) are impaired, which leads to an overactive and dysregulated SNS (Briere & Scott, 2014). However, the role of cortisol is complicated, as studies have shown that children who have been neglected have lower baseline levels of cortisol, while children who have been emotionally maltreated have higher baseline levels of cortisol (Bruce, Fisher, Pears, & Levine, 2009). Regardless of the specific cortisol levels, the evidence suggests that an imbalance of this hormone has negative implications for brain functioning. Figure 1 shows the bodily response to danger described above.

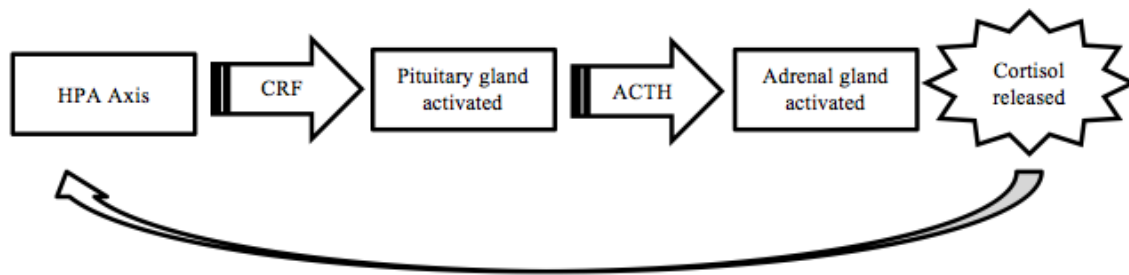


Figure 1. Bodily Response to Danger (Briere & Scott, 2014)

The implications of early maltreatment on other brain structures include increased activity of the amygdala and reduced volume of the hippocampus, corpus callosum, cerebellum, and prefrontal cortex (Heim et al., 2010). Reduced volume in these areas of the brain results in diminished memory, learning ability, regulation of emotion and arousal, coordination, and executive functions (McCrory, DeBridio, & Vining, 2010).

Risk and Protective Factors Associated with Maltreatment

Risk factors. A number of factors place children and families at risk for child abuse and neglect (Murphy, 2011). Circumstances that put parents and families at-risk for child maltreatment include teen parenthood (Oliver et al., 2006); parental history of maltreatment; negative attitudes toward the child; substandard knowledge of child development; parental psychopathology, including substance abuse, depression, anxiety, and antisocial behavior; low household income and poverty; insufficient social support; single parenthood; and family/community violence (Goldman et al., 2003). Additional maltreatment risk factors for very young children include living with four or more young children or living with one biological parent and one stepparent (Oliver et al., 2006).

Child-centered risk factors for maltreatment include children who are very young, have disabilities (Sullivan & Knutson, 2000), challenging behaviors, overwhelming medical care needs (Fisher, Hodapp, & Dykens, 2008), and poor verbal skills (Brown, Cohen, Johnson, & Salzinger, 1998). In addition, children who are physically/emotionally dependent on caregivers and cannot adequately protect themselves from abuse are at greater risk for maltreatment compared to children who are not dependent (Hibbard & Desch, 2007).

Several societal factors also perpetuate risk for initial and ongoing maltreatment of children with disabilities in particular (U.S. Department of Health and Human Services, 2001).

Children who are part of school exclusionary practices that separate them and devalue their abilities are more vulnerable to abuse (Steinberg & Hylton, 1998). Children who are not given adequate sex education are less likely to recognize and report abuse than those who receive this education (Steinberg & Hylton, 1998). In addition, educational personnel often have insufficient training needed to identify signs of child maltreatment, which increases the risk for child abuse and neglect being under-reported (Hibbard & Desch, 2007).

Protective factors. The strength of the parent-child relationship is a protective factor that promotes child and family safety, particularly following a trauma (De Young et al., 2011). Specifically, children who have a secure attachment to their caregiver are less likely to experience abuse and are more likely to recover from instances of trauma, including maltreatment by others (De Young et al., 2011). An important element of the parent-child relationship following trauma is the stability of parenting practices. Caregivers who oscillate between being too strict or too lenient with their children following trauma manufacture further risk for child disruptive behaviors and non-recovery from the trauma (De Young et al., 2011). In addition, individuals who report no challenges with mental health in spite of prior maltreatment have noted in previous studies that they had high quality and loving parent-child relationships with their own children along with supportive peer relationships (Collishaw et al., 2007). Thus, the parent-child relationship and consistent parenting practices prior to and/or following trauma/maltreatment are integral to fostering a resilient child (De Young et al., 2011). The evidence-based treatments available for young children who have experienced trauma focus on minimizing risk factors and maximizing protective factors associated with trauma.

Evidence-Based Treatments for Young Children who Have Experienced Trauma

Many evidence-based treatments for young children with trauma exposures exist. These include Attachment and Biobehavioral Catch-up (Dozier, Meade, & Bernard, 2014), Child-Parent Psychotherapy (Lieberman, Silverman, & Pawl, 2000), Parent-Child Interaction Therapy (Eyberg & Funderburk, 2011), and Trauma-Focused Cognitive Behavioral Therapy (Cohen, Mannarino, & Deblinger, 2012). Several theoretical orientations underlie these interventions, including cognitive behavioral theory, attachment theory, and behavior theory. The empirical support for these interventions is provided following a brief description of the affiliated theoretical frameworks.

Cognitive behavioral theory includes a focus on internal events (cognitions) and the resultant emotions and behaviors (Beck, 2011). Maladaptive thought patterns and the following disturbances in mood and behavior are considered to underlie psychopathology (Beck, 2011). Thus, central components of treatment include an exploration of automatic thoughts and a systematic engagement in behavioral experiments to improve mood and challenge thoughts (Beck, 2011). This type of therapy has been effective with young children and caregivers in treatment for a myriad of concerns, including trauma (Cohen & Mannarino, 1996).

The primary presumption of attachment theory is that a person must cultivate a healthy and lasting bond with at least one caregiver in order for the person to achieve successful social development (Mooney, 2010). Several attachment styles have been researched and validated using Ainsworth's Strange Situation Test (Ainsworth, Blehar, Waters, & Wall, 2015). The attachment styles are secure, anxious avoidant, anxious ambivalent, and disorganized. The latter three styles are considered insecure and are associated with experiencing maltreatment (Mooney,

2010). Therefore, treatment includes a focus on improving the caregiver-child attachment, which also happens to be a significant protective factor against maltreatment (Collishaw et al., 2007).

Behavior theory includes a focus on observable behaviors and the environmental contingencies maintaining them (Cooper, Heron, & Heward, 2007). Behavioral interventions often include multiple components aimed at prevention of challenging behaviors, client-centered instruction of desirable behaviors, and reinforcement of alternative or more desirable behaviors (Cooper et al., 2007). Behavioral interventions are informed by a function and have a main focus of improving socially positive behaviors through functional reinforcement, while minimizing reinforcement of undesirable behaviors (Cooper et al., 2007).

Attachment and Biobehavioral Catch-up (ABC). ABC is a well-established treatment for caregivers and young children in foster care between the ages of 6 months and 2 years (Dozier, Meade, & Bernard, 2014). ABC is based on attachment theory and is aimed at improving children's challenging behaviors and disorganized attachment following a trauma (Dozier et al., 2014). This manualized approach to service delivery focuses on encouraging the caregiver to re-interpret their child's challenging behaviors, helping the caregiver provide a safe environment for their child following a trauma, and providing caregivers with the tools to develop their child's emotion regulation skills (Dozier et al., 2014). Trained clinicians provide this intervention over a 10-week period in the child's natural environment (Dozier et al., 2014).

Dozier et al. (2006) piloted ABC in a randomized controlled trial with 60 children in the foster care system. Half the participants were randomized to receive ABC and the other half were randomized to receive an educational intervention called Developmental Education for Families (DEF). Children were 3.6 to 39.4 months in age; 63% were African American, 32% were White, and 5% were biracial. Parents' reports of challenging behaviors and children's cortisol levels

were used to determine response to intervention. Cortisol was measured using saliva samples and challenging behaviors were measured using an adapted version of the infant-toddler or preschool version of the Parent's Daily Report (PDR/IT; Chamberlain & Reid, 1987). Data were analyzed using a 2 x 2 analysis of variance (ANOVA) for cortisol levels and challenging behaviors. Results indicated children in the ABC condition had significantly lower levels of cortisol compared to children in the control condition ($p < .002$). Caregivers in the ABC condition rated toddlers' challenging behaviors as significantly improved ($p < .05$), while infants' challenging behaviors in the ABC condition were not rated as significantly improved. Caregivers in the control condition did not rate challenging behaviors as significantly improved for any age group. The results of this pilot study provided support for ABC as an effective intervention for toddlers in the foster care system. This study was limited in terms of its generalizability to diverse populations, including those with disabilities. Another significant limitation was the omission of parent behavior and stress as an outcome.

In another study, Dozier, Peloso, Lewis, Laurenceau, and Levine (2008) conducted a randomized controlled trial with 141 children. Of those children, 93 were in the foster care system and 48 were not. The children who were not in the foster care system did not receive intervention services and provided a cortisol comparison to the children who were in foster care. Children in foster care were randomized to receive ABC or DEF. The participants were 15 to 24 months. Children in the ABC group were 59% female, while children in the DEF group were 43% female. Children in the comparison group were 44% female. There were significant racial differences between the intervention and comparison groups. Children in the two intervention groups were primarily from minority backgrounds (71% and 83% for DEF and ABC, respectively). By contrast, the children in the comparison group were primarily Caucasian

(56%). Child outcomes were determined by measuring cortisol levels via saliva samples both before and after a Strange Situation Test (Ainsworth et al., 2015). Samples were taken upon arrival at a clinic, 15 minutes after the Strange Situation Test, and 30 minutes after the Strange Situation Test. It was hypothesized that children with disorganized attachment styles, such as those in the foster care system, would have higher levels of cortisol in a Strange Situation Test compared to children with secure attachment styles. Hierarchical linear modeling was used to analyze the study outcomes. Results showed that none of the children demonstrated increased cortisol levels in response to the Strange Situation Test. Dozier and colleagues hypothesized that the change in routine was possibly a significant stressor in itself, which may explain why cortisol levels did not increase in response to the Strange Situation Test. However, initial cortisol levels of children in the ABC condition were significantly lower than children in the DEF condition ($p < .05$). In addition, children in the ABC and comparison group showed comparable levels of cortisol before and after the Strange Situation Test, indicating that ABC is effective in terms of restoring cortisol levels in response to stress. This research was limited in that only one outcome variable was measured to determine improvement, and given the variability of cortisol levels reported in previous research (e.g., Bruce et al., 2009), this outcome may be difficult to interpret. Another limitation of this study was the significantly different racial backgrounds of the groups, which could have confounded the findings from this study.

Like Dozier and colleagues, Sprang (2009) conducted a randomized controlled trial with 53 parent-child dyads. Participants were included in the study if the child was younger than 6 years old and the caregivers were not taking psychotropic medication and did not have a diagnosis of a severe mental health condition. The average age of the child participants was 42.5 months, and 27 of the child participants were male. There were 26 parent-child dyads

randomized to the ABC condition and 27 dyads were randomized to the control condition. The control condition consisted of bi-weekly support groups. Outcome measures included the Child Abuse Potential Inventory (CAPI; Milner, 1986), the Child Behavior Checklist (CBCL; Achenbach, 1991; Achenbach & Rescorla, 2000), and the Parenting Stress Index—Short Form (PSI; Abidin, 1995). Between group data at each time point were analyzed from baseline to post-test using a one-way ANOVA. Between-group and within-group interactions were analyzed using a repeated multivariate ANOVA. At treatment termination, CAPI scores were significantly higher among the control group ($p = .001$) compared to the treatment group. In addition, post-intervention CAPI scores of the treatment group reduced by 71.6% compared to just .01% in the control group. CBCL scores were significantly higher at post-intervention among the control group compared to the treatment group ($p = .01$ for the Internalizing subscale and $p = .05$ for the Externalizing subscale). Parenting stress was significantly higher at treatment termination for the control group compared to the treatment group ($p = .05$). From pre-intervention to post-intervention, CBCL Internalizing and Externalizing scores and PSI scores reduced significantly for the treatment group compared to the control group ($p = .05$ and $.01$ for the PSI and both CBCL subscales, respectively). Thus, this study contributed to the literature in that it showed both children and parents in the ABC group improved relative to the control group on a number of stress-related and behavioral indicators. The researchers of this study did not report whether children with disabilities were included in the sample; thus, the generalizability of the present findings is questionable.

While other researchers focused on physiological responses to trauma among children, Bernard, Simons, and Dozier (2015) evaluated the effect of ABC on mothers' neurobiological processing of emotion signals, or event-related potential (ERP). This was studied because the

inability to process and interpret emotional cues is associated with maltreatment. Mothers at high risk ($n = 40$) and low risk ($n = 30$) for child maltreatment were included in the study. The high-risk mothers were randomized to receive either ABC ($n = 19$) or DEF ($n = 21$). Low-risk mothers served as the control group. Participants were 74% African American, 16% White, 5% Hispanic, 4% Biracial, and 1% Asian. Children were 58% male and 42% female. ERP data were recorded using electroencephalograms while mothers categorized laughing, crying, or neutral child faces using buttons. Results indicated there were no statistical differences between the ABC and DEF groups in terms of maternal sensitivity at pre-intervention. However, at post-intervention mothers in the DEF group scored significantly lower on maternal sensitivity than the ABC or control group mothers ($p < .001$). Moreover, at post-intervention, there were no statistical differences in maternal sensitivity between the ABC group and control group. ERP data were analyzed using $3 \times 2 \times 3$ ANOVAs, with a main effect for emotion type ($p < .001$) and a significant group interaction ($p < .01$) arising. Further analyses revealed that amplitudes of mothers in the ABC and control groups were significantly modulated by emotion type ($p < .01$), while amplitudes of mothers in the DEF group were not. This indicates mothers in the ABC and control groups were more sensitive to child emotions. Finally, mothers' maternal sensitivity in the ABC group was significantly and positively correlated with ERP responses ($p = .03$). Thus, the ABC intervention was effective at improving at-risk mothers' ability to accurately process child emotion signals. A limitation of this study was that measures of parenting stress and challenging behaviors were not included as outcomes. Like many other studies, the number of children with disabilities was not reported, which possibly limits the generalizability of ABC. A final limitation that applies to all evaluations of ABC is that no follow-up data were collected.

Therefore, the long-term efficacy of this intervention on caregiver and child outcomes is unknown.

Child-Parent Psychotherapy (CPP). CPP is another well-established treatment for young children ages 0 to 5 years that have experienced trauma and their caregivers (Lieberman, Silverman, & Pawl, 2000). The primary focus of CPP is the parent-child relationship and its role in attachment and child behavior. Thus, the primary theoretical orientation is attachment theory; although, elements of psychodynamic and cognitive behavioral theory are also embedded. In addition, a parent-child trauma narrative is created throughout therapy to address and overcome negative associations with the trauma(s). Trained interventionists provide CPP in the home one time per week over a period of 52 weeks.

Toth, Maughan, Manly, Spagnola, and Cicchetti (2002) conducted a randomized controlled trial with 122 mother-child participants. The average age of child participants was 48.18 months. Child participants were 56% male and 44% female. Of the families included in the study, 87 had a history of maltreatment and 35 had no history of maltreatment. The families with no history of maltreatment served as a control group. The dyads with a history of maltreatment were randomly assigned to one of three conditions: CPP ($n = 23$), psychoeducational home visitation (PHV; $n = 34$), or community standard ($n = 30$). Study measures included a children's narrative, which was a story stem featuring moral dilemmas from the MacArthur Story Stem Battery (Bretherton, Oppenheim, Buchsbaum, Ernde, & The MacArthur Narrative Group, 1990) and the Attachment Story Completion Task (Bretherton, Ridgeway, & Cassidy, 1990). The child's response to the story stem provided information regarding the child's understanding of family relationships. The children's narrative was completed at pre-intervention and post-intervention. Child responses were coded for responses congruent with positive mother, negative

mother, controlling mother, incongruent mother, and disciplining mother. Two maternal composites were also derived: adaptive maternal representation and maladaptive maternal representation. Finally, children were coded for responses congruent with positive self, negative self, and false self. Comparisons from pre-intervention to post-intervention were made using general linear modeling, while between-group comparisons from pre-intervention to post-intervention were made using ANOVAs. Scores on the maladaptive maternal representation decreased significantly from pre-intervention to post-intervention for children in the CPP condition ($p < .001$), while no significant differences were found for children in any of the other conditions. In addition, negative self-representation scores decreased significantly from pre-intervention to post-intervention for the CPP group alone ($p < .001$). On the other hand, scores on positive self-representation increased significantly from pre-intervention to post-intervention for children in the CPP group, community standard group, and control group ($p < .001$ for all groups). Between-group comparisons revealed children in the CPP group improved more than children assigned to other groups. Specifically, scores on maladaptive maternal representations improved significantly for children in the CPP group compared to the control group ($p < .05$). Children in the CPP group also improved significantly in terms of negative self-representations compared to the PHV ($p < .01$), community standard ($p < .01$), and control ($p < .05$) groups. Finally, mother-child relationship expectations improved significantly for children randomized to CPP compared to the control group ($p < .05$). Overall, CPP was effective at improving maternal and self-representations of children who had been maltreated, which is an important component to fostering healthy and protective parent-child attachments. A major limitation to this study was the exclusion of objective measures of caregiver and child behavior change over time. In addition, only low-income families were considered for treatment, limiting the generalizability of

the results to a wider population. Disability status of the children included in this intervention also was not reported.

Lieberman, Van Horn, and Ippen (2005) also conducted a randomized controlled trial to examine the efficacy of CPP on children exposed to marital violence with a sample of 65 children and their caregivers. Dyads were randomized to receive CPP ($n = 36$) or case management plus individual psychotherapy ($n = 29$). Child participants were 52% female and 48% male with an average age of 4.06 years. Caregiver participants were excluded if they had abused the child, used illegal substances, were homeless, had an intellectual disability, or had psychosis. Child participants were excluded if they had an intellectual disability or an Autism Spectrum Disorder. Children's racial breakdown was as follows: 38.7% Biracial, 28% Latino, 14.7% African American, 9.3% White, 6.7% Asian, and 2.6% other. Child outcome measures included the Children's Exposure to Community Violence: Parent Report Version (Richters & Martinez, 1993), the CBCL (Achenbach, 1991; Achenbach & Edelbrock, 1983), and the Semistructured Interview for Diagnostic Classification DC: 0-3 for Clinicians (Wieder, 1994). Mothers' outcome measures included the Life Stressor Checklist—Revised (Wolfe, Kimerling, Brown, Chrestman, & Levin, 1996), the Symptoms Checklist 90—Revised (SCL-90-R; Derogatis, 1994), and the Clinician-Administered PTSD Scale (CAPS; Mature, 1994). General linear modeling was used to make between group and within group comparisons. The traumatic stress disorder symptoms (measured by the Semistructured Interview for Diagnostic Classification) of children in the CPP group reduced significantly from pre-intervention to post-intervention ($p < .001$), while there were no statistical changes for children in the case management condition. Furthermore, between group comparisons showed children in the CPP group improved significantly more than children in the case management group in terms of

traumatic stress disorder symptomatology ($p < .001$). The CBCL scores of children in the CPP group also reduced significantly from pre-intervention to post-intervention ($p < .05$). There were no statistical reductions in children's challenging behaviors for children in the case management group. Mothers' CAPS scores showed significant reductions in avoidance symptoms for the CPP group only ($p < .05$). Both groups showed significant reductions in overall CAPS scores ($p < .001$ for CPP and $p < .05$ for case management). In addition, there were significant improvements on the Global Severity Index on the SCL-90-R for the CPP group alone ($p < .001$). Thus, this study extended the CPP literature by providing evidence for the efficacy for CPP in terms of improving both parent and child PTSD symptomatology. A limitation of this study was the high rate of attrition (10 caregiver-child dyads did not complete the intervention).

In response to their first study, Lieberman, Ippen, and Van Horn (2006) completed a six month follow up to the 2005 randomized controlled trial conducted by Lieberman and colleagues. There were 50 participants included in the follow-up, with 27 participants who were randomized to CPP and 23 participants who were randomized to case management plus individual psychotherapy. The average age of child participants was 4.04 years. There were 22 female child participants and 28 male child participants. Children were 38% Biracial, 28% Latino, 16% African American, 12% White, 4% Asian, and 2% other. Child outcomes were measured at follow-up using the CBCL (Achenbach, 1991; Achenbach & Edelbrock, 1983), and mother outcomes were measured at follow-up using the SCL-90-R (Derogatis, 1994). General linear modeling was used to assess improvements between groups and within groups. Children in the CPP group continued to make significant improvements according to CBCL ratings, while the case management group did not ($p < .001$). Additionally, mothers in the CPP group continued to make improvements on the Global Severity Index on the SCL-90-R, while mothers in the case

management group did not continue to make the same improvements ($p < .001$). These results indicate that CPP has sustainable effects on parent and child behavioral and PTSD symptomatology. A limitation of this study was the exclusion of the myriad of outcome measures utilized in the initial study. The findings would have been strengthened if additional outcomes were shown to maintain at follow-up.

Like other researchers, Cicchetti, Rogosh, and Toth (2006) conducted a randomized controlled trial to evaluate the efficacy of CPP with children who had been maltreated and their caregivers. There were 185 dyads in total, with 133 of the dyads presenting with a history of maltreatment and 52 of the dyads presenting with no history of maltreatment. The no history group served as a comparison group to the maltreatment dyads. Participants in the maltreatment group were randomized to receive one of three treatments: CPP ($n = 49$), psychoeducational parenting intervention ($n = 49$), or community standard ($n = 35$). Child participants were 53.4% female and 74.6% minority race/ethnicity. Measures included the Childhood Trauma Questionnaire (CTQ; Bernstein, Fink, Handelsman, & Foot, 1994), Perceptions of Adult Attachment Scale (PAAS; Lichtenstein & Cassidy, 1991), the Maternal Behavior Q-Set (MBQ; Pederson & Moran, 1995), the Adult-Adolescent Parenting Inventory (AAPI; Bavolek, 1984), the Social Support Behaviors Scale (SBS; Vaux, Reidel, & Stewart, 1987), the PSI (Abidin, 1990), and the Strange Situation Test (Ainsworth et al., 2015). MANOVAs were used to evaluate the efficacy of CPP. Parents in the maltreatment group reported significantly higher scores on all CTQ scales at baseline compared to mothers in the non-maltreatment group. Thus, mothers in the maltreatment group experienced significantly more abuse ($p < .01$ for physical/emotional abuse; $p < .05$ for sexual abuse) and neglect ($p < .001$ for emotional and physical neglect) as children compared to mothers in the non-maltreatment group. Moreover, PAAS scores at baseline

indicated mothers in the maltreatment group were significantly more likely to have mothers who were rejecting ($p < .001$), derogatory ($p < .001$), angry ($p < .01$) and less loving ($p < .001$) compared to mothers who were not in the maltreatment group. Baseline Q-sort and AAPI scores indicated mothers in the maltreatment group had significantly lower maternal sensitivity ($p < .001$) and significantly higher inappropriate expectations for their children ($p < .01$), less empathy ($p < .05$), and greater use of physical punishment ($p < .05$) compared to mothers in the non-maltreatment group. Unsurprisingly, mothers in the maltreatment group scored significantly worse on subscales of the PSI and SBS compared to mothers in the non-maltreatment group. With regard to the child participants, only one child in all maltreatment groups was securely attached at baseline compared to 17 children in the non-maltreatment control group ($p < .001$). At post-intervention, there were significant increases in the number of children in the CPP and psychoeducational parenting intervention groups who were securely attached ($p < .001$). In addition, the CPP and psychoeducational parenting intervention groups did not significantly differ from the control group in secure attachment classifications using the Strange Situation Test at post-intervention. The attachment styles of children in the community standard group remained relatively unchanged from pre-intervention to post-intervention. Altogether, the results of this study indicate CPP is effective in terms of repairing parent-child attachments compared to community standard treatment. Outcomes also suggest participation in CPP results in no statistical differences in secure attachment between maltreatment and non-maltreatment groups following intervention. A limitation of this study was the researchers' exclusion of children in foster care. The number of children with disabilities was not reported as well, which potentially limits the generalizability of the present findings.

Parent-Child Interaction Therapy (PCIT). PCIT is a dyadic parent-child therapy that was developed for children ages 2 to 7 years with significant challenging behaviors (Eyberg & Funderburk, 2011). Since its inception, PCIT has been validated for children who have experienced maltreatment. It is theoretically founded upon elements of attachment and behavior theory. Sessions typically occur in a clinic once a week. PCIT includes two phases of treatment that are coached by a trained therapist from a separate room: Child Directed Interaction (CDI) and Parent Directed Interaction (PDI). CDI is the first phase of treatment, and the main focus is on improvement of the parent-child relationship. This is attained by coaching the caregiver to engage in child-centered play, which includes describing the child's appropriate play behaviors, reflecting the child's appropriate speech, and providing specific labeled praises for desirable behaviors. Caregivers must master these CDI skills in order to transition to PDI. Therapists use a specialized coding system known as the Dyadic Parent-Child Interaction Coding System (DPICS; Eyberg, Chase, Fernandez, & Nelson, 2014) to record progress towards mastery criteria during the first five minutes of each CDI therapy session. During PDI, caregivers are coached to use effective commands and Follow Through for non-compliance. Importantly, parents are coached to continue to use CDI skills throughout PDI to maintain the attachment garnered during the first phase of treatment. Like in CDI, caregivers who are in PDI must meet mastery criteria in order to "graduate" from PCIT. Therapists code caregivers' use of PDI and CDI skills at the beginning of specific sessions to monitor progress towards mastery.

Borrego, Urquiza, Rasmussen, and Zebell (1999) published a case study documenting the usefulness of PCIT with a 35-year-old mother involved in CPS and at-risk for abusing her 3-year-old son. Outcome measures included DPICS (Eyberg, Bessmer, Newcomb, Edwards, & Robinson, 1994), Eyberg Child Behavior Inventory (ECBI; Eyberg & Pincus, 1999), CBCL

(Achenbach & Edelbrock, 1983), CAPI (Milner, 1986), and PSI (Abidin, 1990). There were a total of five CDI sessions and six PDI sessions. From pre-treatment to post-treatment, ECBI Intensity and Problem raw scores decreased from 152 to 71 and 14 to 0, respectively. At 16-month follow-up, ECBI Intensity and Problem raw scores remained below pre-treatment levels at 65 and 0, respectively. Scores on all the PSI subscales also decreased substantially over time and maintained at follow-up. These scores were reported as percentages, with the Total Stress score decreasing from 94% to 40%. At 16-month follow-up, the Total Stress score was even lower at 24%. The CAPI was not within the clinical range at baseline; however, the score improved with the introduction of PCIT. The CAPI score at pre-treatment was 74, while the score at post-treatment was 56. The follow-up score remained unchanged at 56. All CBCL subscale scores improved from baseline to post-treatment and follow-up, with the Total CBCL *T*-score decreasing from 74 at pre-treatment to 51 at post-treatment and 16-month follow-up. In addition, DPICS data indicated increases in desirable parent and child behaviors and decreases in undesirable parent and child behaviors. Specifically, from the first CDI session to the last PDI session, labeled praises increased from 10 to 30. Behavior descriptions increased from approximately 10 in the first CDI session to approximately 60 in the last PDI session. The number of questions asked by the parent decreased from approximately 25 in the first CDI session to approximately three in the last PDI session. These improvements sustained at 16-month follow-up. The number of child negative behaviors (e.g., whining) decreased from approximately 21 at pre-treatment to approximately one at post-treatment. However, negative behaviors increased to approximately 13 at 16-month follow-up; although, the authors noted the negative behaviors were predominantly mild whining to use the restroom. Qualitative reports from the mother indicated PCIT was useful in terms of providing her with effective parenting

skills. In all, this case study provided important preliminary support for the use of PCIT with mothers and children at-risk for abuse. This study was limited by its single subject design, thus, restricting the generalizability of these findings to all children at-risk for maltreatment.

Following the initial case study, Chaffin et al. (2004) conducted a randomized controlled trial with 110 caregivers with a history of abusive behavior and their children. Participants were included in the study if parental rights had not been terminated, the caregiver IQ was above 70, the child was between ages 4 and 12 years, and the parent was not a sexual perpetrator. Caregiver participants were 65% female, 52% White, 40% African American, 4% Hispanic, 1% Native American, 1% Asian, and 2% other. More than 62% of the participants lived below the poverty line. Participants were randomly assigned to receive PCIT, enhanced PCIT that included additional mental health support for the caregiver, or standard community care. Study measures included the CAPI (Milner, 1986), Child Neglect Index (Trocme, 1996), Abuse Dimensions Inventory (Chaffin, Wherry, Newlin, Crutchfield, & Dykman, 1997), DPICS (Eyberg et al., 1994), Behavior Assessment System for Children (BASC; Reynolds & Kamphaus, 1992), Beck Depression Inventory (BDI; Beck, Ward, Mandelson, Mock, & Erbaugh, 1961), and the Diagnostic Interview Schedule (Robbins, Helzer, Croughan, & Ratcliff, 1981). Data obtained from the Diagnostic Interview Schedule indicated 32% of parents met criteria for an alcohol or drug use disorder and 16% met criteria for antisocial personality disorder. Twenty-two percent of caregivers exceeded the clinical cutoff on the BDI, and 75% of caregivers exceeded the clinical cutoff for abuse on the CAPI. The average *T*-score for children's challenging behavior on the BASC was 63, indicating most children in the sample had subclinical levels of externalizing behaviors. Results indicated that caregivers and children in the PCIT condition were significantly less likely to be re-reported to CPS ($p < .02$) compared to caregivers in the other two conditions.

In fact, 19% of caregivers in the PCIT condition were re-reported compared to 36% and 49% of caregivers in the enhanced PCIT and community care condition, respectively. Caregivers in all conditions reported significantly lower BDI scores ($p < .05$). Negative parent behaviors (i.e., questions, commands, criticisms) were significantly improved in both PCIT conditions compared to the community care condition ($p < .01$ for both PCIT conditions), and these improved caregiver behaviors predicted lower rates of re-report. The PCIT condition was marginally more effective than the enhanced PCIT condition in terms of reducing the likelihood of re-report possibly because the enhanced condition detracted caregivers from their commitment to behavioral parenting strategies. Results of this study provided a high level of support for child welfare improvement of caregivers and children involved in PCIT compared to a community standard. The sample was socioeconomically homogenous, limiting the generalizability of these findings to a wider population. The researchers did not report whether children with disabilities were included in the sample. The researchers also did not report long-term effects of PCIT.

To show the effects of in-home plus clinic-based PCIT treatment, Timmer et al. (2006) published a case study that included a 42-year-old foster mother and her 4-year-old foster son. The caregiver-child dyad completed a total of 30 PCIT coaching sessions. The dyad received coaching sessions weekly in the clinic and in the home. Measures included the ECBI (Eyberg & Pincus, 1999), PSI (Abidin, 1995), CBCL (Achenbach, 1994), CAPI (Milner, 1986), and DPICS (Eyberg, Nelson, Duke, & Boggs, 2005). Interrater reliability for DPICS was found to be 85%. Pre-treatment raw scores on the ECBI Intensity and Problem scales were in the clinical range (163 and 22, respectively). Post-treatment raw scores on the ECBI Intensity and Problem scales were in the normal range (103 and 4, respectively). *T*-scores on the CBCL Externalizing and Total scores were both in the clinical range at pre-treatment ($T = 66$ and $T = 67$, respectively) but

were in the normal range at post-treatment ($T = 44$ and $T = 49$, respectively). Two subscales on the PSI were in the clinical range at pre-treatment: child as a source of stress (percentile score of 90) and child's distractibility (percentile score of 99). The child acceptability subscale on the PSI was in the borderline range at pre-treatment with a percentile score of 85. At post-treatment, none of the PSI subscales were within the clinical or borderline range. The child as a source of stress subscale reduced to a percentile score of 50. The child's distractibility reduced to a percentile score of 45, and the child acceptability scale reduced to a percentile score of 20. All CAPI scores from pre- to post-treatment were within acceptable ranges. The foster parent's CDI skills also improved exponentially over time. The number of questions coded decreased from approximately 27 at pre-treatment to approximately three at post-treatment. The number of behavior descriptions coded increased from approximately two at pre-treatment to approximately 15 at post-treatment. Finally, the number of praises coded increased from approximately 15 at pre-treatment to approximately 30 at post-treatment. This case study contributed uniquely to the literature surrounding PCIT in that it provided support for the efficacy of PCIT with a foster parent-child dyad. In addition, it lent support to a dual clinic-based and home-visiting PCIT model. However, this foster parent was possibly more committed to the treatment than other foster parents, which may have positively skewed the results of this single case evaluation. The feasibility of this type of service delivery is thus unknown. This study was finally limited by its single subject design.

Somewhat like Timmer and colleagues, Galanter et al. (2007) used a pre-post design with existing data to determine the effectiveness of in-home PCIT for 83 families at-risk for child maltreatment. It is important to note that the behaviors of the children included in this sample were not the target of this intervention; rather, the parenting skills of the caregivers included

were the target. The caregiver sample was 88% female, 55% Latina, 37% African American, and 7% White. Outcome measures included the ECBI (Eyberg & Pincus, 1999), AAPI (Bavolek, 1990), and DPICS (Eyberg et al., 2005). Paired samples *t*-tests were used to determine pre-treatment to post-treatment improvement. Results revealed ECBI Intensity and Problem scores decreased significantly from pre-test to post-test ($p < .0001$ for treatment completers). This translated to an effect size of 1.16. Scores on the AAPI improved significantly from pre- to post-treatment for the inappropriate expectations ($p < .01$), physical punishment ($p < .0001$), and role reversal ($p < .0001$) subscales. DPICS coding from pre- to post-treatment indicated significant improvements with regard to positive parent-child interactions, negative interactions, direct versus indirect commands, child disobedience, and child compliance ($p < .0001$ for all coding categories). This translated to an effect size of .87. Caregivers were highly satisfied with their learning in PCIT and 65.1% of families completed PCIT. Thus, a home-based PCIT adaptation was highly acceptable to families and resulted in improved parenting skills and child behaviors. Although, a discussion of future CPS reports was not provided. Therefore, it is unclear whether PCIT was helpful in terms of reducing future maltreatment. In addition, disability status of the children was not discussed.

Trauma-Focused Cognitive Behavioral Therapy (TF-CBT). TF-CBT is a well-established treatment for children ages 3 to 18 years who have experienced trauma and their caregivers (Cohen, Mannarino, & Deblinger, 2012). The theoretical underpinning of TF-CBT is cognitive behavioral theory. The treatment ranges from 12 to 18 sessions that last approximately 45 minutes. TF-CBT includes individual child sessions, individual parent sessions, and combined parent-child sessions. The focal point of combined sessions is the child sharing his/her trauma narrative with the parent. The components of TF-CBT can be summarized using the acronym

PRACTICE: psychoeducation and parenting skills, affective expression and regulation, cognitive coping and processing, trauma narrative and processing, in-vivo exposure, conjoint parent/child sessions, and enhancing personal safety and future growth.

Cohen and Mannarino (1996) designed a preliminary study to assess the outcomes of TF-CBT on pre-school children who had experienced sexual abuse. Participants must have experienced the abuse in the previous six months and the abuse had to be confirmed by CPS to be included in the study. In addition, children must have scored greater than a seven on the Weekly Behavior Report (WBR; Cohen & Mannarino, 1993) or displayed any sexually inappropriate behavior as indicated on the Child Sexual Behavior Inventory (CSBI; Friedrich et al., 1992) to be included in the study. Participants included 67 children aged 2 to 7 years ($M = 4.68$ years). The demographic makeup of the sample was 58% male, 42% female, 54% Caucasian, 42% African American, and 4% other. Most children lived with at least one biological parent. The child outcome measure used was the Preschool Symptom Self-Report (PRESS; Martini, Strayhorn, Puig-Antich, 1990). Caregiver reported outcome measures included the CBCL (Achenbach & Edelbrock, 1983), the WBR, and the CSBI. Children were randomized to receive TF-CBT or nondirective supportive therapy (NST). The authors used two-tailed t -tests to compare the two treatments from pre-intervention to post-intervention on the PRESS, CBCL, CSBI, and WBR. Results indicated that outcomes for children in the TF-CBT condition were significantly improved on the WBR Total Behavior score ($p < .01$) and the CBCL Internalizing and Behavior Profile—Total ($p < .002$) subscales. T -tests used to identify within group changes on child behavior symptoms indicated that the NST group made no significant within group improvements with the exception of the WBR Total Behavior score ($p < .05$), while the TF-CBT group made significant within group improvements on all outcomes with the exception of the

CBCL Social Competency scale. All within group improvements for the TF-CBT condition were significant at the $p < .001$ level. Repeated measures ANOVA statistics for group by time interactions corroborated findings from the t -tests for the Total Behavior Problems ($p = .02$) and Internalizing ($p = .05$) subscales on the CBCL. Outcomes on the PRESS showed no significant differences between groups or within groups from pre- to post-intervention. Clinical findings showed that no children randomized to the TF-CBT condition required additional treatment. Comparatively, seven children randomized to receive NST required additional treatment. The initial trial for TF-CBT indicated its efficacy as a treatment for pre-school aged children who experienced sexual abuse. In particular, TF-CBT was shown to be effective in terms of reducing child behavior problems and internalizing concerns across multiple measures. This study was limited by its exclusion of children with disabilities. This study also was limited in that the authors did not include an outcome measure specific to posttraumatic stress (although, the measures used could be considered approximations of early childhood posttraumatic stress).

In response to their initial research, Cohen and Mannarino (1997) conducted a one-year follow-up to the first TF-CBT study in order to evaluate the long-term outcomes of the treatment on trauma symptoms. Data were collected at four different time points: pre-intervention, post-intervention, 6-month follow-up, and 12-month follow-up. The sample for this study included 43 children who completed all time points, with 28 in the TF-CBT group and 15 in the NST group. The mean age of children included in this follow-up was 5 years, 9 months. Fifty-six percent of children were female and 44% were male. In addition, 56% of children were Caucasian and 44% were African American. Most children included in the follow-up (55%) lived with their biological mother only. Repeated measures analyses were used to determine the effects of the TF-CBT intervention on trauma symptoms compared to the NST intervention. Results indicated

significant main effects for time on the CBCL ($p < .01$ for the Social Competency scale and $p < .001$ for Behavior Profile—Total, Internalizing, and Externalizing scales), CSBI ($p < .001$), and WBR ($p < .001$ for Type and Total) for the TF-CBT group but not the NST group. Further, there were significant group by time interactions from time one to time four for the CBCL Behavior Profile—Total, Internalizing, and Externalizing subscales ($p < .01$ for all three scales) and the WBR Type and Total subscales ($p < .01$ for both subscales). These effects were present for the TF-CBT intervention group, but not the NST intervention group. Overall, these findings indicated that TF-CBT was a superior treatment to NST in terms of sustaining behavioral improvement of pre-school children who had been sexually abused. This study was limited by the significant loss of participants from the post-intervention data collection to the 12-month follow-up. As mentioned previously, the sample included in this study limits the generalizability of the findings since children with developmental delays were not included in the study.

To determine the effect of specific intervention elements, Deblinger, Mannarino, Cohen, Runyon, and Steer (2011) examined the role of the trauma narrative in improving posttraumatic stress symptoms of 179 children aged 4 to 11 years who had experienced sexual abuse. More specifically, participants were randomly assigned to one of four conditions: eight weeks of TF-CBT with a trauma narrative ($n = 43$), eight weeks of TF-CBT without a trauma narrative ($n = 44$), 16 weeks of TF-CBT with a trauma narrative ($n = 48$), and 16 weeks of TF-CBT without a trauma narrative ($n = 44$). To be included in the study, children must have experienced sexual abuse that was confirmed by CPS, a law enforcement official, or a person with clinical expertise in the identification of sexual abuse. In addition, children needed to exhibit at least five PTSD symptoms, with one avoidance, one re-experiencing, and one arousal indicator each. Children were excluded from the study if they had an intellectual disability or had unsupervised contact

with the perpetrator of the sexual abuse. Child participants were 61% female, 65% Caucasian, 14% African American, 7% Hispanic, and 14% other. The mean age of child participants was 7.7 years. Parent-reported outcome measures included the BDI (Beck, Steer, & Brown, 1996), CBCL (Achenbach, 1991), CSBI (Friedrich et al., 1992), Parent Emotional Reaction Questionnaire (PERQ; Cohen & Mannarino, 1996), and Parent Practices Questionnaire (PPQ; Strayhorn & Weidman, 1988). Child-reported outcome measures included the Children's Depression Inventory (CDI; Kovacs, 1992), fear thermometers (Hersen & Bellack, 1988), Multidimensional Anxiety Scale for Children (MASC; March, Parker, Sullivan, Stallings, & Conners, 1997), Shame Questionnaire (Feiring, Taska, & Lewis, 1999), and What If Situations Test (WIST; Sarno & Wurtele, 1997). If the child was under the age of 7, then they completed only the measures appropriate for their age. The Schedule of Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime Version (K-SADS; Kaufman et al., 1997) was administered to both the parent and the child in order to establish the presence of DSM-IV-TR PTSD symptomatology. Data were analyzed using an analysis of covariance (ANCOVA). Results indicated that parents assigned to the 8-week condition without a narrative reported significantly improved PPQ scores compared to parents in the trauma narrative 8-week condition. On the other hand, parents assigned to the 8-week condition with the narrative reported significantly less emotional distress than parents in the 8-week condition without the trauma narrative. Children assigned to the 8-week trauma narrative condition reported significantly less fear on fear thermometers and significantly lower MASC scores than children in the 8-week condition without the trauma narrative. Children who received 16 weeks of treatment (regardless of whether a narrative was included) improved significantly more on PTSD re-experiencing and avoidance symptoms compared to children in the 8-week conditions.

Overall, the effect of TF-CBT on child and parent outcomes was moderate, no matter what condition to which the dyads were assigned ($d = .34$ to $.57$). Differential outcomes may be attributed to the amount of time focused on parenting skills and trauma processing in the no narrative condition and narrative condition, respectively. While this study has many strengths, including methodological rigor, there are also some concerns. One concern is that many of the outcome measures were not appropriate for children under the age of 7 years. Thus, children aged 4 to 6 years in the study were not included in data analysis for a number of outcomes. In addition, the authors did not report the extent to which children with mild developmental delays were included in the study, which possibly impacts the generalizability of the results.

In response to their initial study, Mannarino, Cohen, Deblinger, Runyon, and Steer (2012) completed a 6-month and 12-month follow-up to the study conducted in 2011 to determine the long-term effects of 8-week and 16-week TF-CBT with and without a trauma narrative component. The final sample for this follow-up study included 158 children and 144 parents. The child participants were 62% female 38% male, 65% Caucasian, 15% African American, 6% Hispanic, and 14% other race. The mean age of the children was 7.6 years. Data were analyzed using repeated measures ANCOVA. Results indicated that parent and child improvements maintained at 12-month follow-up. Further, parent distress and child anxiety levels continued to decrease following treatment. The effect sizes for parent distress and child anxiety were .60 and .61, respectively. Moreover, only 12 children still met criteria for PTSD at 12-month follow-up. While children who participated in TF-CBT sustained improvements at follow-up, the differences between the four conditions (described previously) were no longer present at follow-up. Mannarino and colleagues hypothesized that the differences disappeared because there were more similarities among the conditions than differences. In addition, most

children were exposed to some of the trauma content, regardless of the condition, which may have contributed to increased similarities between the trauma narrative and no trauma narrative conditions. The results of this study validated that TF-CBT was an effective treatment for children who had been sexually abused. Additionally, the results of this study provided evidence that children and caregivers can make improvements in as little as eight weeks. As noted previously, it was concerning that many of the outcome measures were not applicable to young children, thus excluding them from final data analysis.

Limitations to Available Treatments

Though many evidence-based interventions exist for young children who have experienced trauma, they are limited in terms of their financial accessibility and feasibility for young populations with disabilities.

Feasibility for children with disabilities. The exclusionary criteria for the ABC, CPP, PCIT, and TF-CBT efficacy studies often excluded children with disabilities or did not report the number of children, if any, who had disabilities. As a result, no well-established treatments for young children with disabilities who have experienced maltreatment currently exist. Furthermore, no treatments have been created exclusively for young children with disabilities who also have a history of maltreatment. This is especially concerning since young children with disabilities are more vulnerable to maltreatment than other populations (Maclean et al., 2017; Sullivan & Knutson, 2000).

Financial accessibility. The treatments available for young children who have experienced maltreatment or trauma are generally expensive and require third party reimbursable insurance coverage. Unfortunately, at least 1 in 11 children do not have insurance coverage according to the Kaiser Family Foundation 2015 census data. Further, many of the children who

experience maltreatment are of low socioeconomic status (Sullivan & Knutson, 2000), and thus, are less likely to have insurance coverage to pay for these expensive treatments. As a result, the children who are most at-risk for maltreatment are least likely to have access to an evidence-based treatment due financial constraints.

Training and delivery requirements. There are substantial limitations to the trauma treatments available in terms of training cost, minimum provider qualifications, specialized equipment needed to provide the service, and treatment length. ABC is the only evidence-based treatment available that does not require a college education to implement (National Child Traumatic Stress Network, 2016). Despite this, the training required to become an ABC therapist is quite costly and time-intensive. Training in ABC occurs over a two-day period followed by one full year of group and individual supervision, which entails 1.5 hours of time per week (National Child Traumatic Stress Network, 2016). In addition, training and supervision costs a total of \$7,000.

CPP requires at least a master's degree in order to become certified as a provider (California Evidence-Based Clearinghouse, 2015). Training to become certified as a CPP therapist costs between \$2,000 and \$3,500 per day. In addition, therapists must complete both supervision and booster sessions to become certified (National Child Traumatic Stress Network, 2012). Not only are the training requirements rigorous, but also the length of the treatment (52 weeks) is not conducive to a socially acceptable intervention model. This was noticeable upon examination of treatment attendance/attrition rates reported in the efficacy trials (e.g., Lieberman et al., 2005).

PCIT also requires at least a master's degree in order to become certified as a provider (National Child Traumatic Stress Network, 2008). Training costs are variable but average \$3,000

(National Child Traumatic Stress Network, 2008). In order to become a certified PCIT therapist, one must complete 40 hours of training along with successful completion of two supervised cases (California Evidence-Based Clearinghouse, 2015). In addition, specialized equipment such as a two-way mirror and a wireless communication set is required to implement PCIT as intended (National Child Traumatic Stress Network, 2008).

TF-CBT therapists must be enrolled in a graduate degree program or have a master's degree in order to become certified (National Child Traumatic Stress Network, 2016).

Certification requirements include completion of a 10-hour web-based training, two days of clinical training at a total rate of \$4,000 to \$6,000, 12 hours of clinical supervision calls at a rate of \$150 to \$200 per hour, and one day of advanced training at a rate of \$2,000 to \$3,000 (National Child Traumatic Stress Network, 2016). Therapists must complete three cases in order to become certified in TF-CBT (National Child Traumatic Stress Network, 2016).

The myriad of training and equipment requirements for the evidence-based therapies available for child trauma considerably limit the number of certifiable clinicians. As of yet, no financially accessible evidence-based intervention (for both clinicians and families) has been developed to meet the needs of young children with disabilities who also have experienced maltreatment.

Access to Supports

There are a number of pathways by which young children, including those who have experienced maltreatment, can be referred for mental and behavioral health services. For children who are insured, the healthcare system is one way by which children are identified for services (Powell & Dunlap, 2005). Pediatricians are responsible for screening and identifying children who might benefit from intensive supports; although, research has indicated that pediatricians

only identify about half of children with significant mental and behavioral health challenges (Radecki, Sand-Loud, O'Connor, Sharp, & Olsen, 2011).

Another mechanism through which children are identified for mental and behavioral health supports is early care and learning (Powell & Dunlap, 2005). Early care and learning includes settings such as Early Head Start/Head Start and state-funded pre-kindergarten programs. These programs regularly screen and refer children to community supports such as the state's Child Find program in order to determine eligibility for services under federally funded programs such as Part B of the Individuals with Disabilities Education Act (IDEA; Powell & Dunlap, 2005).

Additionally, children can be identified directly through federally funded programs such as Part C and Part B of IDEA, as it is the duty of these organizations to locate and serve children eligible for services (Powell & Dunlap, 2005). Typically, caregivers of young children self-refer to Child Find in order to access a free screening after which the child may be referred for services under IDEA Part C or Part B (United States Department of Education, 2014).

Finally, children involved in foster care may utilize supports through the child welfare system (Powell & Dunlap, 2005). Children can access family supports, mental health services, and developmental screenings through the welfare system (Cavanaugh, Lippitt, & Moyo, 2010).

Individuals with Disabilities Education Act Part C

Services through Part C. Perhaps the most ideal venue for young children with disabilities to receive early intervention for maltreatment and trauma is through the IDEA Part C program. It is an ideally positioned support because young children with disabilities birth to age 3 years are entitled to receive an appropriate education under IDEA Part C (United States Department of Education, 2014). This means that young children who are identified as having a

disability receive low-cost early prevention and intervention services within the natural environment (United States Department of Education, 2014). These services may include supports for the socio-emotional concerns that arise prior to or following maltreatment. To be eligible, children must have, or be at risk for having, a developmental delay in the domains of cognitive development, physical development, communication development, or adaptive development (United States Department of Education, 2014). Eligibility criteria for each of the above listed domains are determined by individual state guidelines (United States Department of Education, 2014).

Florida Early Steps. The Part C program in Florida is known as Early Steps. Children receive services through Early Steps by screening positively for a developmental delay in one of five areas, including physical, cognitive, gross and fine motor, communication, social-emotional, and adaptive development (Children’s Medical Services, 2012). Once a child is found eligible for services, an Individual Family Service Plan is created and specific goals pertinent to the child’s development are included in the plan (Children’s Medical Services, 2012). Families are then assigned an interventionist and begin receiving services in the natural environment within 30 days (Children’s Medical Services, 2012).

There are two types of interventionists who serve children through Early Steps: Infant and Toddler Developmental Specialists (ITDS) and Early Interventionists (EI; Children’s Medical Services, 2012). ITDSs typically hold a bachelor’s degree (sometimes a master’s degree) in a field related to child development, have at least one year of prior experience with young children, and do not hold a professional license (Children’s Medical Services Provider Handbook: Non-Licensed Physician Healthcare Professionals, 2013). EIs typically hold a master’s degree or higher in a field related to child development, hold a professional license

(e.g., LCSW, LMHC, etc.), and have at least one year of prior experience with young children (Children’s Medical Services Provider Handbook: Licensed Non-Physician Healthcare Professionals, 2013). Unfortunately, this variability in training background among interventionists creates discrepancy in the quality and type of services children receive, with some children accessing high-quality evidence-based interventions that are based on a systematic assessment and other children accessing supports uninformed by data (Dickinson, 2016). Thus, “treatment as usual” within Part C is not standardized and is quite different across service providers.

The interventionists at Early Steps undergo specified professional development several times throughout the year, making them a well-suited population to be trained to implement a new, low cost trauma-informed intervention that was specifically designed for young children with disabilities within the child welfare system. This intervention is known as Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma.

Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma

Smart Start was developed specifically to address the gaps in the literature associated with 1) trauma-informed service-delivery for young children with disabilities and 2) financially ascertainable evidence-based interventions for both therapists and families. Bachelor’s level interventionists employed by organizations such as Early Steps are meant to implement Smart Start. Additionally, the training and supervision is free or of low cost to interventionists, making it financially feasible.

Smart Start is a 9-week manualized parenting intervention for children ages 22 to 36 months with developmental delay, challenging behavior, and trauma exposure. It was delineated from the strategies outlined in PCIT and HOT DOCS, and therefore, is based in attachment and behavioral theories. The primary foci of the intervention are to improve positive parenting practices, reduce child disruptive behaviors associated with trauma, educate caregivers about trauma and its manifestations in young children, and create a trauma-sensitive environment for children by teaching caregivers “social-emotional tips.” These goals are achieved through a live coaching model, wherein interventionists provide feedback to caregivers in a play-based context similar to that of PCIT. A week-to-week description of Smart Start is provided in the following chapter.

Agazzi et al. (2016) recently piloted Smart Start with a small sample of eight children and achieved positive results. Agazzi et al. (2016) measured outcomes using a number of scales, including the Young Child PTSD Checklist (YCPC), ECBI, DPICS, and PSI. Child participants were 37.5% female and 62.5% male. Children were 75% White, 12.5% African American/Black, and 12.5% multiracial. The average age of children was 23 months and all were in foster care at the time of intervention. Data were analyzed using the Wilcoxon Signed-Rank test. Significant improvements at the $p < .05$ level were found for the Parent-Child Dysfunctional Interaction scale of the PSI, DPICS behavior descriptions, DPICS reflections, DPICS labeled praises, and DPICS questions. Significant improvements at the $p < .10$ level were found for the YCPC PTSD and Functional Impairment subscales, the PSI Total Stress subscale, and DPICS directions. It is likely that significant improvements were not found on the ECBI because the average T -scores for the Problem and Intensity subscales did not fall within the clinical range at the inception of treatment, leaving little room for improvement. In addition to the quantitative results, Agazzi et

al. (2016) presented qualitative findings to support the progression of the Smart Start intervention in future applications. Findings indicated that interventionists voiced a need for more detailed training and supervision throughout treatment implementation. The interventionists also asked for more treatment generalization strategies within the manual, greater treatment adaptations for children with lower functioning, and increased time to build rapport with the families. Interventionists indicated improved confidence in their ability to serve young children with trauma histories. Both caregivers and interventionists reported the intervention was positive and socially acceptable. Participants agreed Smart Start was an effective intervention in terms of improving positive parenting practices and child behaviors.

The results from the pilot of Smart Start are extremely promising. Thus, there is a need for an evaluation of the intervention with the suggested modifications. In addition, a more rigorous single case design with more stringent behavioral inclusion criteria must be utilized to further validate Smart Start as an efficacious intervention and to provide support for the notion that it is an intervention in need of greater study.

Conclusion and Purpose

Trauma exposures among young children are highly prevalent, with 26% of 4-year-old children exposed to at least one potentially traumatic event (Briggs-Gowen et al., 2010) and 16% of 2 to 18-year-old-children meeting criteria for PTSD (Alisic et al., 2014). There are several potentially traumatic events children may experience, but child maltreatment is one of the most common, especially for young children (U.S. Department of Health and Human Services, 2017). Children ages 0 to 5 years with disabilities are at especially high risk for maltreatment (Jones et al., 2012; Maclean et al., 2017; Sullivan & Knutson, 2000). Symptoms of trauma in early childhood mimic adult symptoms (i.e., intrusion, avoidance/numbing, and hyperarousal), but

they manifest primarily as challenging behaviors (DeYoung et al., 2011). These early-onset symptoms of trauma are associated with deleterious physical, psychological, and neurological health outcomes along with poor academic well-being.

The evidence-based treatments for early childhood trauma are ABC, CPP, PCIT, and TF-CBT. Unfortunately, these treatments are largely inaccessible to clinicians and families due to cost. In addition, the omission of children with disabilities in efficacy studies limits access to evidence-based treatments to a sizeable number of children who experience maltreatment and trauma. This is particularly troublesome considering young children with disabilities are at especially high-risk for maltreatment (Jones et al., 2012; Maclean et al., 2017; Sullivan & Knutson, 2000). The costs of these treatments also are problematic when considering that many young children who have experienced maltreatment are more likely to be of low socioeconomic status (Sullivan & Knutson, 2000) and are less likely to have insurance coverage. Finally, the costs and degree requirements associated with clinician training for evidence-based treatments limit the number of individuals who can serve young children who have experienced trauma. Thus, there is a great need for a cost-effective, easily accessible treatment for young children with disabilities who have trauma exposures.

The purpose of this study was to address the gaps in the trauma treatment literature with regard to 1) trauma-informed service-delivery for young children with disabilities and 2) financially ascertainable evidence-based interventions for both therapists and families. A second aim of this study was to further assess the efficacy of a newly piloted parenting intervention for young children with disabilities who have experienced maltreatment. This intervention is called Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional

Concerns, and Trauma (Agazzi et al., 2016). Targeted outcomes included children's challenging behaviors, children's PTSD symptomatology, parenting stress, and positive parenting practices. There are many contributions this study made to the current knowledge of evidence-based treatments for young children with disabilities that have experienced trauma. The results of this study lent support to the use of a manualized approach to treatment of trauma among young children with disabilities. Additionally, the results of this study supported Smart Start as a cost-effective intervention approach that is easily accessed by bachelor's level early interventionists.

Chapter Three:

Method

This chapter includes a description of the single case methodology, the participant recruitment procedures along with inclusionary/exclusionary criteria, a week-to-week breakdown of Smart Start, the data collection and analysis procedures, and ethical considerations pertinent to this research.

Setting

Early Steps interventionists and practicum students delivered the Smart Start intervention to children who were involved in the child welfare system and who also were eligible for Part C Early Steps services. Families were served in the natural environment.

Research Design

A single case design was used for this study. Specifically, a non-concurrent multiple baseline procedure compared the treatment effects of the Smart Start intervention to treatment as usual. The non-concurrent multiple baseline design was chosen because participants were referred to the study at different times. Thus, the non-concurrent procedure allowed for participants to be randomized to condition assignments regardless of when they entered the study. Moreover, a single case design was chosen because the incidence of young children referred to Early Steps that have challenging behaviors and that also are involved in the child welfare system is relatively low. Additionally, the Smart Start intervention was recently piloted using a pre-/post-test design. This pilot study resulted in positive effects on children's

challenging behaviors, children's PTSD symptomatology, caregivers' stress, and caregivers' positive parenting practices. As a result, there was a need for further study of Smart Start using a more rigorous design. Therefore, this single case design provided additional rigor to the statistical methodology by establishing treatment effects compared to early intervention as usual wherein participants received Smart Start in staggered phases. This design also allowed for greater generalizability across cases and greater internal validity, as treatment effects were shown over time across many participants. Further, this design was preferable to other single case methodology such as the ABAB design because it would have been unethical to remove potentially effective intervention services from children and families who were at-risk.

Dyads were randomized to begin the Smart Start intervention 3 weeks, 5 weeks, or 7 weeks following the initial referral to the study. This randomization pattern was chosen to create the non-concurrent multiple baseline design of this study. The 2-week increments between condition assignments created the stagger for the multiple baseline design. The randomization occurred without replacement. For example, if a dyad entered the study and was randomized to begin treatment at 7 weeks, then the next dyad to enter the study was randomized to receive services at either 3 weeks or 5 weeks (but not 7 weeks) following the initial referral.

Randomization occurred without replacement for all participants. Children received treatment as usual for some period of time before the Smart Start intervention was implemented. The interventionists were instructed to refrain from using any Smart Start procedures that they did not already use as part of usual care prior to the child's randomized start date.

Participants

Four caregiver-child dyads were recruited and consented to participate in the Smart Start study. However, only three caregiver-child dyads completed all pre-intervention and post-

intervention measures. Notably, one of the “dyads” was a caregiver-child triad (participants 2a and 2b). This means that there were four adult participants and five child participants. This met the What Works Clearinghouse criteria for experimental control, wherein three demonstrations of the treatment effect were shown (Kratochwill & Levin, 2014). In addition, 14 volunteer interventionist participants were trained in Smart Start procedures and were consented to participate in the study. Of these participants, four interventionists implemented Smart Start as part of the study. Tables 1 through 3 below describe the demographic characteristics of the dyads and interventionists.

Table 1

Interventionist Demographic Characteristics

| Participant | Age | Sex | Race | Ethnicity | Education |
|-------------|-----|-----|-----------------|---------------------|-------------------|
| 1 | 50 | F | Caucasian/White | Non-Hispanic/Latino | Advanced Degree |
| 2a/2b | 40 | F | Caucasian/White | Hispanic/Latino | Bachelor’s Degree |
| 3 | 26 | F | Caucasian/White | Non-Hispanic/Latino | Advanced Degree |
| 4 | 51 | F | Caucasian/White | Non-Hispanic/Latino | Bachelor’s Degree |

Recruitment procedures. Participants (caregiver-child dyads) were referred to the study by their provider or at the time of their initial evaluation at Early Steps. If participants had the potential to meet inclusion criteria, then they were given a study flyer and encouraged to contact study personnel. In order to be referred to study personnel, the child had to be involved in the child welfare system and rated by the caregiver as engaging in significant challenging behaviors. Significant challenging behaviors were defined as a *T*-score of 60 or greater on either the Intensity or Problem subscale of the ECBI. Interested participants who contacted study personnel were screened for the intervention using a telephone screening procedure (see Appendix B). Those who met inclusion criteria were given the option to participate in the study and subsequently completed all pre-treatment measures at the end of their designated baseline period.

In addition, study staff presented the opportunity to participate in the study to the local child welfare agency.

Caregiver inclusion/exclusion criteria. In order to be eligible for the study, caregivers were required to hear, see, read, and speak English. They also had to be the legal guardian or court-appointed caregiver of the child eligible for the intervention. Finally, caregivers had to be willing to receive services in the home. Potential caregiver participants were excluded from the study if they did not speak English, were deaf or blind, could not read, or received other parent training interventions.

Table 2

Caregiver Demographic Characteristics

| Participant | Relationship to Child | Age | Sex | Race | Ethnicity | Education |
|-------------|------------------------|-----|-----|-----------------|---------------------|-------------------|
| 1 | Foster mother | 42 | F | Caucasian/White | Hispanic/Latino | Advanced Degree |
| 2a/2b | Foster mother | 49 | F | Cuban/Dominican | Hispanic/Latino | Some college |
| 3 | Foster mother | 50 | F | Caucasian/White | Non-Hispanic/Latino | Associate Degree |
| 4 | Foster to adopt mother | 29 | F | Caucasian/White | Non-Hispanic/Latino | Bachelor's Degree |

Child inclusion/exclusion criteria. Children were included if they were at least 18-months-old, accessing services through Early Steps, receiving services through the Hillsborough or Polk county child welfare system (i.e., had a history of maltreatment), and exhibiting significant levels of externalizing behavior problems as demonstrated by clinically significant ECBI *T*-scores. Children were excluded if they were over the age of 3 years, were deaf or blind, did not speak English, or if they had experience with other evidence-based therapies for trauma such as PCIT, CPP, ABC, or TF-CBT.

Table 3

Child Demographic Characteristics

| Participant | Age in Months | Sex | Race | Ethnicity |
|-------------|---------------|-----|-----------------|---------------------|
| 1 | 27 mos. | M | Caucasian/White | Hispanic/Latino |
| 2a/2b | 23 mos. | M/F | Caucasian/White | Non-Hispanic/Latino |
| 3 | 22 mos. | M | Caucasian/White | Hispanic/Latino |
| 4 | 22 mos. | F | Caucasian/White | Hispanic/Latino |

Smart Start for Trauma Treatment Sessions

A simplified breakdown of the Smart Start intervention is listed in Table 4 (see pages 65-66).

Orientation week. This initial session with the family was used to orient the caregiver to the intervention and provide expectations for weekly participation. During this session, the interventionist reviewed results of the Young Child PTSD Checklist and asked the caregiver to complete the ECBI. Next, the interventionist described the structure of the Smart Start intervention and briefly explained Child-Directed Interaction (CDI) skills and Social-Emotional Tips (SE-Tips; trauma-sensitive parenting practices). At the end of the session, the interventionist observed the parent and child playing together and completed the treatment integrity checklist and the Clinical Global Impression—Severity Scale.

Week 1. Week one began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. Next, the interventionist introduced Smart Start and engaged in caregiver psychoeducation about common manifestations of trauma in early childhood. The interventionist used an SE-Tips activity called the Traumatic Stress Storyboard to facilitate the discussion around posttraumatic stress symptoms that may occur after a trauma. Caregivers were assigned homework to consider their child’s posttraumatic stress symptoms in preparation for discussion in week two. The interventionist then transitioned to teaching CDI skills. These are strategies used to improve

parent-child interactions through play situations. Specific strategies that facilitated play (referred to as “Do Skills”) included describing the child’s desired behaviors and emotions, praising specific desired behaviors (e.g., “Thank you for playing gently with your toys”), and reflecting the child’s appropriate speech. Strategies that hindered play (referred to as “Avoid Skills”) included questioning the child, giving the child directions, and criticizing the child. The caregiver practiced using the CDI skills with support and coaching from the interventionist. Specific strategies also were provided for child misbehavior during play. These strategies included planned ignoring for minor misbehaviors and termination of Special Play for aggression. The session concluded with an explanation of appropriate toys and settings for Practice Play (a time during which CDI skills were used exclusively) during the week. Five minutes per day of Practice Play was assigned as homework. The interventionist completed a treatment integrity checklist.

Week 2. Week two began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist completed a follow-up regarding the SE-Tips and Practice Play homework assignments. The interventionist problem-solved any barriers to homework completion. The caregiver and interventionist completed the weekly SE-Tips exercise, which was to provide psychoeducation about parenting change following a child’s trauma. The caregiver was encouraged to consider where their parenting fell on a continuum from too strict to too lenient. The interventionist identified changes in the caregiver’s thinking that may have contributed to a change in parenting practices. For homework, caregivers were instructed to do a “parenting check” to see how their feelings might have influenced their responses to child behavior. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver

and child playing and set goals for improving CDI skills for the remainder of the session. The interventionist spent time coaching and praising the caregiver for using CDI skills. The session concluded with assigning Practice Play for five minutes per day. The interventionist completed a treatment integrity checklist.

Week 3. Week three began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist completed a follow-up regarding the SE-Tips and Practice Play homework assignments and problem-solved any barriers to homework completion. The weekly SE-Tips activity was to discuss the importance of recognizing children's strengths in spite of their challenging behaviors. The caregiver was asked to brainstorm and list their child's strengths and concerns using an activity sheet provided by the interventionist. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver and child playing and set goals for improving CDI skills for the remainder of the session. The interventionist spent time coaching and praising the caregiver for using CDI skills. The session concluded with assigning Practice Play for five minutes per day. The interventionist completed a treatment integrity checklist.

Week 4. Week four began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist reviewed the previous week's SE-Tips activity and completed a follow-up regarding the Practice Play homework assignment. The interventionist problem-solved any barriers to homework completion. The weekly SE-Tips activity was to review the importance of caregiver self-care. The caregiver was asked to identify their own self-care strategies and to brainstorm new strategies to use in the future. The homework for this SE-Tip was to practice at least one self-

care strategy every day. Next, the caregiver and interventionist transitioned to using CDI skills. At this point, the interventionist introduced the concept of Follow Through for Clear Directions in CDI. The interventionist explained the types of directions that were likely to result in child compliance (e.g., one direction at a time, directions stated positively and in a normal tone of voice, etc.). Following the explanation of Clear Directions, the interventionist described a hand-over-hand Follow Through procedure. The interventionist spent time coaching the caregiver to use CDI skills with Clear Directions and Follow Through during a play situation. The session ended with the interventionist coaching the caregiver through a clean-up routine in which Clear Directions with Follow Through were used with the child. Five minutes of daily Practice Play with Clear Directions and Follow Through were assigned for homework. The interventionist completed a treatment integrity checklist.

Week 5. Week five began with a follow-up regarding the child's PTSD symptoms. If caregivers rated the child's symptoms on the Young Child PTSD Screen significantly, then the interventionist provided the caregiver with resources for additional treatments as needed. The interventionist also asked the parent to complete the ECBI. The interventionist inquired about the SE-Tips and Practice Play with Clear Directions homework assignments and problem-solved any barriers to homework completion. The weekly SE-Tips activity was to show caregivers how to encourage their children to appropriately verbalize emotions. For homework, the caregiver was asked to role model labeling their own emotions and linking their emotions to daily life situations. In addition, caregivers were asked to label their child's emotions and to link the child's emotion to daily life situations. The caregiver also was encouraged to use emotion statements in the context of the child's trauma as necessary. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver

and child playing and set goals for improving CDI skills for the remainder of the session. The session concluded with the interventionist coaching the caregiver through a clean-up routine in which Clear Directions with Follow Through were used with the child. Five minutes of daily Practice Play with Clear Directions and Follow Through were assigned for homework. The interventionist introduced using Smart Start parenting skills throughout daily routines and asked the caregiver to try to generalize CDI skills. The interventionist completed a treatment integrity checklist.

Week 6. Week six began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist completed a follow-up regarding the SE-Tips and Practice Play with Clear Directions and Follow Through homework assignments and problem-solved any barriers to homework completion. The weekly SE-Tips activity was to discuss emotion regulation strategies to use with the child. The interventionist explained age appropriate deep breathing techniques and encouraged the caregiver to practice the techniques with the child for homework. At this time, the interventionist introduced the Time Out chair as a consequence for aggressive behavior. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver and child playing and set goals for improving CDI skills for the remainder of the session. The session concluded with the interventionist coaching the caregiver through a clean-up routine in which Clear Directions with Follow Through were used with the child. Next, the interventionist engaged in a discussion surrounding generalization of Clear Directions, Follow Through, and Time Out into daily routines. Five minutes of daily Practice Play with Clear Directions and Follow Through were assigned for homework. Caregivers were encouraged to practice skills in daily outings as well. The interventionist completed a treatment integrity checklist.

Week 7. Week seven began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist completed a follow-up regarding the SE-Tips and Practice Play with Clear Directions and Follow Through homework assignments and problem-solved any barriers to homework completion. The interventionist inquired about success with generalization of skills. The interventionist reviewed all the SE-Tips learned in previous sessions and asked the caregiver to choose one to practice for homework over the next week. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver and child playing and set goals for improving CDI skills for the remainder of the session. The CDI ended with the interventionist coaching the caregiver through a clean-up routine in which Clear Directions with Follow Through were used with the child. The session concluded with the interventionist assigning five minutes of daily Practice Play with Clear Directions and Follow Through for homework. Caregivers were encouraged to practice skills in daily outings as well. The interventionist completed a treatment integrity checklist.

Week 8. Week eight began with completion of an ECBI and a brief check-in and discussion of stressors the caregiver experienced over the previous week. The interventionist completed a follow-up regarding the SE-Tips and Practice Play with Clear Directions and Follow Through homework assignments and problem-solved any barriers to homework completion. The interventionist inquired about success with generalization of skills. Next, the caregiver and interventionist transitioned to using CDI skills. The interventionist briefly observed the caregiver and child playing and set goals for improving CDI skills for the remainder of the session. The CDI ended with the interventionist coaching the caregiver through a clean-up routine in which Clear Directions with Follow Through were used with the child. The interventionist provided the

caregiver with information about generalizing CDI skills, Clear Directions with Follow Through, and Time Out into every day routines. The session concluded with the interventionist highlighting the importance of continuing to use the skills learned through the Smart Start intervention to improve the child's behavior and PTSD symptomatology. The interventionist completed a treatment integrity checklist and the Clinical Global Impression Severity and Improvement scales.

Smart Start Training and Supervision

The Smart Start interventionists received a 9-hour training (six hours in person and three hours on the web) wherein the principles of Smart Start were introduced. Interventionists were given an opportunity to view live coaching and to practice coaching with feedback from study staff. The interventionists also watched training videos showing the use of the intervention inside a real home. In addition to an in-person training, the interventionists attended monthly supervision sessions to reinforce their skills and to problem-solve any barriers to services.

Data Collection Procedures

The ECBI was collected weekly throughout baseline and intervention by the interventionists, while the other four outcome measures were collected at pre-intervention and post-intervention (between the last week of baseline and the orientation session and the end of week eight) by either the interventionists or study staff. In addition, a demographic questionnaire was collected at pre-intervention, the Therapy Attitude Inventory was collected at post-intervention, treatment as usual checklists were collected each week of baseline, and treatment integrity checklists were completed each week of intervention implementation.

Table 4

Weekly Breakdown of Smart Start Intervention

| Smart Start Session | Parenting Skills | SE-Tips | Homework Assigned | Measures Completed |
|---------------------|---|---|---|---|
| Orientation Week | <ul style="list-style-type: none"> • Orientation to treatment • Brief overview of CDI skills | <ul style="list-style-type: none"> • None | <ul style="list-style-type: none"> • None | <ul style="list-style-type: none"> • ECBI • CGI—Severity |
| Week 1 | <ul style="list-style-type: none"> • Introduction to CDI skills • CDI practice • Overview of planned ignoring for minor misbehaviors | <ul style="list-style-type: none"> • Traumatic Stress Storyboard | <ul style="list-style-type: none"> • SE-Tips consideration of child PTSD symptoms • Five minutes of daily Practice Play | <ul style="list-style-type: none"> • ECBI |
| Week 2 | <ul style="list-style-type: none"> • CDI practice | <ul style="list-style-type: none"> • Parenting Balance activity | <ul style="list-style-type: none"> • SE-Tips Parenting Check • Five minutes of daily Practice Play | <ul style="list-style-type: none"> • ECBI |
| Week 3 | <ul style="list-style-type: none"> • CDI practice | <ul style="list-style-type: none"> • Strengths and Concerns activity | <ul style="list-style-type: none"> • Five minutes of daily Practice Play | <ul style="list-style-type: none"> • ECBI |
| Week 4 | <ul style="list-style-type: none"> • CDI practice • Clear Directions • Hand-over-hand Follow Through | <ul style="list-style-type: none"> • Self-Care and You | <ul style="list-style-type: none"> • Daily self-care activities • Five minutes of daily Practice Play with clean-up routine (Clear Directions with Follow Through) | <ul style="list-style-type: none"> • ECBI |
| Week 5 | <ul style="list-style-type: none"> • CDI practice • Clear Directions with Follow Through practice during Special Play and during clean-up • Generalization of skills to daily life | <ul style="list-style-type: none"> • Show Me How You Feel | <ul style="list-style-type: none"> • Use of emotion language throughout daily routines • Five minutes of daily Practice Play with clean-up routine (Clear Directions with Follow Through) • Use skills during daily routines | <ul style="list-style-type: none"> • ECBI • Young Child PTSD Screen |

Table 4 (Continued)

| | | | | |
|--------|---|--|---|---|
| Week 6 | <ul style="list-style-type: none"> • CDI practice • Clear Directions with Follow Through practice during Special Play and during clean-up • Time Out for aggression introduction • Generalization of skills to daily life | <ul style="list-style-type: none"> • Comfort and Calm | <ul style="list-style-type: none"> • Use deep breathing during play and at naptime and bedtime • Five minutes of daily Practice Play with clean-up routine (Clear Directions with Follow Through) • Use skills during daily routines | <ul style="list-style-type: none"> • ECBI |
| Week 7 | <ul style="list-style-type: none"> • CDI practice • Clear Directions with Follow Through practice during Special Play and during clean-up • Generalization of skills to daily life | <ul style="list-style-type: none"> • Reinforce SE-Tips introduced in previous weeks | <ul style="list-style-type: none"> • Caregiver choice of SE-Tip • Five minutes of daily Practice Play with clean-up routine (Clear Directions with Follow Through) • Use skills during daily routines | <ul style="list-style-type: none"> • ECBI |
| Week 8 | <ul style="list-style-type: none"> • CDI practice • Clear Directions with Follow Through practice during Special Play and during clean-up • Generalization of skills to daily life | <ul style="list-style-type: none"> • Reinforce SE-Tips introduced in previous weeks | <ul style="list-style-type: none"> • None | <ul style="list-style-type: none"> • ECBI • CGI—Severity • CGI—Improvement |

Child outcome measures included the ECBI, the Clinical Global Impression (Severity and Improvement scales), and the Young Child PTSD Checklist. Caregiver outcomes included the Parenting Stress Index, Fourth Edition—Short Form and DPICS. Table 5 outlines the assessment schedule for the data collected. Three dyads completed all data collection procedures, while one triad only completed pre-intervention measures and ECBI through Week 5 of Smart Start. Thus, complete data were only available for three dyads.

Table 5

Assessment Schedule

| Variable | Measure | Baseline | Pre-Intervention | Intervention | Post-Intervention |
|--------------------------------------|--------------------------------|----------|------------------|--------------|-------------------|
| Demographic Data | Demographic Questionnaire | | X | | |
| Usual Care Implementation | Treatment as Usual Checklists | X | | | |
| Smart Start Implementation Integrity | Treatment Integrity Checklists | | | X | |
| Disruptive Behaviors | ECBI | X | | X | |
| | CGI Severity | | X | | X |
| | CGI Improvement | | | | X |
| Posttraumatic Stress Symptoms | YCPC | | X | | X |
| Parenting Practices | DPICS | | X | | X |
| Parenting Stress | PSI-4-SF | | X | | X |
| Treatment Satisfaction | TAI | | | | X |

Demographic questionnaire. A demographic questionnaire was completed at pre-intervention for interventionists, caregivers, and children. Study staff solicited the demographic

questionnaire. Specific information gathered about the interventionists included race, ethnicity, sex and gender, level of education, and employment status. Information gathered about the caregiver included race, ethnicity, sex and gender, relationship to the child, number of people living in the household, household structure (e.g., single parent, dual parent, etc.), marital status, level of education, employment status, and household income. Information gathered about the child included additional therapies outside of Early Steps, the child's daily living conditions, the child's race, the child's ethnicity, and the child's sex and gender.

Interventionist outcomes.

Treatment as usual checklists. Interventionists completed treatment as usual checklists each baseline week to ensure Smart Start intervention practices were not used prematurely. These checklists included the parenting practices and SE-Tips taught through Smart Start. The interventionist recorded whether they used each strategy listed on the checklist. If an interventionist used one of the strategies, then they recorded whether it was part of their standard treatment prior to Smart Start training. Procedures recorded as standard treatment prior to Smart Start training were considered treatment as usual, and not an infringement upon baseline standard care. This was the best approximation of "treatment as usual." As stated previously, there was significant variability in the training backgrounds of interventionists working for Early Steps. This means that there was discrepancy with regard to treatment as usual across participants, which could have influenced the trend of the data.

In addition to the treatment as usual checklists, interventionists were asked to respond to a behavioral vignette during one supervision session. They were asked to share their assessment and intervention procedures related to the behavior of concern. The vignette provided additional

insight into the variability across interventionists in terms of their usual care for challenging behaviors.

Treatment integrity checklists. Interventionists completed weekly treatment integrity checklists to determine the extent to which they implemented the intervention with fidelity. This provided descriptive data regarding the feasibility of the current intervention. Integrity checklists also could be used to hypothesize a child's non-response to intervention if integrity was low. Weekly integrity was calculated by dividing the number intervention elements completed by the number of elements completed plus the number of elements left incomplete and multiplying by 100.

In addition to weekly integrity checklists, one member of the research team attended one Smart Start session and completed the treatment integrity checklist against the interventionist's checklist. Interrater reliability was calculated. This provided additional support for the extent to which interventionists completed the service with high degrees of fidelity.

Child outcomes.

Eyberg Child Behavior Inventory (ECBI). The ECBI is a 36-item standardized instrument for children ages 2 to 16 years (Eyberg & Pincus, 1999). This tool was collected each week throughout baseline and intervention by the interventionists. It was used to determine the severity of a child's behavior from the perspective of the caregiver each week over the course of treatment. The ECBI has two subscales: Intensity and Problem. The Intensity subscale measures caregivers' perceptions of the frequency of challenging behaviors from a 1 (never) to 7 (always) scale (Eyberg & Pincus, 1999). The Problem subscale measures whether caregivers find the same challenging behaviors measured by the Intensity subscale as problematic. This is determined using a yes/no scale (Eyberg & Pincus). Each subscale raw score is converted to a *T*-

score. An average *T*-score is 50 with a standard deviation of 10. *T*-scores of 60 or greater are considered clinically significant levels of challenging behaviors.

The ECBI has been re-standardized with a sample of 798 children (Eyberg, Colvin, & Adams, 1999). Indicators of reliability and validity for the ECBI have shown it is an adequate measure of challenging behaviors across time and raters. Ten-month test-retest reliability for both the Intensity and Problem subscales was found to be .75, with no significant differences between Intensity and Problem scores among boys, girls, and age within the Preschool age group (Funderburk, Eyberg, Rich, & Behar, 2003). Significant correlations between the ECBI and Preschool Behavior Questionnaire—Parent Completed (PBQ-P) showed moderate convergent validity (Funderburk et al., 2003). The Intensity scale had a correlation of .53 with the PBQ-P, while there was a correlation of .34 for the Problem subscale (Funderburk et al., 2003). Internal consistency for the Intensity subscale was found to be .93, while internal consistency for the Problem subscale was found to be .95 (Eyberg et al., 1999). Interrater reliability between mothers and fathers was found to be .69 and .61 for the Intensity and Problem subscales, respectively (Eisenstadt, McElreath, Eyberg, & McNeil, 1994).

Young Child PTSD Checklist (YCPC). The YCPC is a 42-item measure of trauma exposure and posttraumatic stress symptoms for young children ages 1 to 6 years (Scheeringa, 2010). This measure was administered at pre-intervention and post-intervention by study staff. The YCPC includes 13 trauma exposure items and two subscales that measure PTSD symptoms (23 items) and functional impairment (six items). For trauma exposure, caregivers rate whether a child was exposed to different types of trauma on a 0 (specific trauma did not happen) to 1 (specific trauma did happen) scale. Caregivers also provide information about the child's age the first time the specific trauma happened, the child's age the most recent time the specific trauma

happened, and how many times the child was exposed to the specific trauma. For PTSD symptoms, caregivers rate a series of trauma-related child behaviors over a two-week period on a 0 (Not at all) to 4 (Every day) scale. Caregivers also rate the functional impairment on a 0 (Hardly ever/none) to 4 (Every day) scale. A Total PTSD score of 26 or greater and a Functional Impairment score of four or greater are the clinical cutoffs that indicate a probable diagnosis of PTSD. The YCPC was developed specifically to mirror the DSM-5 criteria for PTSD among children under the age of 6 years. In addition, the YCPC was developed as a screening procedure, and not a diagnostic procedure. Given that PTSD among very young children is a new area of research, the YCPC has not yet been validated in any empirical studies. In fact, no brief questionnaires (to this researcher's knowledge) have been developed and validated for use with children under the age of 2 years. However, researchers have studied YCPC items using an interview format (i.e., Diagnostic Infant and Preschool Assessment; Scheeringa & Haslett, 2010) and found excellent face validity. Test-retest reliability was found to be .87 when the questions were structured in an interview format (Scheeringa & Haslett, 2010). The YCPC is currently undergoing a construct validation study. Though the Diagnostic Infant and Preschool Assessment (Scheeringa & Haslett, 2010) has been validated for use with very young children, it is not a feasible progress monitoring tool because the interview-style questionnaire takes up to an hour to administer. Thus, results from this measure were interpreted with caution.

Clinical Global Impression (CGI). The CGI is a subjective measure of the severity and improvement of a client's target concern (Zaider, Heimberg, Fresco, Schneier, & Liebowitz, 2003). The CGI includes two scales: Severity and Improvement. The Severity subscale was administered at pre- and post-intervention, while the Improvement subscale was administered at post-intervention only. The interventionists completed the CGI scales. Both scales are 7-point

ratings (1 = No Challenging behaviors to 7 = Extremely severe behaviors; 1 = Very much improved to 7 = Very much worse). Determinations regarding Severity were made based on an ecological approach to behavior, which included the interventionist's clinical experience (i.e., past experience with similar behaviors) and an interview with the caregiver. The interventionist rated the severity of the challenging behaviors in comparison to other children they had served. Determinations regarding the Improvement scale were made based on the interventionist's clinical interpretation of the child's improvement over the course of the intervention along with the caregiver's input. The CGI is a measure used for a variety of clinical conditions, and as a result, psychometric properties are available for many samples, but not for challenging behaviors among young children. For example, the interrater reliability for the CGI—Schizophrenia was found to range from .64 to .88 (Haro et al., 2003). The CGI—Social Anxiety Disorder was highly correlated with both client ($r = .25$ to $.77$) and clinician ($r = .35$ to $.84$) ratings. The correlations for the CGI—Depression were found to be approximately .9 (Kadouri, Corruble, & Falissard, 2007). Though the CGI has not been used in a clinical study with challenging behaviors specifically, it has nevertheless become common practice for clinicians to use as an additional measure of subjective improvement. Importantly, the verbiage of the scale remains unchanged for all target concerns, except to interchange the name of the relevant concern. The CGI was used alongside the ECBI as an additional source of data from a second informant (the interventionist).

Caregiver outcomes.

Dyadic Parent-Child Interaction Coding System (DPICS). DPICS is a system used to observe and monitor caregiver behaviors over the course of treatment (Eyberg et al., 2014). Observers tally the frequency with which the behaviors occur over a period of minutes.

Behaviors observed included negative parent behaviors such as questions, commands, and criticisms and positive parent behaviors such as behavior descriptions, labeled praises, and reflections. DPICS-III were taped and coded by study staff at pre-intervention and post-intervention to evaluate improvements in caregivers' behavior over time. Bessmer (1996) determined the psychometric properties of DPICS-II using 60 caregiver-child dyads. Thirty dyads were a clinic-referred group and 30 dyads served as a comparison group. Reliability of codes during CDI ranged from .25 to .99. Reliability of the codes during PDI ranged from .47 to .99.

Parenting Stress Index, Fourth Edition—Short Form (PSI-4-SF). The PSI-4-SF is a brief, 36-item measure of parenting stress that garners four subscales in addition to a Total Parenting Stress Score (Abidin, 1990). The four scales are Defensive Responding, Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child. This measure was administered at pre-intervention and post-intervention by study staff. It was used to determine improvement in caregiver stress. Caregivers rate items on a 1 (Strongly Agree) to 5 (Strongly Disagree) scale. Scores are interpreted in terms of percentile rankings, and a rank between the 15th and 80th percentile is considered normal. One-year test-retest reliability was determined using a sample of 800 participants and it ranged from .68 (Parent-Child Dysfunctional Interaction) to .85 (Parental Distress; Abidin, 1995). Internal consistency was determined using a sample of 103 participants and it ranged from .80 (Parent-Child Dysfunctional Interaction) to .91 (Total Stress; Reitman, Currier, & Stickle, 2002).

Therapy Attitude Inventory (TAI). The TAI was administered at post-intervention by study staff. It was used to determine caregivers' satisfaction with the intervention. The TAI was developed for use with caregiver behavioral skills training programs (Eyberg, 1993). It includes

10 items related to caregiver satisfaction with the treatment, the parenting practices learned, and improvements in child challenging behavior (Brestan, Jacobs, Rayfield, & Eyberg, 1999).

Caregivers rate satisfaction on a 5-point Likert scale. The TAI was evaluated with 62 clinic-referred caregiver-child dyads (Brestan et al., 1999). Measures of internal consistency yielded excellent results (Cronbach's alpha = .91). Four-month test-retest reliability indicated similarly high results with an alpha of .85. When measured against the ECBI, convergent validity ranged between .36 and .49.

Data Analysis

Visual analysis. The What Works Clearinghouse standards for visual analysis of single case data were used to determine whether there was a relationship between the independent and dependent outcome variable (i.e., the ECBI; Kratochwill & Levin, 2014). The ECBI Intensity and Problem scores were inspected separately. Six features of the data were considered and four steps were taken to analyze the data (Kratochwill et al., 2010). The features considered were level, trend, variability, immediacy of the effect, overlap, and consistency of the data patterns across similar phases. Level refers to the extent to which there was a change in the level of the data between the baseline and intervention conditions. Trend refers to the upward, downward, or stable nature of data patterns across baseline and intervention phases. Variability refers to the level of inconsistency in the data patterns, both within and across baseline and intervention phases. Immediacy of the effect refers to the extent to which the intervention procedure was effective immediately upon treatment implementation. Overlap refers to whether the data within the baseline and intervention phases overlapped with each other. Consistency of the data patterns across similar phases refers to the extent to which all baseline and intervention phases showed similar data trends and patterns. The four steps taken to analyze the data were to 1) document a

predictable baseline pattern, 2) examine the data within each phase, 3) compare the data across similar phases, and 4) integrate the information to determine whether there were three demonstrations of the treatment effect.

Masked visual analysis. A masked visual analysis was used to help control for Type 1 error rates that may have occurred during the visual analysis (Ferron & Jones, 2006). Upon intervention completion, three individuals experienced in single case methodology analyzed all participants' data. The visual analysts, who were blind to the condition assignments, inspected the data and made determinations about the phase to which each caregiver-child was assigned (i.e., at 3 weeks, 5 weeks, or 7 weeks following the referral). The visual analysts were presented with each dyad's baseline and intervention graphs without the phase change line. The analysts were given one opportunity to make a determination about the condition assignment for each participant and each indicator of challenging behaviors (i.e., ECBI Intensity and Problem). If the analysts correctly identified a dyad's intervention assignment, then a p -value was calculated by dividing the number of specifications (i.e., the number of "guesses" about the condition assignments made by the masked visual analysts) by the number of possible assignments (i.e., 1/18). If the visual analysts did not correctly identify a dyad's intervention assignment, then the researcher would fail to reject the null hypothesis and the Smart Start intervention may not have made an effect on caregiver ratings of child challenging behaviors. The correct identification of condition assignments was meaningful because it demonstrated the strength of the intervention in terms of behavioral improvements. Thus, if Smart Start resulted in behavioral changes, then all participants would experience similar trends data and masked visual analysts would be able to detect condition assignments. Significance was determined at a $p < .06$ level.

To maintain the integrity of the analysis, the last four data points and two data points were removed from the 7-week and 5-week conditions, respectively. This ensured that the visual analysts did not easily identify the condition assignments based on the length of the intervention phase since all participants had different baseline lengths but completed nine total weeks of intervention. In addition, one of the twins' graphs was not included in the masked visual analysis since they were both randomly assigned to a condition assignment as a pair.

Multi-level modeling. Hierarchical linear modeling (HLM) was used to synthesize ECBI ratings of behavior change within and across caregiver-child dyads (Ferron, Farmer, & Owens, 2010). Level-1 models were used to analyze data for single participants and level-2 models were used to examine variation across participants. Treatment effects and individual effects were estimated based on an assumption that there were two phases: baseline and intervention. The baseline phase was based on assumptions of autocorrelation, level, and trend. The intervention phase was based on assumptions of autocorrelation, a change in level at intervention implementation, and a change in trend upon intervention implementation. Confidence intervals were calculated and the Kenward-Roger method was used to determine degrees of freedom. The Level-1 model is represented by the regression equation below, where CDI is coded 1 for CDI and 0 for all other observations. Time was centered such that 0 was the last observation.

$$Y = b_{0i} + b_{1i}CDI_{ti} + b_{2i}Time_{ti} + b_{3i}CDI_{ti} * Time_{ti} + e_{ti}$$

The Level-2 model also is represented by the regression equation below.

$$b_{0i} = a_{00} + r_{0i}$$

$$b_{1i} = a_{10} + r_{1i}$$

$$b_{2i} = a_{20} + r_{2i}$$

$$b_{3i} = a_{30} + r_{3i}$$

Wilcoxon Signed-Rank test. A procedure known as the Wilcoxon Signed-Rank test was used to measure presence of significant changes on the Clinical Global Impression from pre- to post-intervention. The Signed-Rank Test is a nonparametric test used with small samples. This test does not include assumptions about normality of the data, and the data are assumed to be independent and continuous. This test statistic is calculated based on positive and negative change, so individuals with no change were excluded from the analysis. The Signed-Rank Test, characterized as $W+$ and $W-$, was calculated by subtracting pre-intervention scores from post-intervention scores. The absolute values were then ordered from lowest to highest and assigned a rank from 1 to n , where 1 was the lowest rank and n was the highest rank. Positive or negative signs were assigned to each rank depending on the original difference score obtained. A $W+$ was calculated by adding the positive ranks, while a $W-$ was calculated by adding the negative ranks. The $W+$ and $W-$ scores were compared to critical values, which determined statistical significance at the $p < .05$ level.

Reliable change index. The reliable change index (RCI) was used to measure change on pre- to post-intervention outcomes (i.e., DPICS, PSI-4-SF, and YCPC; Jacobson & Truax, 1991). The RCI is a test statistic used to measure clinically significant change within individuals from pre-assessment to post-assessment (Jacobson & Truax, 1991). The RCI was calculated by subtracting an individual's pre-intervention score on a given measure from their post-intervention score, and then dividing by the standard error of the difference between the scores (Jacobson & Truax, 1991). If the RCI was larger than 1.96, then the change was considered statistically significant ($p < .05$; Jacobson & Truax, 1991).

Notably, the calculation for the YCPC was limited because the sample characteristics from the current study were used to determine the RCI. The sample characteristics from the

present study were used because there was insufficient information about the measure to calculate reliable change. In addition, the psychometric properties needed to calculate the PSI-4-SF were obtained from more than one study since the authors of the PSI-4-SF did not provide the mean and standard deviation of the subscales on the PSI-4-SF, which were needed to calculate reliable change. In addition, the DPICS RCI was limited in that the psychometric properties of the scale only were provided for families at pre-intervention. Thus, the RCI was highly sensitive to small change from pre-assessment to post-assessment. Finally, the standard deviation and reliability scores from the Bessmer (1996) study were averaged for both direct/indirect commands and information/descriptive questions in order to calculate the RCI for DPICS commands and questions. All psychometric properties for DPICS were obtained from CDI coding instead of PDI.

Descriptive statistics. Descriptive statistics were used to measure caregiver satisfaction with Smart Start and to measure intervention integrity. More specifically, average scores from the TAI were calculated. With regard to treatment integrity, weekly fidelity was calculated by dividing the number intervention elements completed by the number of elements completed plus the number of elements left incomplete and multiplying by 100. The average treatment integrity was calculated.

Ethical Considerations

This research was considered to be minimal risk to participants and was approved by the Institutional Review Board of the University of South Florida. A number of steps were taken to ensure confidentiality was maintained. All research staff completed HIPAA training in order to understand the importance of confidentiality. In addition, caregiver-child participants received intervention services within the privacy of their home. All electronic data were kept on a

password-protected computer. All physical data were kept in a locked file cabinet at USF Children's Medical Services. Identifying information of participants was kept in a separate password-protected file, and participants were referenced in terms of identification numbers on all data documents. All data will be destroyed five years following completion of the study.

Both caregiver-child participants and interventionist participants provided informed consent. In the case that a child was not in the legal guardianship of their biological parents (i.e., the child was in foster care or kinship care), the child's case manager had authority to consent the child to participate. No individual was forced to participate. Study aims, risks and benefits to participation, and the principal investigator's contact information were provided as part of the informed consent process.

Chapter Four:

Results

This chapter includes the results of the multiple baseline evaluation of Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma. Caregiver report of children's challenging behaviors are analyzed and discussed through visual analysis, masked visual analysis, and hierarchical linear modeling. Interventionists' report of children's challenging behaviors is examined using the Wilcoxon Signed-Rank test. Posttraumatic stress symptoms, positive parenting practices, and parenting stress are analyzed with the reliable change index. Finally, interventionists' treatment integrity and caregivers' satisfaction with Smart Start are presented descriptively.

Treatment Integrity

Treatment as usual checklists. Interventionists completed usual care checklists (see Appendix F) to ascertain the extent to which "treatment as usual" included strategies that overlapped with Smart Start procedures. There was significant variability across participants in terms of usual care. The interventionist who served Dyad 1 used planned ignoring, clear directions with Follow Through, child-directed emotion regulation strategies, and caregiver identification of the child's strengths and concerns throughout baseline. Dyads 2a and 2b (the aforementioned caregiver-child "triad") benefitted from planned ignoring, clear directions with Follow Through, child-directed emotion regulation strategies, caregiver education about trauma/challenging behaviors, caregiver identification of strengths and concerns, and caregiver

self-care throughout baseline. Notably, the interventionist who served Dyads 2a and 2b prematurely implemented Smart Start Orientation and Week 1 during the baseline period. It is possible this error contaminated the baseline data; however, the first two weeks of Smart Start are teaching sessions and do not include significant coaching of strategies. The interventionist repeated Smart Start Orientation and Week 1 following the completion of baseline. No Smart Start strategies were used throughout baseline for Dyad 3. Finally, the interventionist who served Dyad 4 used planned ignoring and clear directions with Follow Through during baseline.

No interventionists engaged in coaching of Child-Directed Interactions (CDI) and Time Out during usual care. Thus, components associated with the Smart Start intervention that are critical to improved behavioral outcomes were left untouched throughout baseline for all participants. In addition, interventionists indicated their implementation of overlapping strategies was not as structured as Smart Start. All strategies used throughout baseline sessions were used in the interventionists' sessions prior to training in Smart Start.

Treatment as usual vignettes. All interventionists were asked to review and respond to a behavioral vignette (see Appendix G) to develop a greater understanding of “usual care” at Early Steps. The vignette included an operational definition of a mild tantrum and asked providers to develop an intervention for the child. The interventionist who served Dyad 1 reported that she would have used planned ignoring without differential reinforcement, clear directions (positively stated commands), and Time Out prior to her training in Smart Start. Importantly, she reported that her Time Out procedure would not have been as structured and would not have included a teaching component like the Smart Start procedure. The interventionist who served Dyads 2a/b indicated she would determine the reason for the tantrum and attempt to calm the child through deep breathing. She indicated that if calming strategies were unsuccessful, then she would resort

to planned ignoring until the child quieted. When the child showed appropriate behavior, the interventionist would attempt to engage in discussion with the child about the tantrum. The interventionist responsible for Dyad 3 reported she would determine the function of the child's behavior through observation and parent interview/rating scales. After the function was determined, the interventionist would develop a functionally appropriate intervention plan (e.g., planned ignoring and differential attention for behaviors maintained by attention; functional communication training to ask for breaks for behaviors maintained by escape). Finally, the interventionist who served Dyad 4 reported she would ensure safety before coaching the caregiver through planned ignoring.

Treatment integrity checklists. Interventionists completed treatment integrity checklists throughout each Smart Start session (see Table 6). Interventionists indicated on the checklist whether each session component listed was complete, incomplete, or did not apply to the visit. Integrity was determined by dividing the number of complete session elements by the total number of session elements. Intervention integrity ranged from 67% to 100% ($M = 94.22\%$, $SD = 9.67$). The Week 5 integrity checklist for Dyad 4 was not completed. In addition, interobserver agreement (IOA) was calculated for one session for Dyads 1 and 4. Agreement was found to be 100% across both participants. IOA was not calculated for Dyads 2a and 2b because this triad did not complete the full intervention. IOA was not calculated for Dyad 3 because the interventionist serving this dyad was the independent observer for the other dyads.

Table 6

Percentage Intervention Integrity by Session

| Participant | Orientation | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 |
|-------------|-------------|--------|--------|--------|--------|---------|--------|--------|--------|
| Dyad 1 | 100% | 94% | 100% | 86% | 86% | 67% | 100% | 78% | 75% |
| Dyad 2a/b | 100% | 100% | 100% | 100% | 100% | 100% | N/A | N/A | N/A |
| Dyad 3 | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Dyad 4 | 100% | 100% | 85% | 76% | 86% | Missing | 82% | 100% | 100% |

Note. Dyads 2a/b did not complete the full intervention.

Visual Analysis

Visual analysis was used to examine the behavioral outcomes of Smart Start participants as measured by the Eyberg Child Behavior Inventory (ECBI) Intensity and Problem scales. The What Works Clearinghouse standards for visual analysis of single case data were used to determine whether there was a relationship between the independent and dependent outcome variable (i.e., the ECBI; Kratochwill & Levin, 2014). Features of the data that were considered included level (i.e., mean), trend (i.e., slope), variability (i.e., range and standard deviation), immediacy of the effect, overlap, and consistency of the data patterns across similar phases. In addition, four steps were taken to analyze the data: 1) document a predictable baseline pattern, 2) examine the data within each phase, 3) compare the data across similar phases, and 4) integrate the information to determine whether there were three demonstrations of the treatment effect. It was hypothesized that there would be a more significant change in trend compared to level.

Eyberg Child Behavior Inventory (ECBI).

Intensity scale. A graphical display of ECBI Intensity *T*-Scores across baseline and intervention is shown in Figure 2 below. It should be noted that Dyads 2a and 2b did not complete the entire Smart Start intervention. In addition, the Intensity score for Week 4 is missing for Dyad 1. A consistent baseline pattern was not established for Dyads 1 and 3, as ECBI scores increased throughout baseline for these participants. The ECBI scores for Dyads 2a, 2b, and 4 showed some variability throughout baseline, but a consistent pattern was established

for these dyads overall. All participants showed a slight change in level at intervention implementation. Despite the slight change in level, there was overlap between the baseline and intervention phases for all dyads, indicating limited treatment effects upon intervention implementation. In addition, there was variability in the intervention phase for all participants with the exception of Dyad 2a. More specifically, all participants except Dyad 2a reported a slight increase in Intensity scores during Week 1 (labeled SS 1 in Figure 2) of Smart Start. As expected, the effect of the intervention was not immediate and all dyads, with the exception of Dyad 1, showed a gradual downward trend in the intervention phase compared to baseline (see Table 7 for descriptive statistics). Notably, Dyads 1 and 4 both reported increasing Intensity scores near intervention completion, which may be attributed to an extinction burst. Though Dyad 1 endorsed more frequent challenging behaviors near intervention completion, the caregiver reported qualitatively that the child employed more positive coping strategies like deep breathing that helped mitigate the intensity of the behavior. Positive indicators of well-being such as coping are not captured with the ECBI.

Most participants showed similar data patterns across the baseline and intervention phases. The baseline phase for all participants was relatively stable or increasing in trend with clinically significant *T*-scores. The intervention phase for all participants except Dyad 1 showed a slow decline in *T*-scores, with the majority of participants (2a, 2b, and 3) demonstrating more marked change following Week 2 (labeled SS 2 in Figure 2) of Smart Start. Dyads 2a, 2b, and 3 completed services with *T*-scores below the clinical cutoff, indicating typical levels of behavioral intensity. Data patterns therefore showed three demonstrations of the treatment effect.

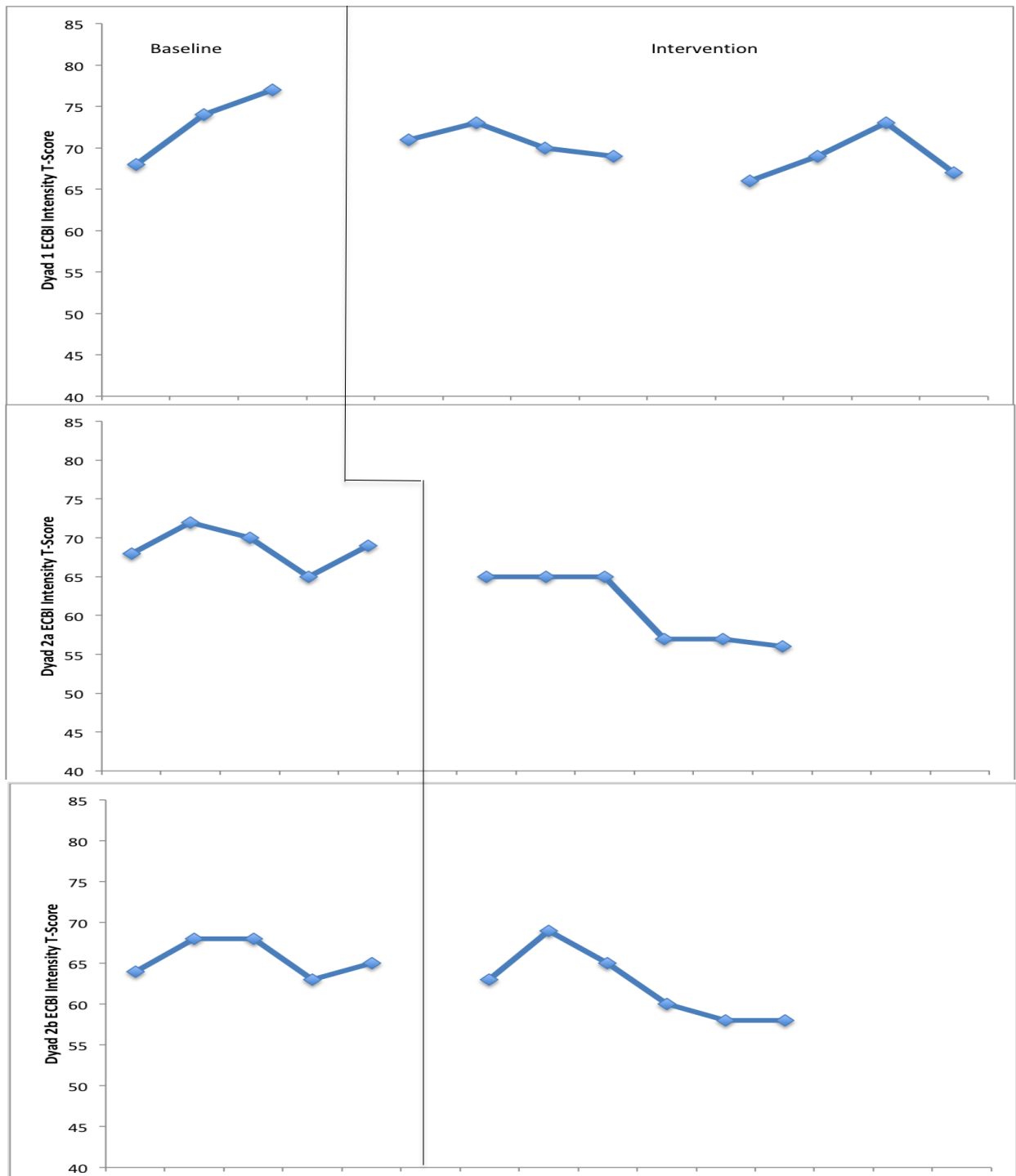


Figure 2. Multiple Baseline Results for ECBI Intensity T-Scores

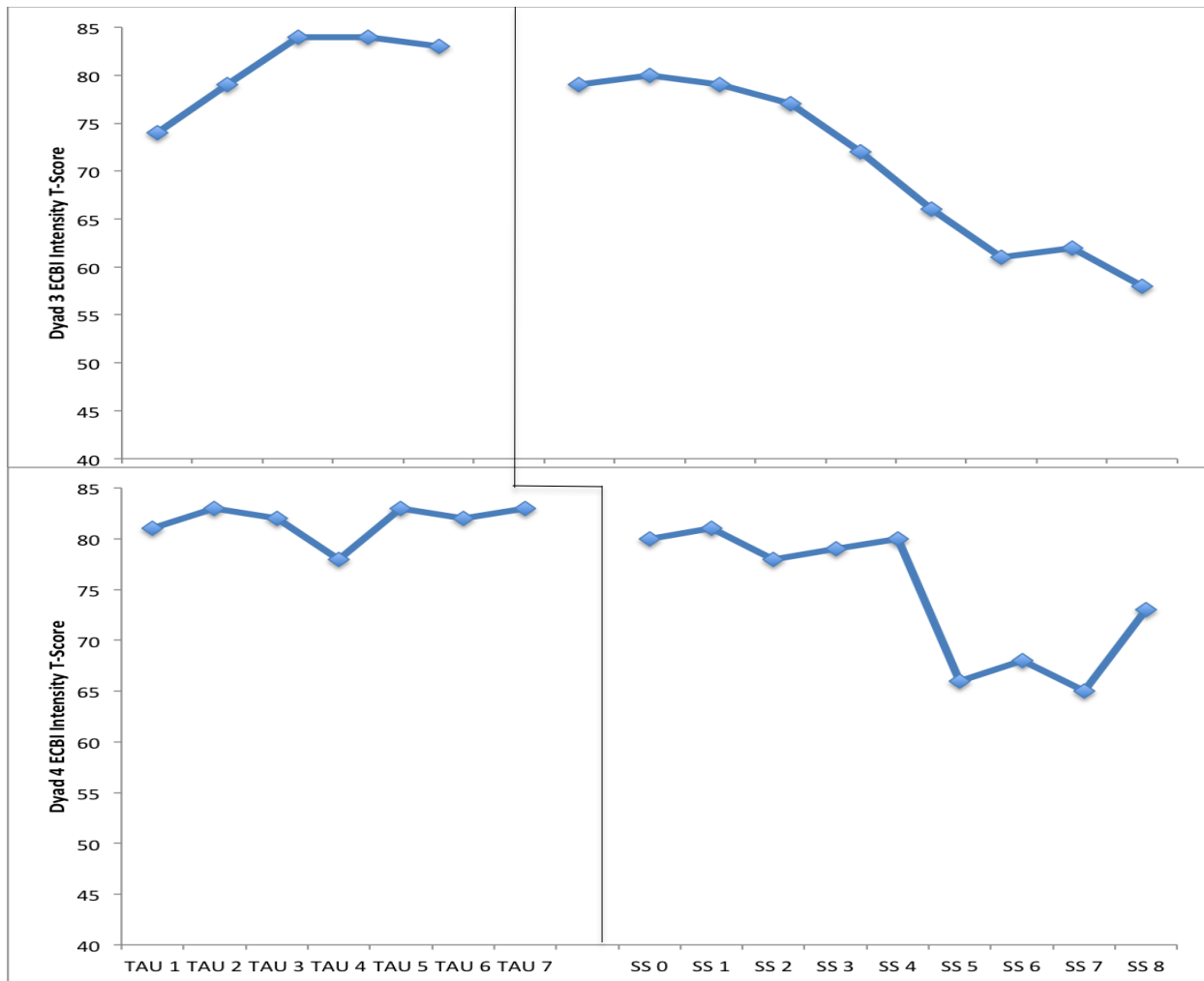


Figure 2. Multiple Baseline Results for ECBI Intensity *T*-Scores

Table 7

Descriptive Statistics for Eyberg Child Behavior Inventory: Intensity Scale

| Participant | Baseline | | Intervention | |
|-------------|--------------|-------------|--------------|-------------|
| | Mean (SD) | Range | Mean (SD) | Range |
| Dyad 1 | 73.00 (4.58) | 68.00-77.00 | 69.75 (2.55) | 66.00-73.00 |
| Dyad 2a | 68.80 (2.59) | 65.00-72.00 | 60.83 (4.58) | 56.00-65.00 |
| Dyad 2b | 65.60 (2.30) | 63.00-68.00 | 62.17 (4.36) | 58.00-69.00 |
| Dyad 3 | 80.80 (4.32) | 74.00-84.00 | 70.44 (8.79) | 58.00-80.00 |
| Dyad 4 | 81.71 (1.80) | 78.00-83.00 | 74.44 (6.54) | 65.00-81.00 |

Problem scale. A graphical display of ECBI Problem *T*-Scores across baseline and intervention is shown in Figure 3 below. It should be noted that Problem scores for the last week

of baseline and Orientation are missing for Dyad 2b. The Problem score for Week 4 is missing for Dyad 1. Dyads 2a, 2b, and 4 showed stable baseline trends, while Dyads 1 and 3 showed decreasing and increasing trends, respectively. Dyads 1, 2a, 2b, and 3 demonstrated a slight change in level upon intervention implementation. Interestingly, Dyad 2b showed an increasing change in level at the beginning of Smart Start, which is the opposite direction of the expected behavior change. Intervention data for Dyads 1 and 2a did not overlap with baseline data, indicating more confidence in the treatment effect for these participants. Intervention data for Dyads 2b, 3, and 4 overlapped with baseline data, which indicates limited treatment effects upon intervention implementation for these participants. In addition, all participants showed some degree of variability within the intervention phase. As expected, all dyads' *T*-scores declined throughout intervention compared to baseline (see Table 8 for descriptive statistics). All participants reported slight increases in Problem *T*-scores at some point during intervention, but slopes were ultimately decreasing. Dyad 4, however, reported significantly worse Problem *T*-scores during Week 8, which was discrepant from the trends of other participants. Changes in family routine or an extinction burst possibly contributed to elevated Problem behaviors reported near intervention completion.

All participants, with the exception of Dyad 4, showed similar data trends in the baseline and intervention phases. However, the variability and range of the trends were quite different across dyads (see Table 8). The baseline phase for Dyads 1, 2a/b, and 4 was relatively stable. All participants except Dyad 3 reported clinically significant *T*-scores throughout baseline. The intervention phase for all participants showed a decline in *T*-scores, and one participant's (Dyad 1) Problem *T*-scores was not clinically significant by intervention completion. Dyads 1, 2a/b, and 3 all showed a slight increase in *T*-scores mid-way through the intervention. Dyad 3 never rated

behaviors in the clinically significant range. Nevertheless, Problem behaviors improved from a *T*-score of 52 during the last week of baseline to a *T*-score of 43 by intervention completion.

Data patterns therefore show three demonstrations of the treatment effect.

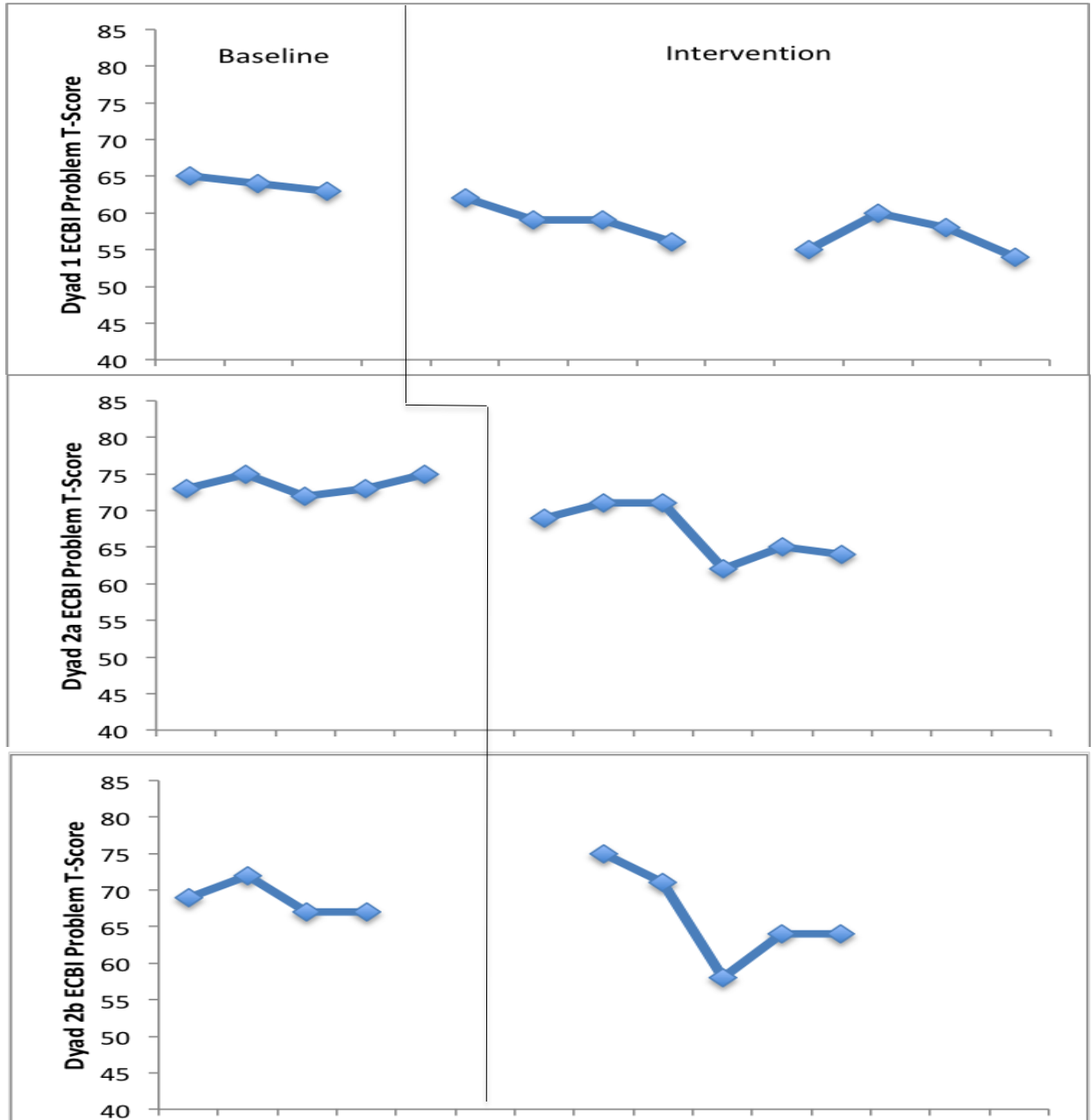


Figure 3. Multiple Baseline Results for ECBI Problem *T*-Scores

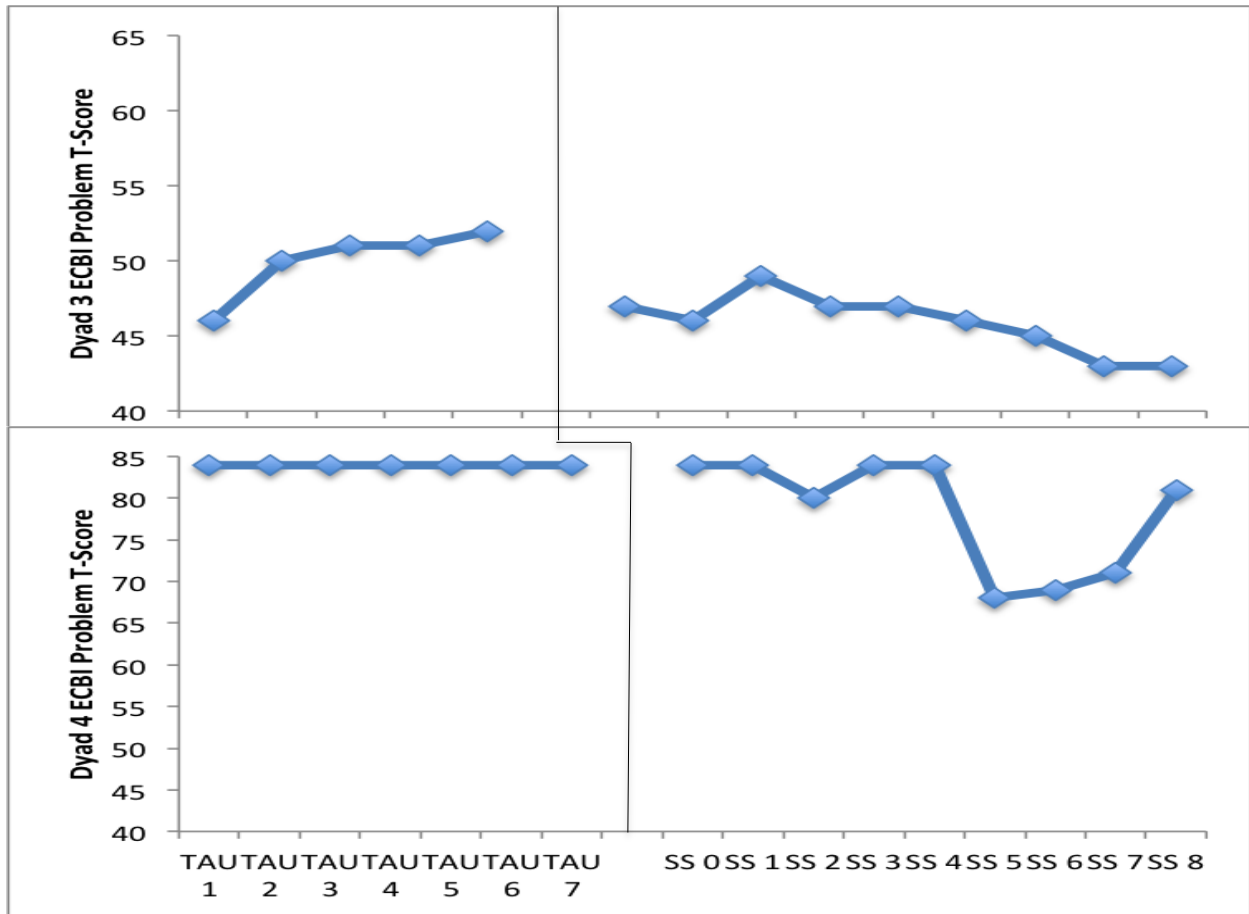


Figure 3. Multiple Baseline Results for ECBI Problem T-Scores

Table 8

Descriptive Statistics for Eyberg Child Behavior Inventory: Problem Scale

| Participant | Baseline | | Intervention | |
|-------------|--------------|-------------|--------------|-------------|
| | Mean (SD) | Range | Mean (SD) | Range |
| Dyad 1 | 64.00 (1.00) | 63.00-65.00 | 57.88 (2.70) | 54.00-62.00 |
| Dyad 2a | 73.60 (1.34) | 72.00-75.00 | 67.00 (3.85) | 62.00-71.00 |
| Dyad 2b | 68.75 (2.36) | 67.00-72.00 | 66.40 (6.66) | 58.00-75.00 |
| Dyad 3 | 50.00 (2.35) | 46.00-52.00 | 45.89 (1.96) | 43.00-49.00 |
| Dyad 4 | 84.00 (0.00) | 84.00-84.00 | 78.33 (6.95) | 68.00-84.00 |

Masked Visual Analysis

A masked visual analysis was used to help control for Type 1 error rates that may have occurred during the visual analysis (Ferron & Jones, 2006). Three individuals experienced in

single case methodology analyzed participants' data. The visual analysts were blind to the condition assignments. They inspected the data and made determinations about the phase to which each caregiver-child was assigned (i.e., at 3 weeks, 5 weeks, or 7 weeks). The last four data points and two data points were removed for the 7-week and 5-week conditions, respectively, to ensure the visual analysts did not easily identify the condition assignments based on the length of the intervention phase. The p -value was calculated by dividing the number of specifications (i.e., the number of "guesses" about the condition assignments made by the masked visual analysts) by the number of possible assignments (i.e., $3*2*1*3 = 18$). Consequently, significance was determined at the $p < .06$ level.

Eyberg Child Behavior Inventory (ECBI).

Intensity scale. The visual analysts correctly determined the intervention assignments using one specifications ($p = .056$). Thus, statistically significant effects were found for the ECBI Intensity T -scores, and there is greater confidence in the rejection of the null hypothesis. The masked visual analysis substantiated the findings from the visual analysis.

Problem scale. The visual analysts correctly determined the intervention assignments on the first specification ($p = .056$). Thus, statistically significant effects were found for the ECBI Problem T -scores, and there is greater confidence in the rejection of the null hypothesis. The masked visual analysis corroborated findings from the visual analysis.

Multi-Level Modeling

Hierarchical linear modeling (HLM) was used to synthesize ECBI ratings of behavior change within and across caregiver-child dyads (Ferron, Farmer, & Owens, 2010). Treatment effects and individual effects were estimated based on an assumption of autocorrelation, level and trend in both baseline and intervention, and a change in level and trend upon intervention

implementation. Confidence intervals were calculated and the Kenward-Roger method was used to determine degrees of freedom.

Eyberg Child Behavior Inventory (ECBI).

Intensity scale. The fixed effects for the ECBI Intensity scale are presented in Table 9. The overall treatment effect of Smart Start was $t(39.80) = -0.74, p > 0.05, 95\% \text{ CI} = [-5.66, 2.62]$. These results indicate a negative, but not statistically significant, change in behavior upon the inception of the intervention. Thus, an immediate treatment effect was not detected. The change in slope throughout the implementation of Smart Start was negative and statistically significant ($t[10.70] = -3.01, p = .0122, 95\% \text{ CI} = [-4.12, -0.63]$) compared to baseline slope. These results indicate confidence that the Smart Start intervention improved the intensity of challenging behaviors among toddlers over time. Predicted means output created with the SAS program further confirm the positive effect of Smart Start on behavioral outcomes compared to treatment as usual, as predicted means revealed worsening data trends during baseline and improving data trends during intervention. Moreover, the changes in level and trend were consistent with results of the visual analysis and masked visual analysis, which provides evidence for the hypothesis that behaviors would improve gradually over time.

Table 9

Fixed Effects for Eyberg Child Behavior Inventory: Intensity Scale

| Fixed Effects | Coefficient | SE | 95% CI | |
|---------------|-------------|------|--------|-------|
| | | | LL | UL |
| Intercept | 75.73*** | 3.47 | 66.91 | 84.55 |
| Phase | -1.52 | 2.05 | -5.66 | 2.62 |
| Time | 0.81 | 0.58 | -0.47 | 2.09 |
| Interaction | -2.38** | 0.79 | -4.12 | -0.63 |

Note. CI = confidence interval, LL = lower limit, UL = upper limit.

^a Covariance parameter estimates of the variance components were 48.90 for baseline level, 0.00 for change in level, 0.00 for baseline slope, 0.38 for change in slope, 0.51 for autocorrelation, and 14.26 for level-1 variance.

* = $p < .05$, ** = $p < .03$, *** = $p < .01$

Empirical Bayes estimates for individual participants' behavior change are presented in Table 10. No participants' ECBI ratings differed significantly from the average baseline level, treatment effect, baseline slope, or change in slope. All participants reported a downward trend that ranged from -2.90 (Dyad 3) to -1.71 (Dyad 1).

Table 10

Empirical Bayes (EB) Eyberg Child Behavior Inventory: Intensity Scale

| Participant | Baseline Level | Treatment Effect | Baseline Slope | Change in Slope |
|-------------|----------------|------------------|----------------|-----------------|
| Dyad 1 | 74.85 | -1.52 | 0.81 | -1.71 |
| Dyad 2a | 70.08 | -1.52 | 0.81 | -2.70 |
| Dyad 2b | 68.59 | -1.52 | 0.81 | -2.31 |
| Dyad 3 | 81.49 | -1.52 | 0.81 | -2.90 |
| Dyad 4 | 83.64 | -1.52 | 0.81 | -2.28 |

Note. * = $p < .05$, ** = $p < .03$, *** = $p < .01$

Problem scale. The overall treatment effect of Smart Start was $t(41.40) = -0.63, p > 0.05$, 95% CI = [-5.08, 2.65]. These results indicate there was a negative, but not statistically significant, change in problem behavior upon the inception of the intervention. Thus, an immediate treatment effect was not detected. The change in slope throughout the implementation of Smart Start also was negative, but not statistically significant ($t[17.80] = -1.96, p > .05$, 95% CI = [-2.45, 0.08]), compared to baseline slope. Though results were not statistically significant at the $p < .05$ level, the results for average slope approached significance ($p = .0653$). These results indicate limited confidence that the Smart Start intervention made an effect on problem behaviors among toddlers over time. However, predicted means output created using the SAS program reveal problem behaviors might have worsened with treatment as usual. On the other hand, the predicted means reveal improved problem behaviors over time with the Smart Start intervention. Thus, the intervention showed promising clinical improvements in spite of the lack of statistical significance. The clinical changes in level and trend were consistent with results of

the visual analysis and masked visual analysis, but the statistical changes in level and trend were not. The fixed effects for the ECBI Problem scale are presented in Table 11.

Table 11

Fixed Effects for Eyberg Child Behavior Inventory: Problem Scale

| Fixed Effects | Coefficient | SE | 95% CI | |
|---------------|-------------|------|--------|-------|
| | | | LL | UL |
| Intercept | 68.61*** | 5.65 | 53.53 | 83.69 |
| Phase | -1.22 | 1.92 | -5.08 | 2.65 |
| Time | 0.24 | 0.50 | -0.79 | 1.28 |
| Interaction | -1.18 | 0.60 | -2.45 | 0.08 |

Note. CI = confidence interval, LL = lower limit, UL = upper limit.

^a Covariance parameter estimates of the variance components were 149.43 for baseline level, 0.00 for change in level, 0.00 for baseline slope, 0.00 for change in slope, 0.32 for autocorrelation, and 12.18 for level-1 variance.

* = $p < .05$, ** = $p < .03$, *** = $p < .01$

Empirical Bayes estimates for individual participants' behavior change are presented in Table 12. The baseline level of Dyads 3 and 4 was significantly ($p < .05$) different from the average baseline level of other participants. In particular, the mean baseline Problem score for Dyad 3 was significantly lower than the average baseline level of other participants, while the mean baseline Problem score for Dyad 4 was significantly higher than the average baseline level of other participants. All participants reported a negative change in level and trend with Smart Start implementation.

Table 12

Empirical Bayes (EB) Eyberg Child Behavior Inventory: Problem Scale

| Participant | Baseline Level | Treatment Effect | Baseline Slope | Change in Slope |
|-------------|----------------|------------------|----------------|-----------------|
| Dyad 1 | 63.91 | -1.22 | 0.24 | -1.18 |
| Dyad 2a | 72.60 | -1.22 | 0.24 | -1.18 |
| Dyad 2b | 70.61 | -1.22 | 0.24 | -1.18 |
| Dyad 3 | 51.42* | -1.22 | 0.24 | -1.18 |
| Dyad 4 | 84.51* | -1.22 | 0.24 | -1.18 |

Note. * = $p < .05$, ** = $p < .03$, *** = $p < .01$

Wilcoxon Signed-Rank Test

The Wilcoxon Signed-Rank test was used to measure presence of significant changes on the Clinical Global Impression (CGI) from pre- to post-intervention. The Signed-Rank Test is a nonparametric test used with small samples. This test does not include assumptions about normality of the data, and the data are assumed to be independent and continuous. This test statistic was calculated based on positive and negative change, so individuals with no change were excluded from the analysis. Statistical significance was determined at the $p < .05$ level.

Clinical Global Impression—Severity. Interventionists rated change for only four of five participants (see Table 13 for descriptive statistics). Consequently, the sample was not large enough to detect significance. Therefore, $p > .05$, indicating interventionists' ratings of the severity of children's challenging behaviors was not statistically significant.

Clinically significant change was found using the CGI Severity and Improvement scales, even though statistical significance was not detected. More specifically, the mean rated Severity scores were 3.6 (SD = 1.34) at pre-intervention (between "mild behaviors" and "moderate behaviors") and 2.2 (SD = .45) at post-intervention (between "challenging behavior slight, transient" and "mild behaviors"). Thus, more interventionists rated challenging behaviors as having little functional impairment on children's daily living at post-intervention compared to pre-intervention. Furthermore, all participants were rated on the CGI Improvement scale as either "minimally improved" (score of 3) or "much improved" (score of 2). Mean Improvement scores were 2.6 (SD = .55), meaning interventionists rated all dyads as showing some improvement throughout the implementation of Smart Start.

Table 13

Baseline and Intervention Clinical Global Impression Scores

| Participant | Baseline | Intervention | |
|-------------|--------------|--------------|-----------------|
| | CGI Severity | CGI Severity | CGI Improvement |
| Dyad 1 | 5 | 3 | 2 |
| Dyad 2a | 5 | 2 | 3 |
| Dyad 2b | 2 | 2 | 2 |
| Dyad 3 | 3 | 2 | 3 |
| Dyad 4 | 3 | 2 | 3 |

Reliable Change Index

The reliable change index (RCI) was used to measure change on all other pre- to post-intervention outcomes (i.e., DPICS, PSI-4-SF, and YCPC; Jacobson & Truax, 1991) for Dyads 1, 3, and 4. Dyads 2a and 2b were not included in RCI analyses due to missing data. The RCI is a test statistic used to measure clinically significant change within individuals from pre-assessment to post-assessment (Jacobson & Truax, 1991). Significant change was determined at the $p < .05$ level.

Young Child PTSD Checklist (YCPC).

Posttraumatic Stress Disorder. Table 14 indicates pre-intervention and post-intervention raw scores on the YCPC for each participant, while Table 15 details RCI scores for individual participants.

The treatment effect for Dyad 1 was negative and statistically significant ($RCI = -5.76, p < .05$), indicating greater confidence that Smart Start resulted in improvements in PTSD symptomatology for Dyad 1. The treatment effect was negative for Dyad 3 and positive for Dyad 4, but the effect was not significant for either ($RCI = -0.36, p > .05$ for Dyad 3; $RCI = 1.62, p > .05$ for Dyad 4). Thus, it is less likely that Smart Start resulted in PTSD symptom changes.

Only one child was rated in the clinically significant range for the PTSD scale during baseline. Therefore, clinically and statistically significant improvements in PTSD symptomatology as measured by the YCPC were difficult to detect. However, two of three dyads rated some improvement from pre- to post-intervention, while one dyad (Dyad 4) rated worse PTSD symptomatology at post-intervention compared to baseline. In fact, Dyad 4 rated the PTSD scale at the clinical cutoff for a possible diagnosis of PTSD at post-intervention.

Functional Impairment. The treatment effect for Dyad 4 was negative and statistically significant ($RCI = -2.44, p < .05$), indicating greater confidence that Smart Start resulted in improvements in PTSD symptomatology for Dyad 4. The treatment effect also was negative for Dyads 1 and 3; however, the effects were not significant ($RCI = -1.22, p > .05$ for both dyads). Therefore, it is less likely that Smart Start resulted in Functional Impairment symptom changes.

All children were rated in the clinically significant range for Functional Impairment during baseline (see Table 14). These ratings indicate that the symptoms of PTSD endorsed by caregivers significantly impaired children's ability to function in daily life activities, even though their PTSD symptoms did not reach the clinical cutoff. All caregivers rated improvements on the Functional Impairment scale following treatment. Dyad 3 rated impairment in the typical range, Dyad 4 rated impairment near the clinical cutoff, and Dyad 1 rated impairment in the clinically significant range following participation in Smart Start. Interestingly, Dyad 4 reported significant clinical improvement in functional impairment, despite rating the PTSD scale worse at post-intervention compared to pre-intervention.

Table 14

Raw Scores for Young Child PTSD Checklist

| Participant | Posttraumatic Stress Disorder | | Functional Impairment | |
|-------------|-------------------------------|--------------|-----------------------|--------------|
| | BL | Intervention | BL | Intervention |
| Dyad 1 | 35 | 3 | 20 | 16 |
| Dyad 3 | 9 | 7 | 6 | 2 |
| Dyad 4 | 17 | 26 | 14 | 6 |

Note. BL = Baseline.

Table 15

Reliable Change Index Scores for Young Child PTSD Checklist

| Participant | Posttraumatic Stress Disorder | Functional Impairment |
|-------------|-------------------------------|-----------------------|
| Dyad 1 | -5.76* | -1.22 |
| Dyad 3 | -0.36 | -1.22 |
| Dyad 4 | 1.62 | -2.44* |

Note. * = $p < .05$

Dyadic Parent-Child Interaction Coding System (DPICS).

Behavior/emotion descriptions. Tables 16 and 17 show raw scores for each DPICS coding category for all participants at baseline and post-intervention. Table 18 shows the RCI scores for each coding category and participant. The treatment effect for behavior descriptions was significant for all participants ($p < .05$). The RCI score for Dyad 1 was 95.83. The RCI score for Dyad 3 was 45.83, and the RCI score for Dyad 4 was 4.17.

Both Dyads 1 and 3 used more than 10 behavior descriptions within the 5-minute coding period, which shows clinically significant improvements in this positive parenting practice. Dyad 1 used 24 behavior descriptions (compared to 1 at baseline), while Dyad 3 issued 11 behavior descriptions (compared to 0 at baseline). Dyad 4, on the other hand, only used 1 behavior description at post-intervention compared to 0 at pre-intervention.

Reflections. Dyads 1 and 3 changed significantly from pre-intervention to post-intervention (RCI = -2.48, $p < .05$ for Dyad 1; RCI = 3.11, $p < .05$ for Dyad 3). The former did

not improve as expected, but rather, regressed significantly in her use of reflections. The treatment effect for Dyad 4 was positive, but it was not statistically significant (RCI = 0.62, $p > .05$).

In addition to statistical significance, Dyad 3 reflected their child 11 times (compared to six times at baseline) within the 5-minute coding period. This change shows clinically significant improvement. Neither Dyad 1 nor 4 made clinically significant improvements, although, Dyad 4 began treatment with a high number of reflective statements (see Table 16), leaving little room for improvement.

Labeled praises. All participants made significant improvements ($p < .05$) using labeled praises from pre-intervention to post-intervention. The RCI scores were 7.51, 3.47, and 2.31 for Dyads 1, 2, and 3, respectively. Dyad 1 used 14 labeled praises within the 5-minute coding period at post-intervention, indicating clinically significant improvements in this particular positive parenting practice. Dyad 3 approached clinical significance, but still showed need for improvement in the area of labeled praise. Interestingly, Dyad 3 demonstrated much greater use of behavior descriptions and labeled praises during the 3-minute warm up period of the DPICS coding than during the coding period. Thus, it should be noted that the coded intervals may not reflect caregivers' "best" use of skills.

Table 16

Raw Scores for Dyadic Parent-Child Interaction Coding System Positive Behaviors

| Participant | Behavior Descriptions | | Reflections | | Labeled Praises | |
|-------------|-----------------------|--------------|-------------|--------------|-----------------|--------------|
| | BL | Intervention | BL | Intervention | BL | Intervention |
| Dyad 1 | 1 | 24 | 7 | 3 | 1 | 14 |
| Dyad 3 | 0 | 11 | 6 | 11 | 0 | 6 |
| Dyad 4 | 0 | 1 | 6 | 7 | 0 | 4 |

Note. BL = Baseline.

Questions. All participants asked significantly fewer questions at post-intervention compared to pre-intervention (RCI = -8.08, $p < .05$ for Dyad 1; RCI = -15.77 $p < .05$ for Dyads 3 and 4), which indicates confidence the Smart Start intervention resulted in reductions in this specific behavior. All dyads began treatment asking astronomical numbers of questions (30, 50, and 43 questions for Dyads 1, 3, and 4, respectively) and completed treatment asking fewer than 10 questions each within the 5-minute coding period, which indicates clinically significant improvements.

Commands. The treatment effect was negative and statistically significant for Dyads 3 and 4 (RCI = -11.56, $p < .05$ for Dyad 3; RCI = -2.04, $p < .05$ for Dyad 4). This means there is greater likelihood that Smart Start resulted in these improved play behaviors for Dyads 3 and 4. Dyad 1 issued fewer commands from pre-intervention to post-intervention, but this change was not significant (RCI = -1.36, $p < .05$). There is less confidence Smart Start resulted in fewer commands delivered by Dyad 1 at post-intervention. Notably, Dyad 1 only delivered three commands at the inception of Smart Start and one command at treatment termination. Therefore, there was little room for improvement. Dyads 3 and 4 delivered 17 and three fewer commands at post-intervention, respectively.

Criticisms. There was no reliable change for any participant because no dyads engaged in criticism during the 5-minute coding period at the beginning or end of treatment.

Table 17

Raw Scores for Dyadic Parent-Child Interaction Coding System Negative Behaviors

| Participant | Questions | | Commands | | Criticisms | |
|-------------|-----------|--------------|----------|--------------|------------|--------------|
| | BL | Intervention | BL | Intervention | BL | Intervention |
| Dyad 1 | 30 | 9 | 3 | 1 | 0 | 0 |
| Dyad 3 | 50 | 9 | 20 | 3 | 0 | 0 |
| Dyad 4 | 43 | 2 | 7 | 4 | 0 | 0 |

Note. BL = Baseline.

Table 18

Reliable Change Index Scores for Dyadic Parent-Child Interaction Coding System

| Participant | Behavior Description | Reflection | Labeled Praise | Question | Command | Criticism |
|-------------|----------------------|------------|----------------|----------|---------|-----------|
| Dyad 1 | 95.83* | -2.48* | 7.51* | -8.08* | -1.36 | 0.00 |
| Dyad 3 | 45.83* | 3.11* | 3.47* | -15.77* | -11.56* | 0.00 |
| Dyad 4 | 4.17* | 0.62 | 2.31* | -15.77* | -2.04* | 0.00 |

Note. * = $p < .05$

Parenting Stress Index, Fourth Edition—Short Form (PSI-4-SF).

No participants responded positively for defensive responding on the PSI at pre-intervention, but Dyad 3 responded positively for defensive responding at post-intervention (defensive responding score of 9 on a cutoff of 10 or less). This change in defensive responding for Dyad 3 occurred as a result of large improvements on two items on the defensive responding scale from pre- to post-intervention.

PSI Total Stress. Table 19 indicates pre-intervention and post-intervention percentile scores on the PSI-4-SF for each participant, while Table 20 details RCI scores for individual participants. The treatment effect for Dyads 1 and 4 was negative but not statistically significant (RCI = -1.25, $p > .05$ for Dyad 1; RCI = -0.14, $p > .05$ for Dyad 4). The treatment effect for Dyad 3 was negative and statistically significant (RCI = -2.35, $p < .05$). There is limited confidence the improvements for Dyads 1 and 4 can be attributed to Smart Start; however, there is greater confidence the improvements reported by Dyad 3 are a result of Smart Start. Notably, the Total Stress score for Dyad 1 improved from clinically significant levels at baseline (percentile rank 92) to typical levels at intervention completion (percentile rank 74). Dyads 3 and 4 did not report clinically significant levels of Total Stress at the outset of Smart Start.

PSI Parental Distress. The treatment effect for Dyads 1 and 3 was statistically significant in a negative direction (RCI = -3.18, $p < .05$ for Dyad 1; RCI = -7.95, $p < .05$ for Dyad 3),

indicating improved levels of Parental Distress from pre-intervention to post-intervention. Thus, there is confidence that distress levels improved following participation in Smart Start for Dyads 1 and 3. The treatment effect for Dyad 4 was positive and not statistically significant (RCI = 1.60, $p > .05$). In other words, levels of Parental Distress worsened from pre-intervention to post-intervention for this participant. There is confidence that this change was not attributable to Smart Start. No dyads reported clinically significant levels of parental distress at pre- or post-intervention.

PSI Parent-Child Dysfunctional Interaction. The treatment effect for Dyads 1 and 3 was statistically significant in a negative direction (RCI = -2.23, $p < .05$ for Dyad 1; RCI = -3.07, $p < .05$ for Dyad 3), which indicates improved parent-child interaction styles at post-intervention compared to pre-intervention. As a result, there is confidence that parent-child interactions improved following Smart Start participation for Dyads 1 and 3. The treatment effect for Dyad 4 was negative but not statistically significant (RCI = -0.28, $p > .05$). Therefore, there is limited confidence that participation in Smart Start improved dysfunctional parent-child interactions for Dyad 4. No dyads reported levels of dysfunctional interactions that were in the clinically significant range at pre- or post-intervention. However, Dyad 1 reported levels of dysfunctional interactions in the elevated range at pre-intervention and typical range at post-intervention, indicating clinically significant improvements.

PSI Difficult Child. The treatment effect for Dyads 1 and 4 was negative but not statistically significant (RCI = -1.24, $p > .05$ for Dyad 1; RCI = -0.93, $p > .05$ for Dyad 4). Thus, there is limited confidence the small improvements in PSI ratings of challenging behaviors can be attributed to Smart Start for Dyads 1 and 4. In addition, both Dyads 1 and 4 reported clinically significant levels of child challenging behaviors on the PSI at both pre-intervention and post-

intervention. The treatment effect for Dyad 3, on the other hand, was negative and statistically significant (RCI = -2.18, $p < .05$). There is confidence the improvements in PSI ratings of challenging behaviors occurred as a result of participation in Smart Start in the case of Dyad 3. Dyad 3 did not rate challenging behaviors in the clinically significant range at pre- or post-intervention.

Table 19

Percentile Scores for Parenting Stress Index, 4th Edition—Short Form

| Participant | Total Stress | | Parental Distress | | Parent-Child Dysfunctional Interaction | | Difficult Child | |
|-------------|--------------|-----|-------------------|-----|--|-----|-----------------|-----|
| | BL | INT | BL | INT | BL | INT | BL | INT |
| Dyad 1 | 92 | 74 | 80 | 64 | 86 | 70 | 98 | 90 |
| Dyad 3 | 68 | 34 | 46 | 6 | 70 | 48 | 80 | 66 |
| Dyad 4 | 76 | 74 | 46 | 54 | 78 | 76 | 98 | 92 |

Note. BL = Baseline, INT = Intervention

Table 20

Reliable Change Index Scores for Parenting Stress Index, 4th Edition—Short Form

| Participant | Total Stress | Parental Distress | Parent-Child Dysfunctional Interaction | Difficult Child |
|-------------|--------------|-------------------|--|-----------------|
| Dyad 1 | -1.25 | -3.18* | -2.23* | -1.24 |
| Dyad 3 | -2.35* | -7.95* | -3.07* | -2.18* |
| Dyad 4 | -0.14 | 1.60 | -0.28 | -0.93 |

Note. * = $p < .05$

Descriptive Statistics

Therapy Attitude Inventory (TAI). Caregivers completed the TAI (Eyberg, 1993) at the completion of Smart Start to determine how satisfied they were with the intervention. Specific determinants surveyed were caregivers' satisfaction with their learning, confidence in their ability to implement behavioral principles, perception of children's behavioral improvement, and satisfaction overall with the treatment. The TAI is rated on a 1 to 5 Likert

scale. The average TAI score for Smart Start was 4.1 with a range of 3.9 to 4.4 and a standard deviation of 0.63. Dyad 4 reported they learned only “a few new techniques” for discipline and they learned “very little” techniques for teaching new skills. Despite these ratings, Dyad 4 reported Smart Start was “very good” in terms of improving child behaviors. All participants reported their caregiver-child relationship and their confidence in behavioral strategies were “somewhat improved” with Smart Start participation. In addition, all participants reported that overall behavior problems and compliance with demands were “somewhat improved.” Further, all participants reported they “liked [Smart Start] very much.” In all, caregivers reported Smart Start was either somewhat helpful or very helpful in terms of improving caregivers’ discipline techniques as well as children’s challenging behaviors. Therefore, it can be inferred that caregivers were satisfied with the Smart Start intervention.

Chapter Five:

Discussion

Approximately 26% of 4-year-old children have been exposed to at least one potentially traumatic event (Briggs-Gowen et al., 2010) and 16% of 2 to 18-year-old-children meet criteria for posttraumatic stress disorder (PTSD; Alisic et al., 2014). There are several traumatic events children may experience, but child maltreatment is one of the most common for young children (U.S. Department of Health and Human Services, 2017). Young children ages 0 to 5 years with disabilities are more vulnerable to maltreatment compared to typically developing populations (Jones et al., 2012; Maclean et al., 2017; Sullivan & Knutson, 2000). Symptoms of PTSD among young children manifest as challenging behaviors (DeYoung et al., 2011), and these early-onset symptoms of trauma are associated with negative physical, psychological, neurological, and academic outcomes. There is a great need for a cost-effective, easily accessible treatment for young children with disabilities who have experienced trauma.

The purpose of this study was to address the gaps in the trauma treatment literature with regard to 1) trauma-informed service-delivery for young children with disabilities and 2) financially ascertainable evidence-based interventions for both therapists and families. A second aim of this study was to assess the efficacy of a newly piloted parenting intervention for young children with disabilities who have experienced maltreatment. Results from visual analysis, masked visual analysis, hierarchical linear modeling, Wilcoxon Signed-Rank test, and reliable change index support the effectiveness of Smart Start.

This chapter outlines the findings from the present study and compares results to extant literature when appropriate. Additional points of discussion include implications for practice, contributions to the literature, limitations, and directions for future research.

Research Question 1: With What Degree of Integrity do Smart Start Interventionists Implement Smart Start?

It was unclear whether bachelor's level interventionists could successfully execute an intervention that borrows strategies from a highly specialized treatment (i.e., PCIT) since most evidence-based treatments require advanced training (i.e., CPP, PCIT, TF-CBT). Thus, treatment integrity was monitored in order to determine the feasibility of Smart Start. In addition, ECBI scores were compared to treatment integrity checklists to make hypotheses surrounding participants' response to intervention.

Interventionists implemented Smart Start with high degrees of fidelity. Average treatment integrity for Smart Start sessions was 94.22% with a range of 67% to 100%. Interobserver agreement during co-visits was 100%. Fidelity to the Smart Start intervention was variable compared to the first iteration of the intervention, where the average integrity scores ranged from 93% to 100% (Agazzi et al., 2016). Fidelity possibly was variable due to the baseline period, as interventionists and caregivers became accustomed to a less structured therapeutic approach throughout baseline. Thus, it could have been more difficult to adhere to a highly structured technique following several weeks of more relaxed care. In addition, distractions unique to the home setting (e.g., other children, dinner/snack, off-topic conversation, etc.) detracted from sessions. In fact, two interventionists qualitatively reported that remaining on-task was highly difficult due to either the verbosity of the caregiver or distractors in the natural environment. Finally, components of the intervention were adapted for some participants depending on the

specific needs of the family. For example, Dyad 1 began using Time Out and generalizing skills to the natural environment in Week 4 (one to two weeks early). The disruptions in the intervention sequence could have resulted in poorer documented intervention integrity since priorities and time were apportioned differently than planned.

Notably, the dyads that received the intervention with higher degrees of fidelity (i.e., Dyads 2a, 2b, and 3) made more consistent behavioral improvements on the ECBI Intensity scale from pre-intervention to post-intervention (see Figure 2). Previous researchers have found that treatment integrity is indirectly related to better behavioral outcomes in parent training programs (Eames et al., 2009). Thus, intervention integrity was likely a contributing factor associated with dyads' behavioral response to intervention.

Usual care practices were analyzed in addition to treatment integrity. Interventionists reported they used a variety of techniques that overlapped with Smart Start procedures while in the baseline period. Interventionists indicated that all strategies used during baseline were typical to their everyday practice. This was verified with treatment as usual vignettes, where the providers indicated how they would respond to a common behavioral concern prior to their training in Smart Start. Importantly, no interventionists coached CDI or Time Out during usual care, which are highly effective behavioral techniques used in Smart Start. Interventionists also reported the overlapping Smart Start strategies used in baseline were not implemented with as much structure as they were in the Smart Start intervention. Despite the use of overlapping strategies, predicted mean output from the HLM analyses (see Figures 2 and 3) revealed worsening data trends in baseline compared to improving data trends in intervention. Thus, it appears data trends throughout intervention were unaffected by baseline care, but data trends during intervention may have been influenced by fidelity to Smart Start in the intervention phase.

Although, other factors such as interventionist experience and buy-in to the treatment certainly may have impacted post-intervention outcomes further.

It should be noted that the interventionist for Dyads 2a/b implemented the Orientation session and Week 1 during the baseline period. Because these two sessions are primarily teaching sessions and do not include extensive coaching, the intervention data are not assumed to have been greatly affected. Moreover, data patterns show increasing or stable trends in baseline, further indicating little contamination occurred between usual care and intervention. The interventionist repeated the Orientation and Week 1 sessions once baseline was over.

Research Question 2: Is There a Functional Relationship Between Participation in Smart Start and Children's Challenging Behaviors?

Caregivers' ratings of challenging behaviors were expected to improve with the implementation of consistent, evidence-based behavioral strategies. Results from the visual analysis and hierarchical linear modeling supported a functional relationship between participation in Smart Start and the intensity/frequency of children's challenging behavior according to caregivers' ECBI ratings. As expected, an immediate treatment effect (i.e., change in level) was not detected with the visual analysis or HLM. However, the visual analysis revealed a slow downward trend in behavior throughout the intervention for all participants such that three dyads (2a, 2b, and 3) terminated treatment with Intensity scores below the clinical cutoff. There was a more pronounced shift in Intensity scores following Week 2 of Smart Start for Dyads 2a, 2b, and 3, while Dyads 1 and 4 reported increases in Intensity scores near the end of the intervention. The HLM analyses supported results from the visual analysis in that a statistically significant change in level (i.e., mean) was not found upon intervention implementation, but there was a statistically significant change in trend (i.e., slope) throughout

the course of treatment compared to usual care. Moreover, the Empirical Bayes estimates did not reveal a statistically significant difference across individual participants in terms of baseline levels, treatment effects, or changes in slope. The masked visual analysis also was statistically significant for Intensity scores, providing further evidence for the effect of the Smart Start intervention on children's challenging behaviors. Furthermore, three participants concluded treatment in the average range for behavioral intensity, which showed clinical significance. Overall, the consistency of treatment effects shown across participants lent support to Smart Start as an effective behavioral intervention.

While the visual, masked visual, and HLM analyses revealed improved Intensity scores during intervention compared to usual care, Problem scores were somewhat different. Visual analysis showed a slight change in level in the expected direction for Dyads 1, 2a, and 3, but not for Dyads 2b and 4. There was a downward trend in Problem scores for all participants, and Dyad 1 completed the intervention with *T*-scores in the normal range. Thus, Dyad 1 considered behaviors to be less invasive to daily living by the end of the intervention compared to baseline. Dyad 3 also reported declining trends in intervention compared to baseline; however, *T*-scores were within typical limits across baseline and intervention. The masked visual analysts found statistical significance for Problem scores. However, the HLM results revealed that level (i.e., mean) and trend (i.e., slope) were not statistically significantly improved in the intervention phase compared to baseline. However, the trends for Problem *T*-scores approached statistical significance ($p = .0653$). Results from Empirical Bayes estimates showed that Dyads 3 and 4 had significantly different average baseline *T*-scores compared to the other participants. The differences between the visual analysis, masked visual analysis, and HLM could be due to the HLM model, which was not powerful enough to detect significant changes in either level or

trend, even though both were determinable by masked analysts. Thus, inconsistent treatment effects were shown for Problem scores across participants, lending some support to Smart Start as an effective behavioral intervention.

There are several reasons the Intensity and Problem HLM results were discrepant. Problem scores might not have been statistically significant due to the inconsistent *T*-scores reported across participants. Because the sample was small, the variability of scores could have influenced the slope. For example, Dyad 3 endorsed very few problem behaviors throughout baseline and intervention. As a result, there was little room for improvement, thereby, impacting the slope.

Second, Dyad 4 consistently endorsed nearly all items on the ECBI. Following discussion with study staff surrounding appropriate interpretation of problem items on the rating scale, the caregiver began considering items more carefully and rating them in the expected direction. After a few sessions, however, the caregiver endorsed nearly all items again, resulting in a flatter trend. The caregiver may have either experienced observer drift (a noted limitation to the use of rating scales), or she may have allowed familial factors external to the target child's challenging behaviors (e.g., behaviors of other children) to influence her ECBI ratings. Additionally, due to the timing of the reported increases in challenging behaviors (Weeks 6 through 8), it is possible the target child experienced an extinction burst following the implementation of Follow Through and Time Out. These behavioral procedures would have restricted the child's access to reinforcement, which could have prompted more intense behaviors. However, the extent to which Follow Through and Time Out were used with this family is unknown, making this particular hypothesis difficult to confirm. Overall, Problem and Intensity *T*-scores could have

worsened and influenced the data patterns due to negligence when completing the ECBI and/or an extinction burst.

The results of the current study were somewhat different than those reported by Agazzi et al. (2016) since the previous evaluators did not find statistically significant improvements on either ECBI subscale. Agazzi and colleagues hypothesized that improvements were not found due to clinically insignificant ECBI ratings at the outset of the intervention. The results of the current study lent partial support to this hypothesis, as statistically significant improvements on the ECBI Intensity scale were found when a population with clinically significant *T*-scores was recruited. Like the pilot investigation, some participants in the current study did not report clinically significant Problem *T*-scores throughout baseline or intervention, and statistical significance was not found for this subscale of the ECBI.

Other studies utilizing the ECBI with populations that were at-risk for or that had experienced maltreatment (i.e., Borrego, Urquiza, Rasmussen, & Zebell, 1999; Galanter et al., 2007; Timmer et al., 2006) found statistically significant improvements on both subscales of the ECBI. Thus, results from the present study are similar to other studies in terms of Intensity subscale improvements, and to some degree, Problem subscale improvements. There are three possible explanations for the differences between past and present research with regard to the Problem subscale: 1) past researchers using the ECBI also used a more intensive clinical intervention called PCIT from which Smart Start was heavily informed 2) Smart Start interventionists did not have adequate training to administer ratings scales, or 3) ECBI norms are somewhat outdated. The third explanation is particularly notable since outdated norming samples certainly could influence interpretations of rating scales for both clinicians and caregivers. As noted previously, Dyad 4 experienced particular difficulty interpreting the meaning of several

items on the ECBI and was consistently unsure whether a behavior truly was a “problem.” Moreover, the interventionist did not have the necessary training to guide the caregiver through the rating scale.

Nevertheless, findings from the current study provide confidence that a statistically and clinically significant functional relationship exists between Smart Start and challenging behaviors as rated by the ECBI Intensity and Problem scales. These results thus provide additional empirical support for Smart Start and extend the findings of Agazzi et al. (2016).

Research Question 3: Do Interventionists Report a Decrease in the Severity of the Child’s Challenging Behavior from Pre-Intervention to Post-Intervention?

Like caregiver ratings of challenging behaviors, interventionist ratings of problem behaviors were suspected to improve with the implementation of consistent, evidence-based behavioral strategies. Results of the Wilcoxon Signed-Rank test did not support a decrease in the severity of challenging behaviors from pre-intervention to post-intervention. The sample was small, so when one participant was rated as showing no change, significant results were not found. Therefore, descriptive statistics might be more meaningful to interpret. The interventionists reported improvements for all participants’ (except Dyad 2b) challenging behaviors on the CGI Severity scale from pre-intervention to post-intervention. Additionally, all interventionists reported improvement on the CGI Improvement scale. Specifically, three participants’ challenging behaviors were rated minimally improved (score of 3), while two participants’ challenging behaviors were rated much improved (score of 2) on the CGI Improvement scale at post-intervention.

Perhaps the interventionist serving Dyad 2b did not report changes on the CGI Severity because behaviors were rated as “slight” and “transient” at pre-intervention, indicating limited

room for improvement. Interestingly, the behavior was rated as “much” improved on the CGI Improvement scale at termination. It is unclear why there was misalignment between the CGI Severity and Improvement scales for Dyad 2b. The overall ratings of challenging behaviors reported by the interventionists serving Dyads 1, 2a, 3, and 4 on the CGI are consistent with caregivers’ ECBI endorsements across time. Dyad 2b, however, rated the ECBI Intensity significantly at pre-intervention and normally at termination, which is discrepant from the interventionist’s “slight” and “transient” behavioral rating at pre-intervention.

Because this is the first known research to use the CGI to measure changes in child challenging behaviors, there is no extant literature to compare current results. Overall, there is promising evidence that Smart Start might improve children’s challenging behaviors from the standpoint of the interventionist, but the small sample size limited confidence in the findings.

Research Question 4: Do Caregivers Report Lower Rates of PTSD Symptomatology in Their Children from Pre-Intervention to Post-Intervention?

Children’s PTSD symptomatology was expected to improve with heightened caregiver-child attachments and more consistent and trauma-informed responses to child behavior. Results from the reliable change index revealed significant improvements on the PTSD scale for Dyad 1. Change rated on the Functional Impairment scale was negative but not significant. Notably, the PTSD scale improved clinically, while the Functional Impairment scale did not improve clinically from pre- to post-intervention for Dyad 1. Altogether, results may indicate that PTSD symptoms still somewhat impacted daily functioning for Dyad 1, even though PTSD symptoms occurred less frequently at post-intervention compared to pre-intervention.

Dyad 3 reported improvements on the PTSD scale and the Functional Impairment scale, but the progress was not significant. Results were not significantly improved because very few

symptoms were endorsed at the outset of the intervention. Despite this, the Functional Impairment scale was rated in the clinical range at pre-intervention and the typical range at post-intervention, indicating clinically significant improvements in daily life functioning from pre- to post-intervention. PTSD symptoms were never rated clinically.

Dyad 4 endorsed more PTSD scale items at post-intervention such that symptoms were in the clinically significant range at the completion of Smart Start; however, these increases were not significant. Interestingly, the Functional Impairment scale was rated as significantly improved at post-intervention compared to pre-intervention. In fact, Dyad 4 rated the Functional Impairment scale just above clinical cutoff at post-intervention, meaning the endorsed PTSD symptoms only slightly impaired daily life functioning for Dyad 4.

The results garnered from this study extend those found by Agazzi et al. (2016). The PTSD scale in the pilot study approached significance ($p = .0586$), with 5 out of 8 participants rating improvement in the initial study (Agazzi et al., 2016). In the current study, 2 out of 3 dyads rated improvement on the PTSD scale, and all dyads rated improvement on the Functional Impairment scale. However, only one dyad showed statistically significant improvement on the PTSD scale (Dyad 1) and the Functional Impairment scale (Dyad 4) in the current study. Results from the pilot study did not show clinically significant improvements on the PTSD scale; however, the average pre-intervention PTSD scale score was not in the clinical range. In the current study, clinically significant improvements were present for Dyad 3 on the Functional Impairment scale. The current study thus extends the work of Agazzi et al. (2016), as statistically significant changes occurred on the PTSD scale for one participant (Dyad 1) and clinically significant changes occurred on the Functional Impairment scale for one participant (Dyad 3). The results of the current study are promising, but because the RCI was calculated using sample

characteristics rather than normative characteristics, the noted improvements are subject to error. For example, variables such as maturation, family distress, and increased stability in the living environment for the child may have resulted in the improvements or regressions.

Research Question 5: Do Caregivers' Positive Parenting Practices Improve from Pre-Intervention to Post-Intervention?

Consistent coaching of positive parenting practices was expected to increase use of acceptable caregiver-child interactions and decrease use of negative caregiver-child interactions. Positive parenting practices did improve significantly according to the reliable change index. Dyad 1 improved significantly in their use of behavior descriptions, reflections, labeled praises, and questions. Commands did not improve significantly, but Dyad 1 did not issue a substantial number of commands at pre-intervention or post-intervention, indicating little room for improvement. Descriptively, commands reduced from three at pre-intervention to one at post-intervention. Furthermore, Dyad 1 used more than 10 behavior descriptions and labeled praises at treatment termination, which is clinically significant. Use of reflections, on the other hand, regressed from pre- to post-intervention. This regression might have occurred if the child did not make many verbalizations during the coding period. Dyad 1 reduced their use of questions greatly from 30 at pre-intervention to nine at post-intervention.

Dyad 3 showed statistically significant reliable change on all coded behaviors except criticisms, which were not given at pre- or post-intervention. Additionally, Dyad 3 made clinical improvements in terms of behavior descriptions and reflections at post-intervention. Clinical significance was not met for labeled praises. In addition, use of questions improved greatly from 50 at pre-intervention to nine at post-intervention, while commands improved from 20 at pre-intervention to three at post-intervention.

Dyad 4 demonstrated statistically significant reliable change on behavior descriptions, labeled praises, questions, and commands. However, the number of positive play behaviors improved only slightly. However, Dyad 4 improved use of questions greatly from 43 at pre-intervention to two at post-intervention.

The present results expand the findings from the pilot of Smart Start, where behavior descriptions, reflections, labeled praises, and questions all improved significantly from pre-intervention to post-intervention (Agazzi et al., 2016). The reduced issuance of commands found with the current study is an expansion of results from the pilot study. However, Dyad 4 did not make the pronounced shifts that Dyads 1 and 3 made. It is possible that fidelity to coaching Child-Directed Interactions impacted the outcomes found with Dyad 4. Homework compliance also might explain why Dyad 4 did not improve as much as other participants in terms of behavior descriptions and labeled praises. The reliable change scores should be interpreted with caution since they were calculated using psychometric properties from families coded at pre-intervention only. Thus, the RCI was highly sensitive to change. Despite the uncertainty of the reliable change scores, the clinical improvements in positive parenting practices are highly promising, as they are similar to expectations for mastery in other evidence-based treatments such as PCIT.

Research Question 6: Do Caregivers Self-Report Improved Levels of Parenting Stress from Pre-Intervention to Post-Intervention?

It was expected that parenting stress would improve as children's challenging behaviors improved and as caregivers gained confidence in their ability to manage children's responses to trauma. Results from the reliable change index for Dyad 1 showed significant improvements on some aspects of the PSI from pre- to post-intervention, namely the Parental Distress and Parent-

Child Dysfunctional Interaction subscales. Dyad 1 did not report reliable change on the Total Stress or Difficult Child subscales. Though changes in Total Stress were not statistically significant for Dyad 1, they were clinically significant, which indicates the caregiver was experiencing normal levels of stress at post-intervention compared to pre-intervention. The Difficult Child subscale, though lower at post-intervention compared to pre-intervention, was not clinically or statistically significant by intervention completion. The results of the Difficult Child subscale are consistent with the slow improvements reported by Dyad 1 on the ECBI Intensity subscale.

Dyad 3 did not rate any aspect of parenting stress as measured by the PSI-4-SF in the clinical range at pre- or post-intervention. Nevertheless, change on all subscales of the PSI-4-SF was large and statistically significant.

Dyad 4 did not endorse reliable change on any subscale of the PSI-4-SF. However, Dyad 4 did not report clinically significant levels of stress, except for the Difficult Child subscale, at pre-intervention. Therefore, significant improvements were more difficult to detect. Despite this, Improvements were noted on the Difficult Child subscale. However, improvements were not clinically significant. On the other hand, the Parental Distress subscale was rated higher at post-intervention compared to pre-intervention. The increase in Parental Distress was not statistically or clinically significant. The worsened Parental Distress levels might be explained by factors unrelated to the intervention. This caregiver was overwhelmed with competing family demands and numerous foster and biological children. In the midst of the intervention, this caregiver dealt with the physical, emotional, and academic battles of other biological and foster children, which might have influenced her stress overall.

The results from the current study are similar to those obtained by Agazzi et al. (2016). In the 2016 pilot, caregivers also reported significant improvements on the Parent-Child Dysfunctional Interaction subscale. The data reported by Dyads 1 and 3 are consistent with Agazzi et al. (2016) and even expand results from the pilot with significant improvements on the Parental Distress subscale for Dyads 1 and 3. On the other hand, the results from Dyad 4 did not corroborate findings from the pilot of Smart Start. Other researchers that used the PSI Short Form to measure change after implementation of ABC (Sprang, 2009) and PCIT (Borrego et al., 1999) found clinically and/or statistically significant improvements on the Total Stress subscale, which is consistent with the present findings for Dyads 1 and 3, but not for Dyad 4. As such, Smart Start might be comparable to other evidence-based interventions in terms of stress improvement, but overall results should be interpreted with caution due to the sample size. In particular, variables such as maturation, family distress, and increased stability in the living environment for the child may have resulted in the improvements or regressions.

Research Question 7: How Satisfied are Caregivers with Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma?

Given the newness of Smart Start, it was unclear whether the intervention would be acceptable to key stakeholders. Thus, the Therapy Attitude Inventory was disseminated to each participant at intervention completion. Caregivers reported high levels of satisfaction with the Smart Start intervention, which averaged 4.10 out of 5.00 across participants. Individual TAI averages ranged from 3.9 (Dyad 4) to 4.4 (Dyad 3). The results from the current study are consistent with the Smart Start pilot, where TAI scores ranged 4.13 to 4.88 (Agazzi et al., 2016). It is therefore reasonable to conclude that Smart Start is an acceptable intervention in terms of

caregivers' confidence in their ability to manage challenging behaviors, caregivers' perceptions of challenging behaviors, and caregivers' satisfaction with intervention techniques.

Implications for Practice

The results of this study have provided further empirical support for a financially feasible trauma-informed intervention approach that can be implemented by bachelor's level early interventionists. The positive results garnered from the present study hold promising implications for future trauma-focused early intervention practices. First, Early Steps administrators should consider training Bay Area Early Steps interventionists in Smart Start more systematically. More widespread training will ensure trauma-informed interventionists are assigned to families when children with challenging behaviors and trauma histories present for evaluation. To ensure interventionists feel prepared to enact Smart Start, a seasoned mentor could be assigned to the case. Mentorship would enable providers to access collegial supervision and thereby build capacity in the implementation of trauma-informed behavioral services. In addition to local training opportunities, administrators with Bay Area Early Steps might disseminate the Smart Start intervention to other Early Steps areas by training regional directors in Smart Start and collaborating with directors as they begin to use Smart Start.

Though the findings from this study are encouraging, there are several adaptations that must be considered in order to enhance the potential for intervention effectiveness. In particular, training endeavors must be modified as they relate to interventionist buy-in, use of ratings scales, and fidelity to Smart Start.

Buy-in is an important step to ensuring Smart Start is used with integrity. Early Steps employs interventionists that vary in background knowledge, years of experience, and area of expertise. These differences in training backgrounds can lead to discrepancies in philosophical

beliefs regarding early intervention services. As a result, some individuals might not find alignment between their own training and the strategies used in Smart Start. It is important for critical thinking and discussion to occur at the outset of training so interventionists can make connections between their theoretical orientation and Smart Start. By making these connections, providers will be more likely to find value in intervention integrity.

In addition to buy-in, progress monitoring the response to intervention must be addressed. Previous research has shown that Early Steps interventionists fail to adequately monitor children's behavioral improvement over time (Dickinson, 2016). Providers' inexperience with progress monitoring was evident throughout this research project, namely with Dyad 4. Additionally, data reviewing and sharing are components of PCIT that are used to help families reflect more critically on behavior change over time (Eyberg & Funderburk, 2011). Future Smart Start training opportunities should include a segment about data-based decision making, and more specifically, use of rating scales such as the ECBI. If interventionists better understood how to administer and interpret data, then their practice and directions for service delivery could be vastly improved.

Another training need that should be addressed is fidelity to the treatment approach. The interventionists responsible for Dyads 1 and 4 did not consistently adhere to treatment procedures as intended, which was evident in the treatment integrity checklists. The data patterns for Dyads 1 and 4 indicate that treatment integrity, or lack thereof, might be important to improving challenging behaviors. Future Smart Start training should enhance participants' understanding of and practice with highly structured techniques such as CDI, Follow Through, and Time Out. Not to mention, fidelity checklists should be revised to capture the importance of certain aspects of treatment sessions (e.g., coaching CDI) over others, as the current protocol

weights each element of the protocol equally. One way this might be achieved could be to measure the number of minutes spent in intervention activities and calculate percentages out of 60 minutes. For example, if coaching occurred for 15 minutes instead of 30 minutes and all other intervention minutes were met, then the integrity percentage would be 45 out of 60. Additionally, interventionists must be trained to understand and handle extinction bursts. Though extinction bursts were not noted by providers in this iteration of research, it is a gap in the training experience of Smart Start interventionists. Finally, training opportunities should highlight the importance of fidelity as it relates to outcomes for child behavior. This explanation could foster interventionists' buy-in to treatment integrity.

As alluded previously, the transition from a long baseline period to a structured approach such as Smart Start was likely difficult for families and providers. This transitional difficulty might partly explain the variability in Smart Start integrity. One way to bridge the gap between interventionists' typical practice and the rigidity of Smart Start could be to update the manual to be more flexible. For example, the manual might be edited to include a "flex" option if time is short. This option could be used when an interventionist experiences time constraints in the session. The "flex" option would help interventionists determine which activities are most important to complete in the session and which activities can be shortened or eliminated. One "flex" option could be to spend 5 minutes coaching CDI before teaching Follow Through for 10 minutes during Week 4.

A final implication for future practice is related to the structure of the Smart Start manual. Given that the intervention is relatively short, little time is dedicated to generalization of skills, which is the vision of all behavioral interventions. Thus, generalization tips should begin in Week 3 of Smart Start in order to give families adequate practice using the skills outside of

sessions. In addition, it might be beneficial for Time Out to be taught earlier in the intervention if appropriate for a specific child.

Contributions to the Literature

There were a number of contributions to the literature that are very important to note. First, the results of this study lent support to the use of a manualized approach to treatment of trauma among young children with disabilities. Heretofore, no researchers had developed an intervention specifically for this population. Given that young children with disabilities are at extremely high risk for maltreatment (Maclean et al., 2017; Sullivan & Knutson, 2000), the introduction of a treatment approach such as Smart Start was timely and apropos.

Second, Smart Start is an intervention approach that is cost-effective and easily accessed by bachelor's level early interventionists. No other evidence-based treatments are both cost-effective and available to individuals who have not acquired at least a master's degree. Thus, Smart Start is a service that is easily accessible within the community mental health setting. Adding to its cost-effectiveness is the short period of time over which Smart Start is implemented. Smart Start therefore has been shown to address the unique needs of both children who have experienced a trauma and clinicians in need of strategies to support such children.

Limitations

There were some notable limitations with regard to this study. First, the small sample of participants limited the generalizability of the findings. Further research is needed to elucidate the findings of this study. Because the child participants in this study were developmentally delayed, these findings are unlikely to be generalizable to typically developing toddlers who have experienced trauma.

A second limitation to this study was the racial homogeneity among child and caregiver participants. One potential explanation for the lack of diversity is that this intervention was implemented in the home only, and there are possibly demographic differences among individuals who are available to be seen in the home during business hours throughout the week.

A third limitation to this study was the potential for “practice effects” in relation to the behavioral outcome measure. As caregivers completed the ECBI (especially Dyad 4), they may have become increasingly careless in their responses. This could have resulted in unreliable data. Additionally, caregivers may have habituated to the questions on the ECBI, which could have led to different interpretations of the questions over time. The results from the CGI Severity and Improvement scales buffered against this limitation by providing an additional source of subjective data with regard to severity and improvement of challenging behaviors.

In addition to “practice effects,” concerns were presented with the ECBI normative sample. The measure was normed over 15 years ago, which calls question to the reliability of the tool. Additionally, several items on the ECBI (e.g., “Wets the bed”) do not apply to samples of toddlers due to their developmental level. Thus, caregivers are instructed to circle “1” (Never) and “No” (the behavior is not a problem) on the ECBI. When several items are not applicable to the population, the resultant *T*-scores are questionable. Moreover, the ECBI does not include positive indicators of well-being (e.g., use of coping strategies) needed to understand complete mental health.

Some of the measures that were used in this study (i.e., YCPC, CGI) have not been validated yet. Specifically, the YCPC has not been psychometrically validated for use as a reliable measure of PTSD symptomatology among young children. However, no scales currently exist to reliably measure this construct. Because the YCPC has not been validated, the

psychometric properties (i.e., subscale standard deviations) could not be used to calculate the RCI. As a result, the standard deviations from the study sample were used, thereby reducing the reliability of the data. In addition, the questions on the YCPC are written as though the caregiver was present when the traumas occurred, which was not the case for all participant in the study, making the question stems on the YCPC difficult to answer with accuracy. The CGI also has not been used in a research study to measure severity of and change in challenging behaviors for young children over time. However, use of the CGI in clinical practice has become increasingly common for a myriad of target concerns. With these concerns noted, results from the YCPC and CGI should be interpreted with caution.

In addition to concerns for measure validation, the psychometric properties needed to calculate the RCI for the PSI-4-SF were obtained from separate studies since the authors of the PSI-4-SF did not provide the mean and standard deviation of the subscales on the PSI-4-SF, which were needed to calculate reliable change. Furthermore, the DPICS RCI was limited in that the psychometric properties only were provided for families at pre-intervention. Thus, the RCI was highly sensitive to small change from pre-assessment to post-assessment. Furthermore, the standard deviation and reliability scores from the Bessmer (1996) study were averaged for both direct/indirect commands and information/descriptive questions in order to calculate the RCI for DPICS commands and questions. Altogether, RCI results from the PSI-4-SF and DPICS should be interpreted with caution.

Another limitation was that long-term follow-up data were not collected. As such, it is unclear whether gains from this intervention will be maintained over time, especially in the case of foster care where the child is likely to experience re-placement. Furthermore, two children

(Dyads 2a and 2b) only completed Orientation through Week 5 of the intervention, so the full effect of the intervention for these dyads was not obtained.

A final limitation with regard to this study was the concept of “treatment as usual.” Previous research has shown that Early Steps interventionists may engage in significantly different procedures as part of their usual care for behavioral challenges (Dickinson, 2016). This variability could have influenced data patterns across participants, as each child had a different interventionist. The treatment as usual checklists and behavioral vignette provided some insight into the variability among participants and was used as a supplemental source of data when analyzing results across participants.

Directions for Future Research

The results of the current study are extremely promising. Thus, future evaluations of Smart Start are warranted. There are numerous directions for future study. The next logical step for study would be a low power randomized controlled trial (RCT). More specifically, a trial wherein children are randomized to control, treatment as usual, and Smart Start would be beneficial in terms of understanding how the current intervention compares to usual care and no treatment. The treatment effect of the current study compared to usual care was difficult to analyze due to the instability in baseline phases. Thus, the proposed RCT model would help to disentangle the treatment effect of Smart Start compared to usual care or no care.

Another interesting research endeavor might be to measure behavior change using different behavioral outcome instruments. For example, future researchers might determine behavior change by operationally defining a behavior, and then monitoring that specific behavior over time using frequency counts provided by caregivers or obtained via observation. Future

researchers also should consider measuring children's use of positive coping strategies, like deep breathing or functional communication, in addition to reductions in challenging behaviors.

Since Smart Start has shown promise, future researchers should pilot the intervention in different settings. Many children are served by Early Steps in the daycare. Therefore, future research might be conducted in daycare environments with daytime caregivers. Another audience that should be targeted is biological caregivers. Future researchers should consider coaching caregivers to use positive parenting practices during supervised visits in an effort to aid in successful reunification. On the other hand, families that are at-risk for child abuse and neglect (e.g., families receiving temporary assistance) could be coached in order to prevent removal by the state.

Another future direction for research would be a pilot of Smart Start with children and families that have experienced other traumas (e.g., community violence, accidents, medical trauma). The children included in the present study were limited by their traumatic experience, even though many children who experience other types of trauma are served by Early Steps. Inclusion criteria for this study were rigid, which meant recruitment was especially challenging because that the definition of "trauma" was restrictive. Study staff were pressed with the task of identifying individuals who would meet inclusion criteria for the study. It would be interesting and informative to ascertain the effectiveness of Smart Start with other traumas. Not to mention, expanding the definition of trauma for intervention purposes would boost the generalizability of Smart Start.

Finally, future researchers should pilot a 10-week or 12-week implementation of Smart Start. Time Out is currently taught in Week 6 of the intervention, which provides little time for caregivers to learn and practice the procedure with coaching. Furthermore, extinction bursts are

likely with the implementation of Time Out, but there is insufficient time for the behaviors to show stable improvement between application of Time Out and treatment termination. A longer treatment approach would provide additional time for caregivers to master CDI skills, Follow Through, and Time Out. Additionally, a lengthened treatment approach would allow for more stable patterns of behavior to be established and maintained.

Summary

Up to 26% of children experience a potentially traumatic event by the age of 4 years (Briggs-Gowan et al., 2010), and 16% of 2 to 18 year olds go on to develop posttraumatic stress disorder (PTSD; American Psychiatric Association, 2013). There are a multitude of circumstances that could lead to PTSD, but child maltreatment is one of the most common traumas young children experience. In fact, children ages 0 to 3 years are more susceptible to maltreatment compared to older populations (U.S. Department of Health and Human Services, 2017). Of the children who experience abuse and neglect, children with disabilities are up to 3.4 times more likely to be maltreated than children with no documented disability (Jones et al., 2012; Maclean et al., 2017; Sullivan & Knutson, 2000; U.S. Department of Health and Human Services, 2006). The average first incidence of maltreatment for children with disabilities occurs prior to the age of 5 years, indicating that very young children with disabilities are uniquely vulnerable to abuse and neglect compared to typically developing populations (Maclean et al., 2017).

Children who experience maltreatment at a young age frequently develop a set of challenging behaviors that influence social-emotional outcomes (De Young et al., 2011). Additionally, early adverse experiences place children at risk for a myriad of negative outcomes, including stunted neurological growth (Felitti et al., 1998). Children who experience trauma and

maltreatment are vulnerable to poor psychological, physical, and academic outcomes compared to children who have not experienced trauma (Felitti et al., 1998). Moreover, the implications of trauma exposure are more detrimental when the trauma occurs during infancy compared to middle childhood (Font & Berger, 2015). Given the deleterious effects of trauma in early childhood, it is imperative that evidence-based interventions are accessible.

Several evidence-based treatments are available to young children who have experienced trauma. These treatments include Attachment and Biobehavioral Catch-up (Dozier, Meade, & Bernard, 2014), Child-Parent Psychotherapy (Lieberman, Silverman, & Pawl, 2000), Parent-Child Interaction Therapy (Eyberg & Funderburk, 2011), and Trauma-Focused Cognitive Behavioral Therapy (Cohen, Mannarino, & Deblinger, 2012). Unfortunately, none of these treatments have been validated for young children with disabilities, even though children with disabilities are at high-risk for maltreatment. Not only are the evidence-based interventions invalid for children with disabilities, but also the treatments are expensive and frequently require health insurance coverage, which limits the families who can access high quality care. Finally, the treatments available often entail extensive graduate training and supervision in order for providers to ethically deliver them.

The purpose of this study was to address the gaps in the trauma treatment literature with regard to 1) trauma-informed service-delivery for young children with disabilities and 2) financially ascertainable evidence-based interventions for both therapists and families. A second aim of this study was to assess the efficacy of a newly piloted parenting intervention for young children with disabilities who have experienced maltreatment. This intervention is called Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma (Agazzi et al., 2016). Smart Start was developed using the principles from Parent-Child

Interaction Therapy and Helping Our Toddlers: Developing Our Children's Skills. Bachelor's and Master's level early interventionists were trained to use this manualized intervention with families who were receiving services through IDEA Part C and the child welfare system. Serving children through Part C allowed children with disabilities to access treatment for free within the natural environment.

A non-concurrent multiple baseline study was designed to evaluate the effects of Smart Start compared to treatment as usual on young children with disabilities that had experienced maltreatment. Five caregiver-child dyads were included in the study, but only three dyads completed all outcome measures at both pre- and post-intervention. Outcomes assessed included caregiver/interventionist ratings of children's challenging behaviors, caregiver ratings of children's PTSD symptomatology, caregiver ratings of parenting stress, caregiver use of positive parenting practices, caregiver satisfaction with treatment, and interventionist fidelity to the treatment approach. Measures used to determine response to intervention included the Eyberg Child Behavior Inventory (ECBI), Clinical Global Impression (CGI), Young Child PTSD Checklist (YCPC), Parenting Stress Index, Fourth Edition—Short Form (PSI-4-SF), Dyadic Parent-Child Interaction Coding System (DPICS), Therapy Attitude Inventory (TAI), and weekly treatment integrity checklists. The ECBI was completed weekly by the caregivers. Thus, these data were analyzed using visual analysis, masked visual analysis, and hierarchical linear modeling (HLM). The CGI was completed at pre- and post-intervention by the interventionists for all participants. Results were examined using the Wilcoxon Signed-Rank test. The YCPC, DPICS, and PSI-4-SF were collected at pre-intervention and post-intervention for three participants and were analyzed using the reliable change index (RCI) and descriptive statistics. The TAI and integrity checklists were analyzed descriptively.

Results from the current study were highly promising. Interventionists implemented Smart Start with variable, but high degrees of fidelity. Visual analysis, masked visual analysis, and HLM showed caregivers' ECBI Intensity ratings improved significantly throughout intervention compared to treatment as usual. Visual analysis and masked visual analysis showed caregivers' ECBI Problem ratings improved significantly during intervention compared to treatment as usual; however, the HLM model did not support these findings due to low power. The Wilcoxon Signed-Rank test did not show statistically significant changes in interventionists' rating of the severity of children's challenging behaviors; although, all interventionists but one reported improved behaviors from pre- to post-intervention. Children's PTSD symptomatology improved overall, and two participants of three made statistically significant improvements on either the PTSD scale or the Functional Impairment scale of the YCPC. Positive parenting practices improved greatly for two of three participants, and all participants showed statistically significant improvement in their use of behavior descriptions, labeled praises, and questions. Some aspects of parenting stress improved significantly for two of three participants. Finally, all participants reported high satisfaction with the Smart Start intervention. The present findings were mixed, but when amalgamated, there is confidence the Smart Start intervention was effective in terms of improving both child and caregiver outcomes. Future research with a larger sample is highly recommended in order to elucidate these exciting findings.

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Appendices

Appendix A: IRB Approval



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX(813)974-7091

5/9/2017

Heather Agazzi, Ph.D.
Pediatrics
13101 N. Bruce B. Downs Blvd.
Tampa, FL 33612

RE: **Full Board Approval for Initial Review**
IRB#: Pro00029566
Title: Trauma-Informed Behavioral Parenting

Study Approval Period: 4/21/2017 to 4/21/2018

Dear Dr. Agazzi:

On 4/21/2017, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s):

Protocol Document(s):

[TIBPprotocol 5-1-17.docx](#)

Consent/Assent Document(s)*:

[TIBP adult minimal risk 5-1-2017.docx.pdf](#)

[TIBP ComboConsentV1 4-25-17.docx.pdf](#)

[TIBP phone screen 3-8-17 Version 1.docx**](#)

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent documents are valid until the consent document is amended and approved. ****verbal consent forms are unstamped**

Your study qualifies for a waiver of the requirements for the informed consent process as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the

research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. As described in additional detail below, a waiver of informed consent process/parental permission is granted for children whose biological parents' rights have not been terminated who are in the care of a temporary legal custodian.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117(c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. This waiver of documentation of informed consent is granted to allow the study team to conduct obtain verbal consent prior to conducting the phone screen.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45CFR164.512(j) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI. An alteration of HIPAA Authorization is granted for the child/caregiver cohort of this study. The study team will obtain Authorization verbally as part of the screening/recruitment process. Therefore, this alteration exempts the study team from the Privacy Rule's requirement that Authorizations obtained during screening be signed and dated. Participants who meet inclusion criteria and decide to participate in the research will provide written Authorization as part of the informed consent process.

No PHI will be obtained from the early interventionists enrolled in this study, thus Authorization is not required from this cohort.

Research Involving Children as Subjects: 45 CFR §46.404

This research involving children as participants was approved under 45 CFR 46.404: Research not involving greater than minimal risk to children is presented.

Requirements for Assent and/or Permission by Parents or Guardians: 45 CFR 46.408

Permission of one parent is sufficient.

Assent is not appropriate due to the age, maturity and/or psychological state of the child.

Waiver of Parental Permission: 45 CFR 46.408(c)

In addition to the requirements found in 45 CFR 46.116(d), the IRB determined the research protocol is designed for conditions or for a subject population for which parental or guardian

permission is not a reasonable requirement to protect the subjects. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. The waiver is not inconsistent with Federal, State, or local law. [Children whose biological parents' rights have not been terminated and are in the care of a temporary legal custodian, for whom an advocate and the custodian will sign the consent document.]

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kristen Salomon', followed by a horizontal line.

Kristen Salomon, Ph.D., Vice Chairperson
USF Institutional Review Board

Appendix B: Phone Screen

Part 1: Screening Verbal Consent

Hello, my name is [name] with the study named “Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma.” This study has a number, eIRB# Pro00029566, and I work at the University of South Florida. Thank you for agreeing to talk to me today.

First, I want to briefly explain the study and see if you are interested in completing the study screener. The purpose of this study is to provide parent training to caregivers of young children with challenging behaviors and/or a trauma history who also have a developmental delay. We are working with families who are receiving Early Steps services and (if applicable) who receive child welfare services. In this study, families will receive 8 weekly early intervention sessions, like the ones that were discussed at your Early Steps eligibility meeting. These sessions are focused on teaching you skills that help children feel calm, safe, and teach them to follow directions and get along with you.

Are you interested in hearing more information?

Okay, I would like to take a minute before we begin the screening to review your rights in relation to this study.

1. You are free to stop participating in this screening interview or in the study at any time.
2. To our knowledge, there may be personal benefits to you by participating in this study. If you are eligible to take part in the study, you will learn strategies that may improve parent-child relationships, reduce behavior problems, and reduce parent stress.
3. If you are not eligible to take part, you will continue to receive your Early Steps intervention services.
4. There are no known risks to those who take part in this screening interview. You will not be paid for this screening interview.
5. Your comments will be kept confidential and your name will not be attached to any transcript or report. However, the USF IRB and Department of Health and Human Services can review all research records. If you have any concerns you can call the PI [Heather Agazzi] at [727-767-7292] or the Division of research Integrity and Compliance at the University of South Florida at (813) 974-5638.

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By verbally assenting, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below. In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;

- Each research site for this study including *USF Children's Medical Services, USF Rothman Center.*
- The USF Institutional Review Board (IRB) and their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.
- There may be other people and/or organizations who may be given access to your personal health information, including the FICW, the Early Childhood Coalition (ECC,) the USF Women's Health Collaborative, and Crisis Center of Tampa Bay.

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By verbally providing Authorization, you are giving your permission to use and/or share your health information as described before. As part of this research, USF may collect, use, and share the following information:

- Your research record
- All your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

You can refuse to provide your Authorization. If you do not consent, you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke, or withdraw, it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this Authorization, please write to:
 Heather Agazzi, PhD, MS
 For IRB Study # *Pro00029566*
 880 6th Street South, Suite 460
 St. Petersburg, FL 33701

While we are conducting the research study, we cannot let you see or copy the research

information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Would you like to participate in this screening interview?

Do you have any questions before we begin? During this conversation, we will need to ask you some questions to gather some initial information about you and your child to determine if you will be eligible to take part in this study. Our conversation should last about 10 minutes.

Part 2: Pre-Study Screening

Name of Interviewer: _____
Date of Interview: _____
Respondent's Name: _____ Phone #: _____
Respondent's relationship to child: Biological Mom/Dad Foster Mom/Dad Adoptive Mom/Dad Other: _____

Child Name: _____

Child's Date of Birth: _____ Age (in months): _____
(Note to Interviewer: Child must be between 18 months and 33 months old at time of recruitment to ensure child does not turn 3 years during intervention. If yes, continue. If no, read DNQ statement below).

Trauma Inclusion Questions

Answers to these questions must be yes:

- Does your child currently receive services through Bay Area Early Steps?

- Does your child currently receive services through a Hillsborough or Polk County child welfare agency? _____
If yes, what is the name of the case management agency? _____
- Does your child engage in challenging behaviors? _____
- Do you and your child speak English fluently? _____
- If your child qualifies for this program, Early Steps services need to be updated on the Individualized Family Support Plan to receive our study treatment. These services must occur with you in the home, which would be 1 hour per week for approximately 8 weeks. Are you willing to have these services **in your home**?

Answers to these questions must be no:

- Are you or your child currently receiving or previously received any of the following behavior interventions:
 - Parent-Child Interaction Therapy (PCIT) _____
 - Attachment and Biobehavioral Catch-up (ABC) _____
 - Child-Parent Psychotherapy (CPP) _____
 - Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) _____
- Are you or your child deaf or blind? _____

(DNQ) IF THE RESPONDENT ANSWERED NO TO ANY OF THE FIRST 5 QUESTIONS OR IF THE RESPONDENT ANSWERS YES TO THE LAST 2 BULLETS, SAY THE FOLLOWING: Thank you for your time. Your child is not eligible for participation in this study. Your child's Early Steps services will continue as they currently are

Challenging Behavior Inclusion Questions

Answers to these questions must be yes:

- Does your child currently receive services through Bay Area Early Steps?
- Does your child engage in challenging behaviors?
- Do you and your child speak English fluently?
- If your child qualifies for this program, Early Steps services need to be updated on the Individualized Family Support Plan to receive our study treatment. These services must occur with you in the home, which would be 1 hour per week for approximately 8 weeks. Are you willing to have these services **in your home**?

Answers to these questions must be no:

- Are you or your child currently receiving or previously received any of the following behavior interventions:
 - Parent-Child Interaction Therapy (PCIT) _____
 - Attachment and Biobehavioral Catch-up (ABC) _____
 - Child-Parent Psychotherapy (CPP) _____
 - Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) _____
- Are you or your child deaf or blind?

(DNQ) IF THE RESPONDENT ANSWERED NO TO ANY OF THE FIRST 4 QUESTIONS OR IF THE RESPONDENT ANSWERS YES TO THE LAST 2 BULLETS, SAY THE FOLLOWING: Thank you for your time. Your child is not eligible for participation in this study. Your child's Early Steps services will continue as they currently are

(If child is eligible proceed to next page)

If eligible, say: You and your child qualify to participate in this study. At the end of this conversation, I will ask you if you are willing to participate.

The next step is that our Project Coordinator, Sarah Dickinson, will schedule an appointment to come to your house to complete the study consent form and questionnaires with you. This is estimated to take an hour. Then you will be assigned an early interventionist who will teach you behavioral parenting strategies for the next 8 weeks. After these 8 weeks, all participants will complete the study measures during a 1 hour final session.

Do you have any questions?

Would you like to participate in the study?

Yes (Study participant #: _____)

No

Thank you again for your time! Have a great day/evening.

Participant's E-mail: _____

Participant's Home Address: _____

Appendix C: Adult Minimal Risk Informed Consent

Study ID:Ame3_Pro00029566 Date Approved: 1/25/2018



Informed Consent to Participate in Research Involving Minimal Risk

Pro #00029566

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma

The person who is in charge of this research study is Dr. Heather Agazzi. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

This research is being partially sponsored by the Florida Institute for Child Welfare (FICW), the Early Childhood Coalition (ECC), and partially sponsored by the USF Women's Health Collaborative

Purpose of the study

The purpose of this research study is to train Early Steps service providers to deliver a behavioral parenting program to caregivers of children with challenging behaviors and/or in the child welfare system that have experienced trauma and who are also enrolled in Early Steps. Additionally, the goal is for this program to reduce caregiver-reported child disruptive behaviors, decrease caregiver reported stress, increase positive parenting skills, and reduce potential symptoms of child post-traumatic stress.

Why are you being asked to take part?

We are asking you to take part in this study because you are a Smart Start Early Interventionist for the Bay Area Early Steps program. Information obtained from your participation in the program will likely help improve the quality and feasibility of Smart Start services.

Study Procedures:

If you take part in this study, you will be asked to:

- Attend two 3-hour trainings at the USF main campus, Tampa, that will help you become proficient with intervention procedures and one 3-hour web-based training
- Take part in a pre- and post-assessment that evaluates your general knowledge of intervention principles or concepts at the initial training at USF main campus, Tampa.
- Evaluate children and families using the Clinical Global Impression at pre- and post-treatment in the child's home
- Conduct home visits using the 9-week intervention plan in the child's home
- Complete weekly treatment integrity checklists (at child's home or when you return to office) that assess whether you engaged the family in the essential elements of the session
- Attend monthly supervision in person at USF main campus or on phone: 1 hour per month from July 2017-April 2018

Total Number of Participants

Up to 16 Early Interventionists will participate in Smart Start.

Alternatives / Voluntary Participation / Withdrawal

If you decide not to take part in this study and you do not participate, that is okay.

You should only take part in this study if you want to participate. You should not feel that there is any pressure to take part in the study to please the study investigator or the research staff.

You can decide after signing this informed consent form that you no longer want to take part in this study. We will keep you informed of any new developments which might affect your willingness to participate in the study. However, you can decide to stop taking part in the study for any reason at any time. If you decide to stop taking part in the study, tell the study staff as soon as you can.

Benefits

The potential benefits of participating in this research study include learning new intervention strategies that may be effective at improving positive parenting practices and reducing challenging behaviors associated with early childhood challenging behaviors and/or trauma.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

There will be no compensation for participation in this study.

Costs

There will be no additional costs to you as a result of being in this study.

Conflict of Interest Statement

The person leading this medical research study might benefit financially from this study. Specifically, Drs. Heather Agazzi, Alison Salloum and Emily Shaffer-Hudkins are authors of the new treatment being studied. Research studies like the one you are thinking about joining are done to determine whether the new treatment is safe and effective. If research shows the new treatment is safe and effective, Drs. Agazzi, Salloum, and Shaffer-Hudkins would receive a part of the profits from any sales of this treatment.

The Institutional Review Board that reviewed this study and a committee at the University of South Florida have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Privacy and Confidentiality

The purpose of the intervention is for research purposes only. You will not have access to the research data, and the data collected are not for forensic or court purposes.

We will keep your study records confidential to the extent permitted by law.

Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, all other research staff, and the Data and Safety Monitoring Board who monitor the data and safety of the study.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.
- The sponsors of this study (FICW, ECC, USF Women's Health Collaborative).

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns, or complaints about this study, call Dr. Heather Agazzi at 727-767-7292.

If you have questions about you or your child's rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638.

Consent to Take Part in this Research Study

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Signature of Person obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent

Appendix D: Combo Consent

Study ID:Ame1_Pro00029566 Date Approved: 8/1/2017



Consent to Participate in Research & Parental Permission for my Child to Participate in Research and Authorization to Collect, Use and Share Your Health Information

Pro #00029566

The following information is being presented to help you and your child decide whether or not you would like to be a part of a research study. Please read this information carefully. If you have any questions or if you do not understand the information, we encourage you to ask the researcher.

We are asking you to take part, and to allow your child to take part, in a research study called: **Smart Start: Parenting Tools for Children with Developmental Delay, Social-Emotional Concerns, and Trauma**

The person who is in charge of this research study is Dr. Heather Agazzi. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at your home location where you currently receive Early Steps early intervention services.

This research is being partially sponsored by the Florida Institute for Child Welfare (FICW), the Early Childhood Coalition (ECC), and partially sponsored by the USF Women's Health Collaborative

Purpose of the study:

The purpose of this research study is to train Early Steps service providers to deliver a behavioral parenting program to caregivers of children with challenging behaviors and/or in the child welfare system that have experienced trauma and who are also enrolled in Early Steps. Additionally, the goal is for this program to reduce caregiver-reported child disruptive behaviors, decrease caregiver reported stress, increase positive parenting skills, and reduce potential symptoms of child post-traumatic stress.

Why are you & your child being asked to take part?

We are asking you and your child to take part in this study because your child was found eligible for the Bay Area Early Steps program, has challenging behaviors, and/or is reported to be enrolled in Hillsborough or Polk County Child Welfare services and has likely experienced a trauma. Information obtained from your participation in the program will likely help increase availability of behavioral parenting interventions in your county.

Study Procedures:

Both the caregiver and child will be asked to participate in the study. Caregiver-child participants will be assigned to receive Smart Start for either trauma or challenging behaviors as appropriate. These services will be provided as part of Early Steps early intervention services. The study is designed for one caregiver to take the lead on working with the child and the Early Steps early intervention provider (your early interventionist), and this caregiver will be considered the lead caregiver. A caregiver is an adult who is the legal guardian of the child. An interventionist is an Early Steps provider who delivers services to children and families in the home. The interventionist is also a participant in this study.

Early Intervention Smart Start:

As part of Smart Start, you will be asked to meet with an Early Steps provider, who is called an Early Steps early interventionist or infant toddler developmental specialist, in your home for 9 weekly sessions that are one-hour each. These sessions will occur on a day and time that is convenient for your family routines.

If you take part in this study as the lead caregiver, you and your child will be asked to do the following:

First assessment: You will be asked to participate in a 1-hour assessment. We will ask you questions about you and your child. We want to learn how upset your child is about the traumatic event(s) (if applicable) and what types of challenging behaviors they have. We also want to learn about the parenting stress you experience and what types of parenting skills you use with your child. This assessment will be used as a baseline assessment meaning it will be used to see if any improvements happen as a result of participating in the Smart Start program. Smart Start will include information on how bad experiences affect young children, how to make the child feel safe and calm, how to teach the child to follow directions, and strategies to improve your relationship with the child. Smart Start will involve an Early Steps provider coming to your home to meet with you and your child for one hour weekly.

Questions we will ask you will include questions about your parenting stress. We will also ask you questions about your child, including those about your child's past bad experiences (e.g., removal from parents, abuse, neglect), if applicable, and about emotions and behaviors your child is showing.

All lead caregivers are asked to take part in this assessment. This means one caregiver will participate for each child enrolled in the study. This same person will be asked to complete all study assessments over the 8-week intervention.

Mid-treatment assessment: At the middle point of treatment, you will be asked to repeat a questionnaire about your child's symptoms of trauma, if applicable. This will take about 10 minutes.

Post-assessment: After treatment, you will be asked to repeat all of the measures that were completed in the first assessment. This assessment will take approximately 1 hour.

In total, you will be asked to participate in 9 hours of Smart Start intervention and 2 hours 10 minutes of assessment.

Audio and video recording

The initial and post assessments will include a video/audio recording of you and your child playing. The purpose of this is to have a blinded-rater (someone not familiar with which study group you are in) evaluate the types of parenting skills you use during a play session with your child. These digital recordings will only be watched by Dr. Armstrong, one of the research staff. She will analyze the words and phrases you use during play with your child. If information is used from video/audio recordings for examples of parent-child play, no identifiable information about you or your child will be used. False names will be used. No identifying information will be reported. Dr. Agazzi will keep the video/audio digital recording/files on her password protected computer that is locked in her office at the USF Rothman Center.

After data are collected from the sessions, the data will be transferred to a computer, and then destroyed/deleted immediately from the video camera. You and your child will not have access to the video recordings. The recordings are for research purposes only.

Total Number of Participants

Up to 13 caregiver-child pairs (13 total adults, 13total children) will take part in this study.

Alternatives / Voluntary Participation / Withdrawal

If you decide not to let your child take part in this study and you do not participate, that is okay. Instead of being in this research study, you and your child can choose not to participate and continue with Early Steps early intervention services.

You and your child should only take part in this study if both of you want to participate. You or your child should not feel that there is any pressure to take part in the study to please the study investigator or the research staff.

You can also decide after signing this informed consent form that you no longer want your child or yourself to take part in this study. We will keep you informed of any new developments that might affect your willingness to participate or to allow your child to continue to participate in the study. If you and/or your child decide to stop taking part in the study, then tell the study staff as soon as you can.

Benefits

The potential benefits to participating in Smart Start include: 1) learning about the effects of bad experiences early in life (stress reactions that occur after trauma exposures), if applicable, 2) learning parenting strategies to treat child disruptive behaviors, and 3) learning strategies to reduce your parenting stress. We do not know if your child will benefit by experiencing less stress, although we hope he/she will feel less stress. We believe your child will benefit by engaging in fewer disruptive behaviors but we do not know for sure.

Risks or Discomfort

There are no known risks to those who take part in this study. However, you may experience mild discomfort resulting from the discussion of potentially difficult topics such as traumatic events, if applicable. We will not discuss such topics in front of your child.

You may also feel some loss of privacy with having someone come to your home and coach you in strategies to use with your child. In our experience, this typically lessens over a few sessions, and then most caregivers welcome the coaching.

Compensation

There will be no compensation for participation in this study.

Cost

Your insurance company, Medicaid, Early Steps, or a third party payer will be expected to pay the costs for the sessions. This is true whether you are in this study or whether you are enrolled in regular early intervention. You will not pay for Early Steps early intervention services, even if your health insurance company denies the claim. Early Steps will ultimately cover the session if your health insurance does not.

Conflict of Interest Statement

The person leading this medical research study might benefit financially from this study. Specifically, Drs. Heather Agazzi, Alison Salloum and Emily Shaffer-Hudkins are authors of the new treatment being studied. Research studies like the one you are thinking about joining are done to determine whether the new treatment is safe and effective. If research shows the new treatment is safe and effective, Drs. Agazzi, Salloum, and Shaffer-Hudkins would receive a part of the profits from any sales of this treatment.

The Institutional Review Board that reviewed this study and a committee at the University of South Florida has reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Privacy and Confidentiality

The purpose of the assessments and therapy data are for research purposes only. You and your child will not have access to the research data including video recordings, and the data collected are not for forensic or court purposes.

We will keep your child's study records confidential to the extent permitted by law. For example, if there is reasonable cause to suspect that a child is abused, neglected, or abandoned by a parent, legal custodian, caregiver, or other person responsible for the child's welfare, a report of such knowledge or suspicion will be made to the appropriate authorities.

If we learn information about you that suggests intent to harm oneself (suicide) or another, then we will share information with the Crisis Center of Tampa Bay therapists, or in cases of acute suicidality, with an emergency mental health service such as crisis assessment unit or a hospital, or we will make referrals for further evaluation to keep you, your child, and others safe. We will also consult with other study team members.

Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, all other research staff, and the Data and Safety Monitoring Board who monitor the data and safety of the study.
- Any agency of the federal, state, or local government that regulates this research.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.
- The sponsors of this study: FICW, ECC, USF Women's Health Collaborative.

We may publish what we learn from this study. If we do, then we will not include your name. We will not publish anything that would let people know who you are.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns, or complaints about this study, call Dr. Heather Agazzi at 727-767-7292.

If you have questions about you or your child's rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the

research and listed below.

The following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;
- Each research site for this study including USF Children's Medical Services, USF Rothman Center for Pediatric Neuropsychiatry;
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research;
- Data Safety Monitoring Boards or others who monitor the data and safety of the study;
- There may be other people and/or organizations who may be given access to your personal health information, including the FICW, ECC, USF Women's Health Collaborative and Crisis Center of Tampa Bay.

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your child's eligibility status for Early Steps, the Individualized Family Support Plan, and the results of the developmental evaluation.
- Your research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This includes, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and

- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator: Heather Agazzi

For IRB Study # **Pro00029566**

880 6th Street South

Suite 460

St. Petersburg, FL 33701

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies. You will receive a signed copy of this form.

Consent to Participate and Parental Permission for My Child to Participate in this Research Study and Authorization to Collect, Use and Share His/Her Health Information for Research

I freely give my consent to take part and to let my child _____ (child's name) take part in this study and authorize that his/her health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in and to let my child take part in research. I have received a copy of this form to take with me.

Signature of Person and Caregiver of Child Taking Part in Study Date

Printed Name of Person and Caregiver of Child Taking Part in Study

Child Advocate/Case Manager from Child Welfare Agency Date

Printed Name of Child Advocate/Case Manager from Child Welfare Agency

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Signature of Person Obtaining Informed Consent Date

Printed Name of Person Obtaining Informed Consent

Please check if you agree to be video/audio recorded for the assessment and focus group sessions.

Yes, I agree to be video/audio recorded for the assessment sessions.

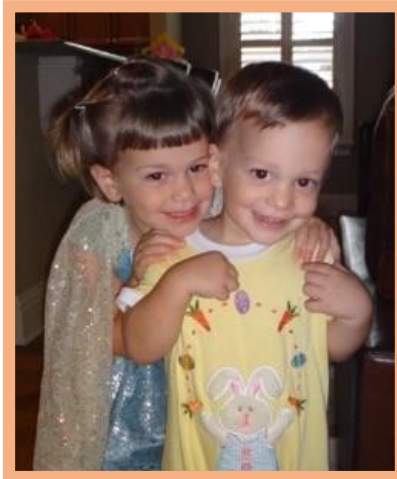
No, I do not agree to be video/audio recorded for assessment sessions.

Appendix E: Recruitment Flyer



If your child (ages 18 months to 35 months) has 1) challenging behaviors *OR* 2) challenging behaviors associated with an adverse event/trauma (separation from parent, abuse, neglect, etc.), you and your child may qualify to receive 8 weeks of therapy through a research study.

*To receive services for trauma, your child must be receiving services from both Bay Area Early Steps and from Eckerd Community Alternatives (Hillsborough County) or Heartland for Children (Polk County) to participate in this study.



* To receive services for challenging behaviors alone, your child must be receiving services from Bay Area Early Steps to participate in this study.

Heather Agazzi, Ph.D. at USF is conducting research on how to provide behavioral parenting strategies through Early Steps to help caregivers. Does your child have problems with:

- Sleeping
- Bathing
- Eating
- Following Directions
- Dressing
- Calming Down
- Temper Tantrums

This research is conducted under the direction of Dr. Heather Agazzi, University of South Florida, Morsani College of Medicine. IRB# (Pro00029566). Study title : Smart Start: Parenting Tools for Children with Developmental Delay, Social/Emotional Concerns, and Trauma. The study is partially funded by the FSU Florida Institute for Child Welfare and the USF Women's Health Collaborative.



FLORIDA INSTITUTE
for CHILD WELFARE



In Hillsborough or Polk County call:

727-767-7292

or E-mail:

sdickinson@mail.usf.edu

hcurtiss@health.usf.edu

Appendix F: Treatment as Usual Checklist

Please place a check mark next to each item below to indicate whether you used this strategy during your session with the family.

| Strategy | Yes | No | Is this a strategy you used before Smart Start training (Y/N)? |
|--|------------|-----------|---|
| CDI skills/practice play | | | |
| Planned ignoring | | | |
| Clear directions with follow through | | | |
| Time out | | | |
| Education about challenging behaviors or trauma | | | |
| Education about balancing parenting | | | |
| Caregiver identification of child's strengths and concerns | | | |
| Caregiver self care | | | |
| Education about identification and expression of feelings | | | |
| Emotion regulation strategies (e.g., deep breathing) | | | |

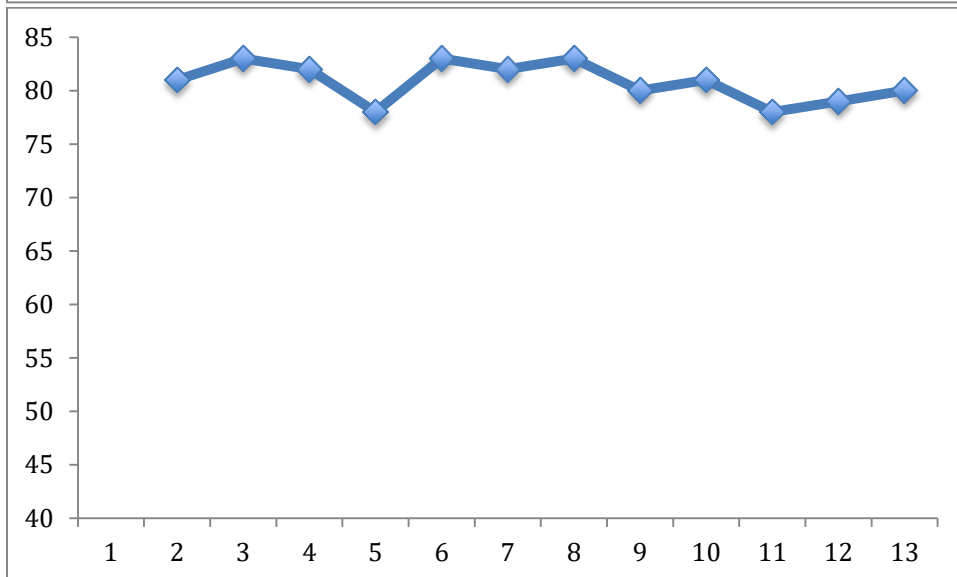
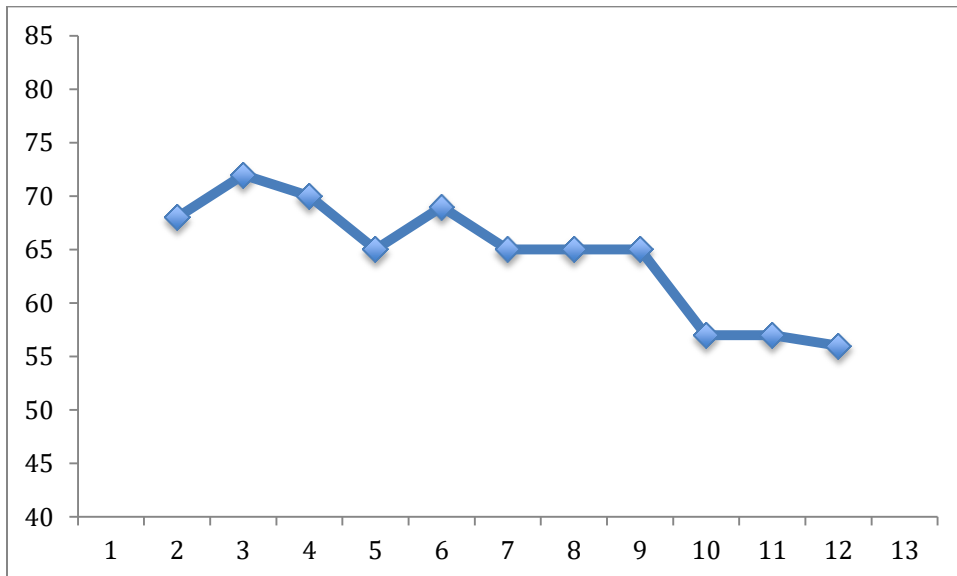
Appendix G: Behavioral Vignette

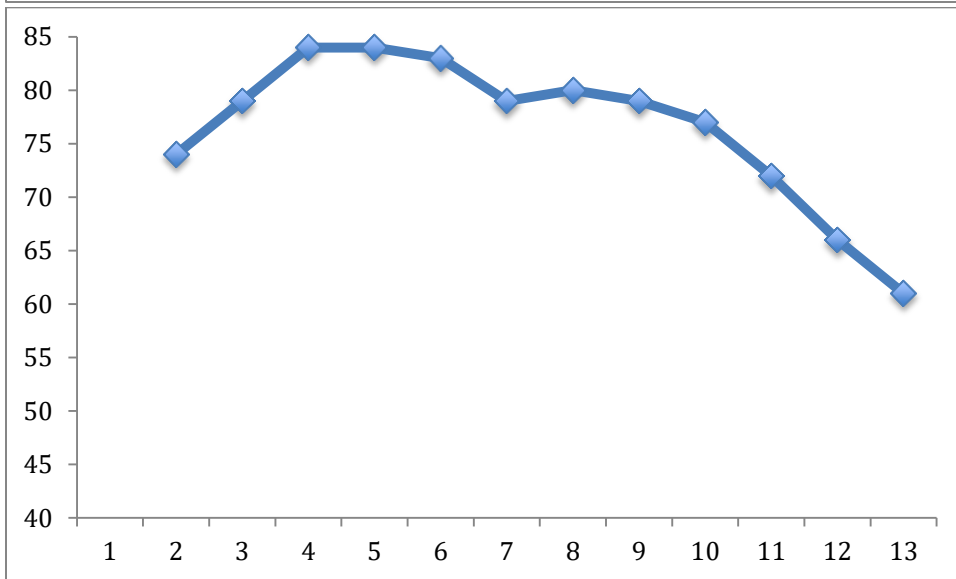
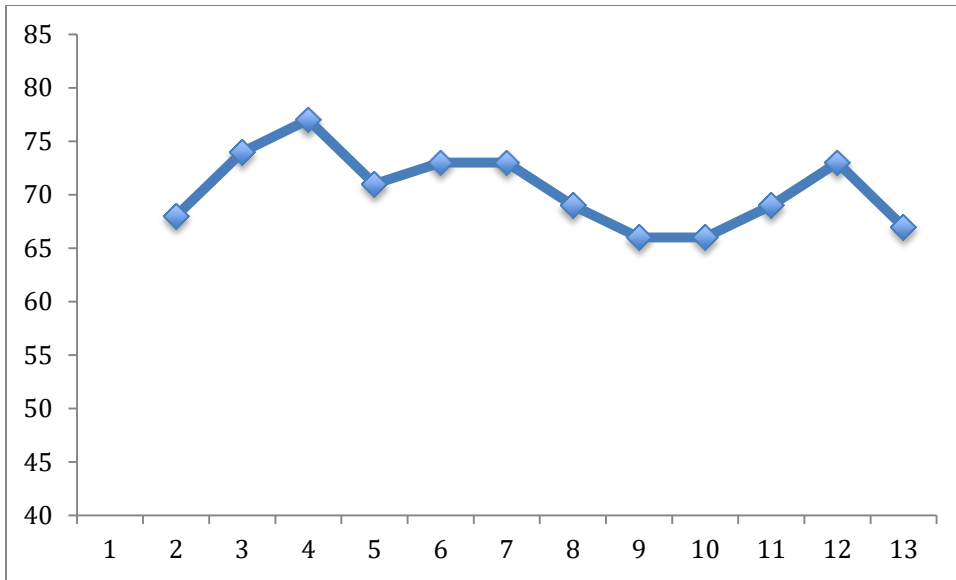
For the following scenario, please describe how you would identify and develop an intervention for the parent and child. How would you know the intervention is working? If it is not working, what would be your next steps? Respond to this scenario as if you had not already received training in Smart Start (i.e., how would you have responded to the following before Smart Start training?).

Diego is 20-month-old boy who lives with his foster parents. Diego's foster parents tell you he has been engaging in significant tantrum behaviors. Tantrumming looks like Diego laying down on his back or stomach on the floor and refusing to get up, crying for at least five minutes, clenching his hands into fists and hitting the floor with them, or extending his legs up and down while on the floor.

Appendix H: Masked Visual Analysis Graphs

These graphs represent *T*-scores for behavioral Intensity rated by caregivers on the ECBI. Participants were randomized to either a 3-week, 5-week, or 7-week baseline condition. Most participants experienced improvements in Intensity at the Week 3/4 marker. Some participants also experienced extinction bursts near the end of treatment. Please take a look at the following graphs and determine which condition you think each participant was assigned.





These graphs represent *T*-scores for behavioral Problems rated by caregivers on the ECBI. Each participant was randomized either to the 3-week, 5-week, or 7-week condition. Some participants experienced improvements in Problem at intervention implementation. Please take a look at the following graphs and determine which condition you think each participant was assigned. Any breaks in the data indicate missing points.

