

**INVESTIGATING TRAJECTORIES OF CHANGE IN ATTACHMENT AND
BIOBEHAVIORAL CATCH-UP:
A RANDOMIZED CLINICAL TRIAL**

by
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A thesis submitted to the Faculty of the University of Delaware in partial fulfillment
of the requirements for the degree of Master of Arts in Psychology

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by
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ABSTRACT

Attachment and Biobehavioral Catch-up (ABC) is a manualized, 10-session intervention that was developed at the University of Delaware to improve parenting abilities and subsequently increase the rate of children's secure attachments and self-regulatory capabilities in high-risk populations. The aims of the current randomized clinical trial were two-fold; the first aim was to investigate whether there were significant differences in parental sensitivity, intrusiveness, and positive regard after completion of ABC when compared to a control condition. The second aim was to explore the rate and shape of change in parenting behaviors. Participants were 24 mothers and their biological children who were randomly assigned to ABC ($n = 13$) or a control condition ($n = 11$). A structured play assessment with each mother and her child was video-recorded prior to randomization into the study, prior to each intervention session, and at a follow-up visit. A total of 259 videos were coded for sensitivity, intrusiveness, and positive regard. Hierarchical linear growth models were used to estimate the total change and rate of change in parenting qualities across the 10 intervention sessions when comparing ABC to a control condition. Piecewise hierarchical linear growth models were used to investigate patterns of change across the 10 sessions for mothers within ABC. Results indicated that mothers in the ABC condition showed greater increases in sensitivity and decreases in intrusiveness when compared to mothers in the control condition. No significant differences in positive regard were found. Preliminary evidence for nonlinear patterns of change in parental sensitivity and intrusiveness among mothers in ABC was also indicated. Results contribute to the growing evidence

suggesting that the first few sessions of an intervention or therapy generate the most change and provide additional support that this brief parenting intervention is effective in changing parenting behaviors.

Chapter 1

INTRODUCTION

Children who have experienced early adversity, such as neglect, are at high risk for negative outcomes across multiple domains (Ehlert, 2013). Neglected children have a greater probability of developing disorganized attachments (Carlson, 1998; van Ijzendoorn, Schuengel, & Bakermans-Kranenburg, 1999), experiencing disruptions in hypothalamic-pituitary-adrenal (HPA) axis functioning (Dozier et al., 2006; Dozier, Peloso, Lewis, Laurenceau, & Levine, 2008; Bosch et al., 2012), and they are at a greater risk for mortality due to chronic diseases (Miller, Chen, & Parker, 2011) than children in low-risk environments. Parenting interventions have shown promise in ameliorating such outcomes among children who have experienced early adversity (Barlow, Parsons, & Stewart-Brown, 2005; Juffer, Bakermans-Kranenburg, & van Ijzendoorn, 2005; Kumpfer & Alvarado, 2003). Attachment and Biobehavioral Catch-up (ABC), an intervention for high-risk parents and children that was developed at the University of Delaware, has been shown to be effective in increasing the rate of secure attachments to caregivers (Bernard et al., 2012), and in improving children's regulatory functioning (Dozier et al., 2006; Bernard, Dozier, Bick, & Gordon, in press) and emotion expression (Lind, Bernard, Ross, & Dozier, 2014) when compared to a control condition through randomized clinical trials. To further our understanding of the processes by which these changes come about through ABC, the current study examined whether changes in parenting behavior emerged and investigated trajectories of change in parenting behaviors across the 10-session intervention. Such process-

oriented research questions can provide clues as to when the most change occurs and what factors may inhibit or facilitate change in an intervention or treatment (Hayes, Miller, Hope, Heimberg & Juster, 2008; Laurenceau, Hayes, & Feldman, 2007).

1.1 The Need for Parenting Interventions

In 2012, over two million cases of child neglect, child physical abuse, and child sexual abuse were reported and investigated by a child protective service (CPS) agency within the United States (USDHHS, 2013). Of these cases, 78.3% were classified as child neglect. Children younger than one year of age had the highest victimization rate (21.9 per 1,000 children). Poverty (Lee & Goerge, 1999; Slack, Holl, McDaniel, Yoo, & Bolger, 2004), community characteristics (Ernst, Meyer, & DePanfilis, 2004), prevalence of domestic violence (Shepard & Raschick, 1999) and caregiver substance abuse (Jaudes, Ekwo, & Van Voorhis, 1995) hamper parenting abilities and place children at risk for neglect. Without intervention, parents of neglected children struggle to provide sensitive and nurturing care that is required for children's optimal development (Hildyard & Wolfe, 2002).

During the first year of life, infants form an attachment to caregivers that is based on experiences of their caregivers' availability and support, especially in times of distress (Ainsworth, Blehar, Waters, & Wall, 1978). Attachment quality varies and is associated with differences in later social, emotional (Bohlin, Hagekull, & Rydell, 2000; Urban, Carlson, Egeland, & Sroufe, 1991; Veríssimo, Santos, Fernandes, Shin, & Vaughn, 2014), and academic functioning (Jacobsen & Hofmann, 1997). Organized attachments, which include secure or insecure (i.e., avoidant and resistant)

classifications, are marked by a child behaving in a predictable way with his or her caregiver, especially when the infant is in distress (Carlson, 1998). More specifically, secure attachment, which is one form of organized attachment, is marked by a child seeking comfort from his or her parent when distressed and calming down after receiving the comfort. Alternatively, children with an insecure attachment, the second form of organized attachment, may actively avoid comfort from their caregiver when in distress or may initiate comfort from their caregiver, but have difficulty calming down.

Some infants, however, show a breakdown in their otherwise predictable behavior with the caregiver or show a lack of a coherent emotion regulation strategy that can be used during stressful situations, such as unusual behaviors (e.g., freezing, stilling) or engaging in inconsistent behaviors, which is known as a disorganized attachment (Carlson, 1998). Disorganized attachment has been linked with higher incidence of externalizing symptoms (Lyons-Ruth, Alpern, & Repacholi, 1993; Pasco Fearon & Belsky, 2011), internalizing symptoms (Brumariu & Kerns, 2013; Kerns & Brumariu, 2014; Lecompte, Moss, Cyr, & Pascuzzo, 2014), and dissociative symptoms (Carlson, 1998) than organized attachment. Links between early attachment disorganization and the development of psychopathy in adults are also beginning to surface (Schimmenti et al., 2014). Children in high-risk environments, such as children of neglecting birth parents, are more likely than children in low-risk environments to develop disorganized attachments (Cyr, Euser, Bakermans-Kranenburg, & Van Ijzendoorn, 2010).

Parental behaviors have long been ascribed as the mechanism for individual differences in children's attachment development. For instance, one important determinant of secure attachment is parental sensitivity, or the caregiver's ability to respond appropriately to his or her child's signals (Ainsworth, Blehar, Waters, & Wall, 1978). Parental frightening behaviors have explicitly been shown to predict disorganized attachment (van Ijzendoorn, Schuengel, & Bakermans-Kranenburg, 1999). Frightening behaviors can include both physical and verbal behaviors. Examples of frightening behaviors include intensely tickling a child while the caregiver ignores the child's cues to stop, threatening a child, or physically harming a child. Main and Hesse (1990) postulated that this creates a "fright without solution" paradox in infants, where the caregiver is both a source of fear and protection for the child, resulting in disorganized attachment. Insensitive parenting, or not responding appropriately to a child's signals, has also been identified as a predictor of later disorganized attachment classifications (van Ijzendoorn, Schuengel, & Bakermans-Kranenburg, 1999). These findings highlight the need for interventions aimed at improving caregiving qualities in order to disrupt the adverse pathway, especially in high-risk populations.

1.2 Attachment and Biobehavioral Catch-up

In response to the need to improve caregiving qualities in high-risk populations, several interventions have incorporated increasing caregiver sensitivity as an important target or outcome in populations of children at-risk for developing disorganized attachments (Toth, Gravener-Davis, Guild, & Cicchetti, 2013) including

interventions for parents of internationally adopted children (Juffer, Hoksbergen, Riksen-Walraven, & Kohnstamm, 1997; Juffer, Bakermans-Kranenburg, & van IJzendoorn, 2005) and maltreated children (Bernard, Dozier, Bick, Lewis-Morrarty, Lindhiem, & Carlson, 2012). Attachment and Biobehavioral Catch-up (ABC) is one intervention that aims to improve caregiving quality through promoting three intervention targets identified as playing a key role in a child's development when faced with early adversity: behaving in sensitive and delighted ways when a child is not distressed, providing nurturance when a child is distressed, and reducing frightening behavior at all times (Dozier & the Infant-Caregiver Laboratory, 2013). Parent coaches gradually incorporate intervention targets into each session's goals using various strategies, including discussion of research findings, video demonstrations of other parents and children, and video clips from previous sessions. A key strategy thought to lead to changes in parenting behaviors is parent coaches' In the Moment (ITM) commenting (Meade & Dozier, 2012). Starting in session one, parent coaches are expected to provide feedback to caregivers on behaviors that are targeted by ABC. Initially, parent coaches point out parents' naturally occurring behaviors as they meet the intervention targets. Later, once rapport has been established, parent coaches use scaffolding techniques to encourage on-target behaviors when parents fail to behave in nurturing, sensitive, and non-frightening ways. Parent coaches' quality and rate of comments are monitored during ongoing supervision. In Meade and Dozier's (2012) study investigating the association between parent coaches' frequency of on-target comments and changes in parent

behavior, parents showed greater improvements in intervention targets when their parent coaches made more frequent on-target comments than when parent coaches made less frequent on-target comments.

Through randomized clinical trials, ABC's efficacy has been shown to improve parenting qualities of caregivers with children who have faced early adversity in multiple contexts, including children in foster care and children living with neglecting birth parents. Bick and Dozier (2013) examined foster parents' sensitivity to their children's cues during a 10-minute play task; foster parents who were randomized into ABC showed greater improvements in sensitive behavior during the play interaction than foster parents who received the control condition. More recently, Meade, Dozier, Weston-Lee, and Haggerty (2014) also found improvements in caregiver quality after implementing ABC in community-based settings. Caregivers were more sensitive, less intrusive, and showed more positive regard during 7-minute play tasks with their child after participating in ABC than at pre-intervention. Persistence of these changes in caregiving qualities has also been supported (Bernard, Yarger, Meade, & Dozier, 2014). Caregivers of children adopted internationally that were randomized into ABC continued to show significantly higher levels of sensitive parenting and positive regard more than one year after completion of the intervention than caregivers in a control condition.

Studies investigating the effectiveness of ABC have also found promising results related to children's HPA axis functioning, attachment behaviors, and executive functioning. In relation to children's HPA axis functioning, post-

intervention results examining the diurnal cortisol pattern indicated that children who had undergone the ABC intervention showed a higher wake-up cortisol value and steeper slope than those assigned to a control condition (Bernard, Dozier, Bick, & Gordon, in press). Patterns of higher wake-up cortisol values and steeper slopes are normative for HPA axis functioning in typically developing children and coincide with sleep/wake patterns (Gunnar & Donzella, 2002). Changes in cortisol production have also been shown to persist for three years after intervention completion (Bernard, Hostinar, & Dozier, in press). Regarding attachment outcomes, over 50% of children whose parents were randomly assigned to ABC were found to have secure attachments as compared to 33% in the control condition (Bernard et al., 2012). Finally, Lewis-Morrarty, Dozier, Bernard, Terracciano, and Moore (2012) demonstrated long lasting change on children's executive functioning, such that six-year-olds whose foster parents had completed ABC performed more closely to children never placed in foster care on two executive functioning tasks than children who received the control condition. In sum, these findings provide evidence that ABC yields changes in caregiving quality and interrupts the negative effects of early adversity on children's physiological regulatory systems and attachment-related behaviors.

1.3 Psychotherapy Process Research

ABC has consistently shown improvements in parent and child outcomes. A necessary next step to understand efficacious treatments is to identify when and how change occurs (Kazdin, 2001; Laurenceau, Hayes, & Feldman, 2007). Multiple researchers have posited the importance of psychotherapy process research,

as it can influence the development and implementation of interventions, as well as offer insight into underlying pathological processes (Eddy, Dishion, & Stoolmiller, 1998; Greenberg, 1986; Kazdin & Nock, 2003; Laurenceau, Hayes, & Feldman, 2007). Psychotherapy process research can also provide useful information to clinicians, such as when change should occur during a treatment so that treatment approaches can be adjusted accordingly (Hayes, Hope, Heimberg, & Juster, 2008). Moreover, therapeutic change is not always a linear process (Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007). For example, in Exposure-Based Cognitive Therapy for Depression, Hayes et al. (2007) found a cubic pattern of change in patients' depression symptoms, such that patients experienced an initial decrease in symptomatology, followed by an increase, and finally, another decrease in symptoms. In addition, Tang and DeRubeis (1999) found that there were *sudden gains*, or sudden improvements in depressive symptoms within 2 sessions, demonstrating that change in depression symptoms was a nonlinear process. Finally, a psychotherapy process research approach to data collection rather than traditional pre- to post- comparisons can also create an informative context to investigate differences between responders and non-responders in treatments. To achieve a more thorough understanding of patterns of change, more intensive data collection is necessary (Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007).

In an attempt to explore when change occurs in caregivers randomized into ABC or a control condition, Lindhiem and Dozier (2010) assessed change in parental sensitivity by coding parenting behavior during intervention sessions. Findings from

this study suggested a nonlinear pattern of change in caregiver sensitivity, such that caregiver sensitivity increased from session 1 to 4, decreased from session 4 to 7, and increased from session 7 to 10. However, the intervention has since implemented ITM comments at a higher rate than in previous implementations of the intervention (Bernard, Meade, & Dozier, 2013). Currently, coaches are expected to make at least one comment per minute during each session addressing a targeted parenting behavior. As long as coaches maintain a steady rate of commenting throughout each intervention session and ITM comments are thought to be the catalyst of change in parenting behavior, linear change in parenting behavior might be expected.

Although ABC's process of intervention implementation has changed to focus on ITM commenting, Lindhiem and Dozier's (2010) previous findings might still explain how change occurs within ABC; other factors may impact a parent's ability to maintain changes in caregiving behavior as various intervention components are introduced. In the nonlinear trajectory of change in parental sensitivity, ITM commenting would still be seen as increasing sensitivity across the first 4 sessions of the intervention. Session 7 asks parents to reflect on their own experiences of being parented and how that might hold them back from behaving in sensitive ways with their own children. These discussions require a higher level of thinking and focus from parents and might subsequently impact their ability to maintain the gains in sensitivity during the first 4 sessions and/or internalize the ongoing comments the coach is making. In addition, the initial introduction of caregivers' own personal issues might be the most difficult for them to reflect upon initially, reducing their

ability to remain sensitive during their interactions with the child. Session 8 continues to discuss these issues, but may be more accepted by parents and require less attention since the initial processing of their previous experiences were already discussed. Once caregivers have finished exploring these avenues, the remaining 2 sessions are less cognitively focused. A nonlinear pattern of change in parental intrusiveness is also possible. Parent coaches do not begin commenting on intrusive or frightening behaviors during session 1. Instead, parent coaches focus on sensitivity and positive regard while building rapport until introducing comments that address intrusive behavior in session 4 and do not discuss intrusive or frightening behaviors until session 5. In this case, one might not expect to see changes in caregiver intrusiveness until session 5 when ITM comments are directly targeting such behaviors while parent coaches are simultaneously discussing the importance of decreasing the intrusive behaviors. Thus, questions remain as to when change occurs across the 10 sessions of ABC.

1.4 The Current Study

Given ABC's efficacy as an intervention improving parent and child outcomes, one necessary next step in understanding how ABC works is to focus on session-by-session change in parenting behaviors. Therefore, the current study had multiple aims and hypotheses. The first aim of the current study was to investigate whether ABC showed significant changes in parenting behaviors when compared to a control condition. More specifically, the current study hypothesized that mothers randomized into ABC would show significant increases in overall levels of parental sensitivity

(*Hypothesis 1*), significant decreases in overall levels of parental intrusiveness (*Hypothesis 2*), and significant increases in overall levels of positive regard (*Hypothesis 3*) when compared to a control condition. A second aim of the current study was to examine the rate and shape of change, as well as when the most change occurred in parenting behaviors across the 10 intervention sessions for mothers who were randomized into ABC only. Two non-linear trajectories of change were examined and hypothesized. Based on results from previous research (Lindheim & Dozier, 2010), a 3-piece model of change in parental sensitivity was hypothesized (*Hypothesis 4*) where significant increases in sensitivity would be found from session 1 to 4, significant decreases from session 4 through 7, and significant increases from session 7 to 10. Finally, a 2-piece model of change in parental intrusiveness was hypothesized (*Hypothesis 5*), where a flat slope from sessions 1 to 5 and a significant decrease in parental intrusiveness from sessions 5 to 10 was predicted.

Chapter 2

METHOD

2.1 Participants

Twenty-four mothers and their biological children participated in the current study. After consenting to the study, 13 mothers were randomized into ABC, and 11 mothers were randomized into a control condition (Developmental Education for Families; DEF). One family from ABC only completed 3 intervention sessions and one family from DEF only completed 4 intervention sessions. Post-visits for these two families were not included in the current analyses. In addition, at the time of data analyses, two ABC families and one DEF family were still participating in the intervention (up to sessions 6 and 9 for ABC, and session 8 for DEF). Intervention play data that were collected during these intervention sessions were included in the current analyses.

At the initial screening visit, mothers ranged in age from 16 to 42 years ($M = 26.59$, $SD = 5.95$). 45.8% of the mothers were African American, 47.7% were European-American, and 12.5% were Hispanic. Children ranged in age from 6.24 to 21.06 months ($M = 14.08$, $SD = 4.09$). Thirteen (54.2%) of the children were male. Household income ranged from \$0 to \$30,000 and the average income level for families was \$12,109.18 ($SD = \$9,621.24$). Table 1 presents demographic characteristics for ABC and DEF separately, as well as a test of whether these groups differed significantly on demographic characteristics.

2.2 Procedures

2.2.1 Referral and Screening Process

From December 2013 through July 2014, 945 potential participants were referred to study staff by the Division of Family Services (DFS) if they had an unsubstantiated report of neglect within the state of Delaware. Research staff then contacted potential participants via mail and telephone calls and scheduled a screening interview for interested caregivers. Forty-two screening visits were completed in mothers' homes by a member of the research staff. A brief demographic questionnaire assessing multiple factors including household income, sources of income, and age of the child was completed with the mother. Next, a 7-minute play assessment of sensitivity, intrusiveness, and positive regard was conducted and coded while in the home or shortly after completion of the home-visit. Based on results of these behavioral and demographic screenings, eligible mothers were approached to participate in the study. Eligibility criteria included: if a mother had a child between the ages of 6 and 20 months, reported household incomes of less than \$35,000, and evidenced low levels of sensitive behaviors or high levels of intrusive behaviors. These criteria were used in order to include a sample of caregivers that would benefit from an intervention targeting improvements in sensitivity and decreasing intrusive behaviors. A total of 7 mothers were excluded at the screening visit due to a household income of more than \$35,000 and a total of 3 mothers were excluded due to not meeting the parenting behavior criteria. Once consent was obtained, participants were stratified by race and then randomly assigned to receive either ABC or a control

intervention (Developmental Education for Families, DEF). Figure 1 provides a flow chart of mothers' participation throughout the study.

2.2.2 Data Collection

Demographic questionnaires were completed during the screening visit. Seven-minute play assessments were collected at screening, prior to each intervention session, and at a post visit, providing an opportunity to collect 288 play assessments. At the time of analyses, 10 mothers (76.9%) had completed all 10 intervention sessions of ABC and 9 mothers (81.8%) had completed all 10 intervention sessions of DEF. Average time to completion from session 1 to the follow-up visit for ABC was 17.9 weeks ($SD = 4.9$) and ranged from 9.7 to 26.1 weeks. Average time to completion from session 1 to the follow-up visit for DEF was 16.2 weeks ($SD = 3.6$) and ranged from 12.0 to 24.1 weeks. Time from intervention session 1 to the follow-up visit was not significantly different between groups ($t(17) = -.82, p = .42$).

2.2.3 Interventions

For both interventions, experienced interventionists adhered to an intervention manual and completed 10 weekly hour-long sessions. All sessions were video-recorded for later fidelity checks.

Experimental Intervention. Attachment and Biobehavioral Catch-up (ABC) is an intervention conducted in the home aimed at teaching parents to provide nurturance to their children when they are distressed, respond in sensitive, contingent ways when a child is not distressed, delight in their child, and behave in non-frightening ways. Specifically, sessions 1 and 2 focus on introducing the idea that children need

nurturance even when they are not providing clear cues. During sessions 3 and 4, caregivers are encouraged to behave in sensitive and delighted ways by following the child's lead. Sessions 5 and 6 help caregivers identify and appropriately respond to children's signals while introducing the idea that some play interactions can be frightening and/or intrusive. Sessions 7 and 8 are intended to provide a supportive context for caregivers to explore their own experiences of being parented and how those experiences may interfere with their ability to meet intervention targets. Sessions 9 and 10 provide an additional opportunity for parent coaches to build upon intervention targets and focus more closely on specific areas with which caregivers are still struggling, as well as a time to celebrate the caregivers' accomplishments. (For a more detailed description of each session, see Bernard, Dozier, Bick, Lewis-Morrarty, Lindhiem, & Carlson, 2012). Homework assigned each week facilitates further comprehension of intervention components focused on during the session.

Control Intervention. Developmental Education for Families (DEF) is also an intervention conducted in the home and was adapted from previous interventions shown to improve children's gross and fine motor skills, cognition and language abilities (Brooks-Gunn, Klebanov, Liaw, & Spiker, 1993). Specific activities completed with each child were adjusted according to the child's developmental level. The control intervention was developed and used in the current study to be structurally similar to ABC such that it was a manualized treatment, included 10 one-hour long intervention sessions, and had a parent coach interacting with the parent and child.

2.2.4 Measures

Demographics. A brief questionnaire assessing demographic variables was read to each mother. Variables of interest included mother and child ethnicity, mother and child date of birth, household income, sources of income, and mother's highest level of education.

Parenting Behavior. Each mother was instructed to "Play with your child as you normally would for seven minutes," with a standardized set of toys. The standardized set of toys included 2 puppets, 2 rattle balls, 2 toy telephones, a piano, chirping eggs, and a light-up ring stacker. No specific instructions regarding proximity to the child or which toys to play with were given.

A total of twelve videos were to be collected for each mother and child, including one at the consent visit, one before each intervention session, and one at the follow-up visit approximately four weeks after intervention completion. At study completion, a total of 260 videos had been collected, but 1 video was missing at the time of coding. A total of 259 videos were coded on 5-point Likert scales (1 – 5) by 11 undergraduates using an adapted version of the Observational Record of the Caregiving Environment (ORCE; NICHD ECCRN, 1996). In instances where coders were assigned more than one video from the same family, at least one month had elapsed between coding of the family and/or it was not a session adjacent to a previously coded session. Constructs of interest included sensitivity, positive regard, and intrusiveness. Coders were blind to study condition, intervention session, date of collection and study hypotheses. About 17% ($n = 44$) of the play assessments were

double-coded and used to calculate a one-way random effects intra-class correlation (ICC) for each of the scales. ICCs were .60 for sensitivity, .76 for intrusiveness, and .73 for positive regard; thus reliability between coders ranged from good to excellent.

The ORCE sensitivity scale was used to measure mothers' ability to "follow the child's lead" or respond appropriately and contingently to the child's interests, cues, and capabilities. High levels of sensitivity are marked by mothers who respond in a contingent fashion to their child's non-distressed play behaviors. For example, if a child plays keys on a toy piano, the mother also plays keys on the piano or comments on the child's playing. Low levels of sensitivity are marked by mothers who have few, if any, instances of contingent play behaviors, and are more likely to lead the interaction. At initial screening, caregivers' level of sensitivity ranged from 1 to 4 ($M = 1.96$, $SD = .75$).

The ORCE intrusiveness scale was used to measure mothers' level of intrusive or over-stimulating behavior during the play interaction. High levels of intrusiveness may be marked by mothers who disregard a child's cues for disengagement or engage in unwanted physical contact with the child. For example, mothers may push a stuffed animal into a child's face, or tickle the child. Low levels of intrusiveness are marked by mothers who have few, if any, instances in which they are verbally or physically intrusive with the child. At initial screening, mothers' level of intrusiveness ranged from 1 to 5 ($M = 3.38$, $SD = 1.34$).

The ORCE positive regard scale was used to measure mothers' positive feelings, or "delight," toward their child. High levels of positive regard are marked by

mothers who show positive feelings toward their child during most of the play interaction. For example, mothers may smile, laugh, or speak in a warm tone throughout the interaction. Low levels of positive regard are marked by few, if any, instances in which the mother shows positive feelings toward their child. At initial screening, mothers' level of positive regard ranged from 1 to 5 ($M = 3.50$, $SD = 1.06$).

Chapter 3

RESULTS

3.1 Bivariate Correlations and Data Analytic Approach

Bivariate correlations ranged from 0.07 ($p = 0.78$) to -0.70 ($p < 0.01$) between parental sensitivity and intrusiveness, from 0.22 ($p = 0.33$) to 0.76 ($p < 0.01$) between parental sensitivity and positive regard and ranged from -0.01 ($p = 0.97$) to -0.45 ($p < 0.05$) between intrusiveness and positive regard across the 10 sessions. Individual scatterplots of mothers' sensitivity, positive regard, and intrusiveness were examined to visually investigate patterns of change across time. A total of 288 videos would have been collected and coded if all mothers completed all intervention sessions. However, at the time of data analyses, 259, or 90% of videos were collected and coded, resulting in 10% missing data. Therefore, full information maximum likelihood was used to account for the missing data, which allows for the use of all available data and provides an unbiased estimate of parameters when data is missing at random (Enders & Bandalos, 2001).

Hierarchical linear growth models were used to estimate change in mothers' sensitivity, intrusiveness, and positive regard after completion of the interventions using HLM software (HLM7 Student Version; Raudenbush, Bryk, Cheong, Congdon, & DeToit, 2011) which allows sessions to be nested within individuals. Each outcome (sensitivity, intrusiveness, and positive regard) was entered as the dependent variable. The level-1 (within-persons) variable was session. In all analyses, both the pre-intervention home-visit play assessment and the play assessment immediately

before the first intervention session were coded as “0” so that HLM calculated an average level of parenting behavior before the intervention started. Subsequent coding for play assessments was based on the previous intervention session completed (i.e., a play assessment collected prior to beginning intervention session 5 was coded as 4). The post-visit was coded as a measure of session 10’s parenting quality. Next, the sessions were scaled in order to represent the change in the outcome across a one unit change in time and were spaced equally across this interval (i.e., divided by 10 to represent the 10 assessments). This allowed for an assessment of the total average change in the outcome across the full intervention period. The level-2 variable (between-persons) was intervention group. Linear growth models were specified for sensitivity, intrusiveness, and positive regard, separately. Models were estimated using the following equations:

Level-1 Model: $\text{Behavior}_{ti} = \pi_{0i} + \pi_{1i} * (\text{SessionScaled}_{ti}) + e_{ti}$

Level-2 Model: $\pi_{0i} = \beta_{00} + \beta_{01} * (\text{Intervention}_i) + r_{0i}$

$$\pi_{1i} = \beta_{10} + \beta_{11} * (\text{Intervention}_i) + r_{1i}$$

In the level-1 model, Behavior_{ti} represents the parenting behavior outcome (sensitivity, intrusiveness, or positive regard) at session t for each mother i . π_{0i} is the intercept or model-implied baseline level of parenting behavior (averaging both play assessments from the consent visit and pre-intervention 1 visit). π_{1i} is slope coefficient for the total change in parenting behavior across the 10 sessions. e_{ti} is the residual variance of mother i ’s parenting behavior at time t from her predicted growth trajectory. In the level-2 model, the within-persons intercept, π_{0i} , is estimated by

adding β_{00} which represents the model-implied, fixed effect, baseline level of parenting behavior for DEF, β_{01} which represents the fixed effect difference between ABC and DEF at baseline levels of parenting behavior, and r_{0i} which represents the deviance for individual i from the predicted baseline level of parenting behavior. Finally, the within-persons slope, π_{1i} , is estimated by adding β_{10} , the fixed effect change in parenting behavior across the 10 sessions for the control group, β_{11} , the fixed effect difference between ABC and DEF's average parenting behavior rate of change across the 10 sessions, and r_{1i} which is the deviance for individual i from the average slope.

3.2 Change in Sensitivity

As shown in Table 2, the intervention groups did not differ significantly at baseline levels of sensitivity (DEF = 2.34, ABC = 2.15; $p = 0.45$). As hypothesized, at the end of the 10 intervention sessions, mothers who participated in ABC were significantly more sensitive than mothers who participated in DEF. In addition, mothers in ABC showed a steeper rate of change in sensitivity than mothers in DEF. More specifically, DEF was estimated to show a 0.16 unit increase in sensitivity (β_{10}) across the 10 sessions, whereas ABC was estimated to show a 1.09 unit increase in sensitivity ($\beta_{10} + \beta_{11}$) across the 10 sessions and these were significantly different ($p = 0.02$). Therefore, our hypothesis that mothers who participated in ABC would show significant increases in parental sensitivity when compared to a control condition was supported.

3.3 Change in Intrusiveness

As shown in Table 3, the intervention groups did not differ significantly at baseline levels of intrusiveness (DEF = 2.83, ABC = 3.15; $p = 0.32$). Again, as hypothesized, at the end of the 10 sessions, mothers who participated in ABC were less intrusive than mothers who participated in DEF. In addition, mothers in ABC showed a steeper rate of change in intrusiveness than mothers in DEF. At the end of the 10 intervention sessions, DEF was estimated to show a 0.22 unit decrease in intrusiveness (β_{10}) across the 10 sessions, whereas ABC was estimated to show a 1.2 unit decrease in intrusiveness ($\beta_{10} + \beta_{11}$) across the 10 sessions and these were significantly different ($p = 0.03$). Therefore, our hypothesis that ABC would show significant decreases in parental intrusiveness when compared to a control intervention was supported.

3.4 Change in Positive Regard

As shown in Table 4, Intervention groups did not differ significantly at baseline levels of positive regard (DEF = 3.57, ABC = 3.38; $p = 0.61$). At the end of the 10 intervention sessions, DEF showed a 0.06 unit decrease in positive regard, whereas ABC showed a 0.25 unit decrease in positive regard ($p = 0.59$). There were no significant differences in mothers' positive regard between mothers who participated in ABC and mothers who participated in DEF.

3.5 Piecewise Analysis of Sensitivity

Next, piecewise linear growth modeling, which allowed for the estimation of separate growth trajectories between different groupings of sessions (Raudenbush &

Bryk, 2002), was used to explore two nonlinear patterns of change across the 10 sessions for mothers who were randomized into ABC only.

The first piecewise model investigated whether there were 3 different stages of change in parental sensitivity within the intervention group. More specifically, we investigated whether there were increases in sensitivity from session 1 to 4, decreases from session 4 through 7, and increases from session 7 to 10. Intervention sessions were recoded to represent the three pieces of the linear growth model. More specifically, piece 1 was coded with consent and pre-intervention 1 as 0, session 1 as 1, session 2 as 2, and session 3 as 3, and sessions 4 through 10 as 4. Piece 2 was coded with consent through intervention session 4 as 0, session 5 as 1, session 6 as 2, and sessions 3 through 10 as 3. Piece 3 was coded with the consent visit through session 7 as 0, session 8 as 1, session 9 as 2, and session 10 as 3. The model was estimated using the following equations:

Level-1 Model: $Sensitivity_{ti} = \pi_{0i} + \pi_{1i}*(Piece1_{ti}) + \pi_{2i}*(Piece2_{ti}) + \pi_{3i}*(Piece3_{ti}) + e_{ti}$

Level-2 Model: $\pi_{0i} = \beta_{00} + r_{0i}$

$$\pi_{1i} = \beta_{10} + r_{1i}$$

$$\pi_{2i} = \beta_{20} + r_{2i}$$

$$\pi_{3i} = \beta_{30} + r_{3i}$$

In the level-1 model, $Sensitivity_{ti}$ represents sensitivity at session t for each mother i . π_{0i} is the intercept or model-implied baseline level of sensitivity. π_{1i} is the slope coefficient for the change in sensitivity for a 1-unit increase in time within the

first piece of treatment (sessions 1 through 4). π_{2i} is the slope coefficient for the change in sensitivity for a 1-unit increase in time within the second piece of treatment (sessions 5 through 7). π_{3i} is the slope coefficient for the change in sensitivity for a 1-unit increase in time within the third piece of treatment (sessions 7 through 10). e_{it} is the residual variance of participant i 's sensitivity at time t from their predicted growth trajectory. In the level-2 model, the within-persons intercept, π_{0i} , is estimated by adding β_{00} which represents the model-implied, fixed effect, baseline level of sensitivity for ABC and r_{0i} which represents the deviance for individual i from the predicted baseline level of sensitivity. Next, the within-persons slope of Piece 1, π_{1i} , is estimated by adding β_{10} , the fixed effect change in parenting behavior across the first 4 sessions for ABC and r_{1i} which is the deviance for individual i from the average slope across the first 4 sessions. The within-persons slope of Piece 2, π_{2i} , is estimated by adding β_{20} , the fixed effect change in parenting behavior across sessions 5 through 7 for ABC and r_{2i} which is the deviance for individual i from the average slope across sessions 5 through 7. The within-persons slope of Piece 3, π_{3i} , is estimated by adding β_{30} , the fixed effect change in parenting behavior across sessions 8 through 10 for ABC and r_{3i} which is the deviance for individual i from the average slope across sessions 8 through 10.

The rate of change, or slope, for the first piece of the model was significantly different from zero ($\beta_{10} = 0.24, p < 0.01$). The second and third pieces did not show significant rates of change that were significantly different from zero ($\beta_{20} = -0.05, p = 0.62$ and $\beta_{30} = 0.14, p = 0.26$, respectively). In order to test whether the slopes were

significantly different from each other, a chi-square test of differences was completed using the hypothesis testing function within HLM. Table 5 shows results of the piecewise linear growth model and hypotheses tests. Figure 2 depicts model-estimated change across time for mother sensitivity. Results indicate that mothers have a steeper increase in sensitivity during the first piece of treatment than the second piece of treatment, but not a significantly steeper increase than the third piece of treatment. Thus, our hypothesis was partially supported, such that the first four sessions showed the steepest rate of change in sensitivity when compared to the second piece, but not the third.

3.6 Piecewise Analysis of Intrusiveness

The second and final piecewise model explored whether intrusiveness had a flat slope until the intervention component was introduced in intervention 5, at which time it was also targeted through parent coaches' comments. Thus, we investigated whether the slope from play assessments collected from sessions 1 through 5 was different than the slope from play assessments collected from sessions 5 through 10. Intervention sessions were recoded to represent the two pieces of the linear growth model. More specifically, piece 1 was coded with consent and pre-intervention 1 as 0, session 1 as 1, session 2 as 2, session 3 as 3, 4 as 4, and sessions 5 through 10 as 5. Piece 2 was coded with consent through intervention session 5 as 0, session 6 as 1, session 7 as 2, and so on until intervention session 10 was coded as 5. The model was estimated using the following equations:

Level-1 Model:
$$\text{Intrusiveness}_{ii} = \pi_{0i} + \pi_{1i} * (\text{Piece1}_{ii}) + \pi_{2i} * (\text{Piece2}_{ii}) + e_{ii}$$

Level-2 Model: $\pi_{0i} = \beta_{00} + r_{0i}$

$$\pi_{1i} = \beta_{10} + r_{1i}$$

$$\pi_{2i} = \beta_{20} + r_{2i}$$

In the level-1 model, $\text{Intrusiveness}_{it}$ represents the intrusiveness at session t for each mother i . π_{0i} is the intercept or model-implied baseline level of intrusiveness. π_{1i} is the slope coefficient for the amount of change in intrusiveness after a 1-unit increase in time across the first phase of treatment (sessions 1 through 5). π_{2i} is the slope coefficient for the amount of change in intrusiveness after a 1-unit increase in time across the second phase of treatment (sessions 5 through 10). e_{it} is the residual variance of participant i 's intrusiveness at time t from their predicted growth trajectory. In the level-2 model, the within-persons intercept, π_{0i} , is estimated by adding β_{00} which represents the model-implied fixed effect and r_{0i} which represents the deviance for individual i from the predicted baseline level of intrusiveness. Next, the within-persons slope of Phase 1, π_{1i} , is estimated by adding β_{10} , the fixed effect change in parenting behavior across the first 5 sessions for mothers in ABC and r_{1i} which is the deviance for individual i from the average slope across the first 5 sessions. Finally, the within-persons slope of Phase 2, π_{2i} , is estimated by adding β_{20} , the fixed effect change in parenting behavior across sessions 5 through 10 for mothers in ABC and r_{2i} which is the deviance for individual i from the average slope across sessions 5 through 10.

The rate of change, or slope, for the first piece of the model was significantly different from zero ($\beta_{10} = -0.26, p < 0.01$). The second piece did not show a

significant rate of change in parental intrusiveness ($\beta_{20} = -0.02, p = 0.80$). In order to test whether the slopes were significantly different from each other, a chi-square test of differences was again conducted using the hypothesis testing function within HLM. Table 6 shows results of the piecewise linear growth model and hypothesis test. Figure 3 depicts change across time for parental intrusiveness. Results indicate that mothers have a steeper decline during the first piece of treatment when compared to the second piece of treatment.

Table 1

<i>Demographic Characteristics by Intervention Group</i>			
Variable	ABC (<i>n</i> = 13)	DEF (<i>n</i> = 11)	Test of difference
<i>Caregiver Race</i>			$\chi^2 (2, 24) = 1.87, p = .39$
African-American	38.5 (5)	54.5 (6)	
Caucasian	53.8 (7)	27.3 (3)	
Hispanic	7.7 (1)	18.2 (2)	
<i>Caregiver Age</i>	24.70 (4.19)	28.82 (7.09)	$t (22) = 1.77, p = .09$
<i>Child Age</i>	13.18 (4.38)	15.14 (3.64)	$t (22) = 1.18, p = .25$
<i>Child Gender</i>			$\chi^2 (2, 24) = .62, p = .43$
Male	61.5 (8)	45.5 (5)	
Female	38.5 (5)	54.5 (6)	
<i>Household Income</i>	\$11,015.54 (\$8,438.78)	\$13,688.89 (\$11,463.91)	$t (22) = .63, p = .54$
<i>Household Education</i>			$\chi^2 (2, 24) = 1.58, p = .66$
Did Not Complete High School	30.8 (4)	18.2 (2)	
High School or GED	46.2 (6)	36.4 (4)	
Some College	15.4 (2)	36.4 (4)	
College or Technical School	7.7 (1)	9.1 (1)	

Table 2

Parameter Estimates for Linear Growth Model of Sensitivity as a Function of Intervention Group

Fixed Effects	Coefficient	SE	<i>t</i> -ratio	<i>p</i> -value
DEF Baseline Level of Sensitivity β_{00}	2.34	0.18	13.03	< 0.001
ABC Baseline Difference Level of Sensitivity β_{01}	-0.19	0.24	-0.76	0.45
DEF Slope at Session 10 β_{10}	0.16	0.26	0.64	0.53
ABC Slope Difference at Session 10 β_{11}	0.93	0.35	2.64	0.02
Level-2 Random Effects	<i>SD</i>	Variance	<i>p</i> -value	
Intercept Variance r_{0i}	0.41	0.17	0.004	
Slope Variance r_{1i}	0.25	0.06	0.35	

Table 3

Parameter Estimates for Linear Growth Model of Intrusiveness as a Function of Intervention Group

Fixed Effects	Coefficient	SE	<i>t</i> -ratio	<i>p</i> -value
DEF Baseline Level of Intrusiveness β_{00}	2.83	0.23	12.23	<0.001
ABC Baseline Difference Level of Intrusiveness β_{01}	0.32	0.32	1.01	0.32
DEF Slope at Session 10 β_{10}	-0.22	0.30	-0.72	0.48
ABC Slope Difference at Session 10 β_{11}	-0.98	0.42	-2.37	0.03
Level-2 Random Effects	<i>SD</i>	Variance	<i>p</i> -value	
Intercept Variance r_{0i}	0.55	0.31	0.01	
Slope Variance r_{1i}	0.06	0.004	>0.50	

Table 4

Parameter Estimates for Linear Growth Model of Positive Regard as a Function of Intervention Group

Fixed Effects	Coefficient	SE	<i>t</i> -ratio	<i>p</i> -value
DEF Baseline Level of Positive Regard β_{00}	3.57	0.28	12.87	<0.001
ABC Baseline Difference Level of Positive Regard β_{01}	-0.19	0.38	-0.52	0.61
DEF Slope at Session 10 β_{10}	-0.06	0.26	-0.25	0.81
ABC Slope Difference at Session 10 β_{11}	-0.19	0.35	-0.55	0.59
Level-2 Random Effects	<i>SD</i>	Variance	<i>p</i> -value	
Intercept Variance r_{0i}	0.80	0.65	<0.001	
Slope Variance r_{1i}	0.13	0.02	0.44	

Table 5

Piecewise Linear Growth Model of Sensitivity and Slope Comparisons for Caregivers in ABC

Fixed Effects	Coefficient	SE	<i>t</i> -ratio	<i>p</i> -value
Baseline Level of Sensitivity β_{00}	1.98	0.19	10.35	<0.001
Piece 1 Slope β_{10}	0.24	0.06	3.86	0.002
Piece 2 Slope β_{20}	-0.05	0.10	-0.51	0.62
Piece 3 Slope β_{30}	0.14	0.12	1.17	0.26
Slope Comparisons	Estimate	SE	χ^2	<i>p</i> -value
Piece 1 versus Piece 2	-0.29	0.14	4.20	0.04
Piece 1 versus Piece 3	-0.10	0.13	0.54	>0.50
Piece 2 versus Piece 3	0.19	0.20	0.93	>0.50

Table 6

Piecewise Linear Growth Model of Intrusiveness and Slope Comparisons for Caregivers in ABC

Fixed Effects	Coefficient	SE	<i>t</i> -ratio	<i>p</i> -value
Baseline Level of Intrusiveness β_{00}	3.37	0.26	12.87	<0.001
Piece 1 Slope β_{10}	-0.26	0.07	-3.72	0.003
Piece 2 Slope β_{20}	-0.02	0.06	-0.26	0.80
Slope Comparisons	Estimate	SE	χ^2	<i>p</i> -value
Piece 1 versus Piece 2	0.25	0.11	4.70	0.03

Figure 1

Flow chart of mothers' participation during the study

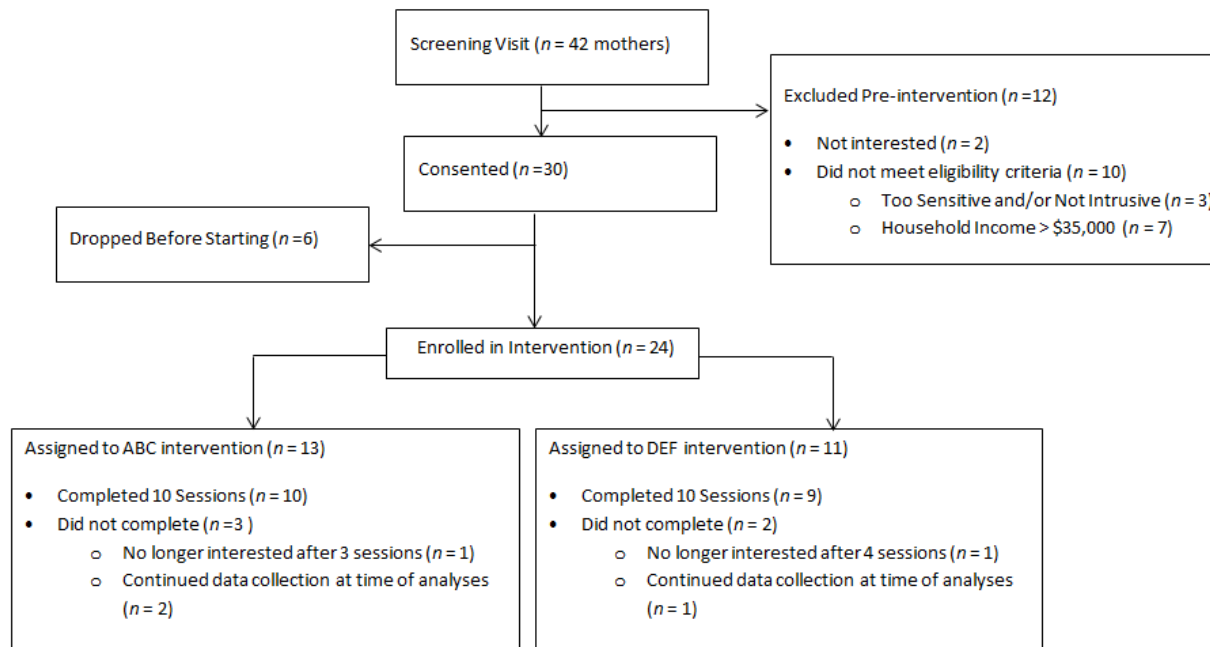
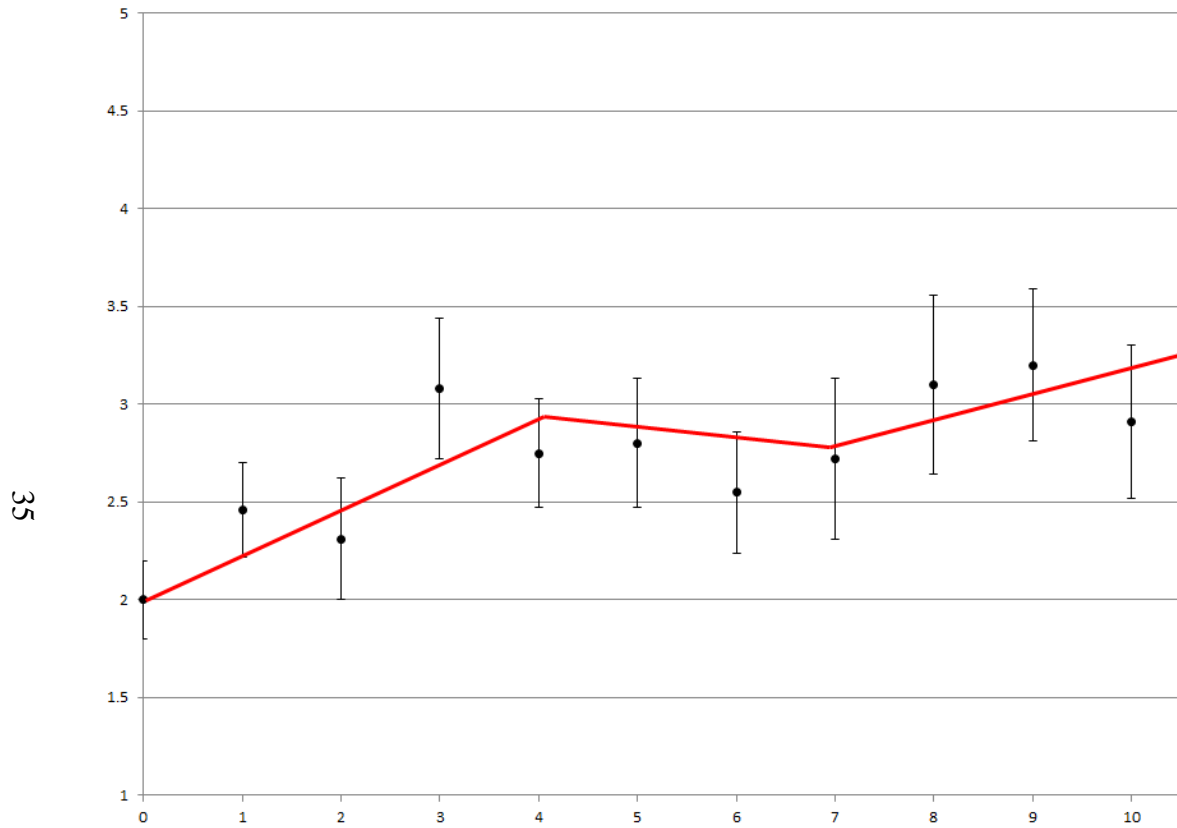


Figure 2

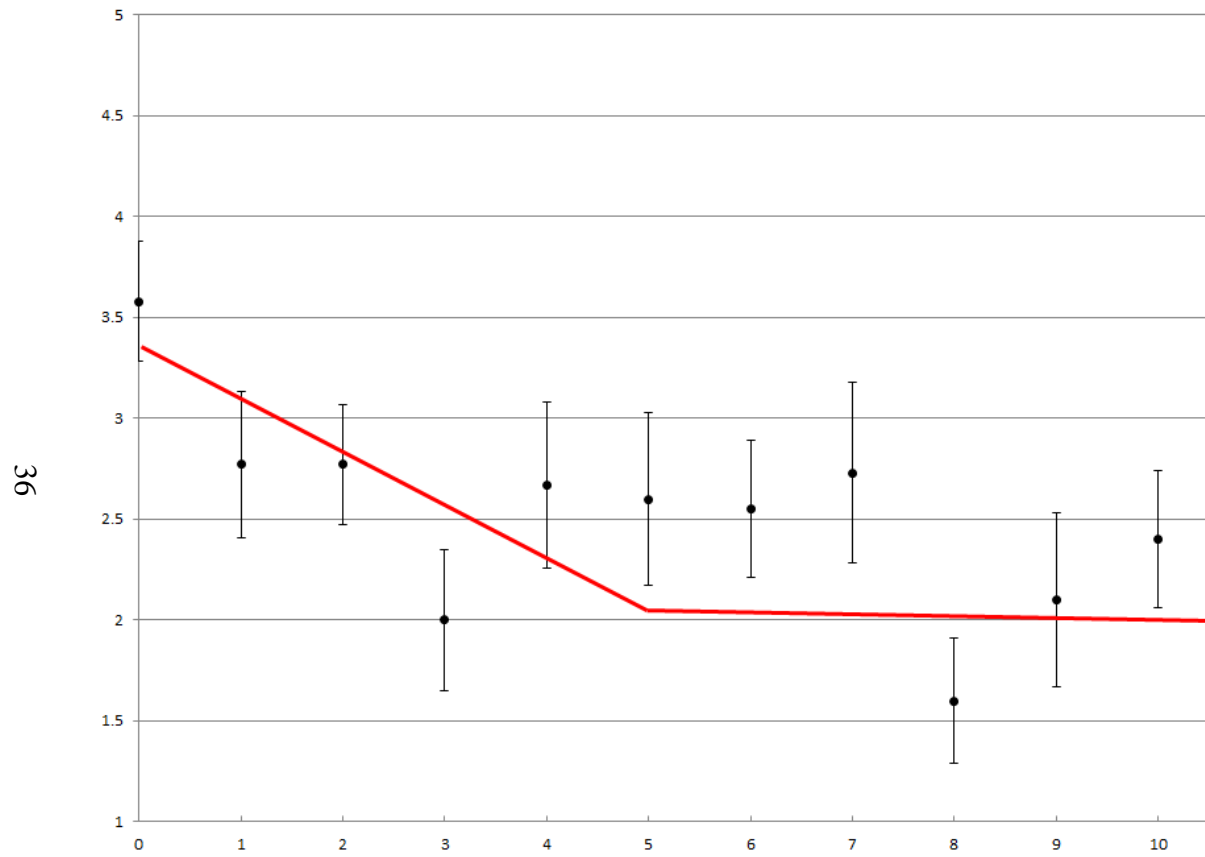
Session-by-session change in parental sensitivity for mothers in ABC only



Note. The red line depicts the HLM model-estimated slopes for pieces 1, 2, and 3.

Figure 3

Session-by-session change in parental intrusiveness for mothers in ABC only



Note. The red line depicts the HLM model-estimated slopes for pieces 1 and 2.

Chapter 4

DISCUSSION

Interventions that target improving parenting quality are especially important for children with neglecting birth parents in order to disrupt negative developmental trajectories. Further, once treatment efficacy has been established, an important next step in understanding how treatments work is investigating when change occurs (Laurenceau, Hayes, & Feldman, 2007). Therefore, the current study was developed to begin to answer these questions in a CPS-involved sample of mothers who were randomized into Attachment and Biobehavioral Catch-up or a control condition.

The current study had multiple aims and hypotheses. The first aim of the current study was to investigate whether ABC was successful in changing parenting behaviors according to ABC's intervention targets (i.e., sensitivity, intrusiveness, and positive regard). More specifically, the current study hypothesized that mothers in the ABC intervention would show greater increases in overall parental sensitivity (Hypothesis 1), greater decreases in overall parental intrusiveness (Hypothesis 2) and greater increases in overall positive regard (Hypothesis 3) over the course of the 10 sessions when compared to a control condition. The second aim of the current study was to investigate two possible nonlinear trajectories of change by examining the rate and shape of change in sensitivity and intrusiveness across ABC's 10 intervention sessions, as well as by comparing the slopes between each of the model's pieces to determine when the most change occurred. It was hypothesized that sensitivity would

change according to a nonlinear, 3-piece model (Hypothesis 4), where there would be a significant increase from session 1 to 4, a significant decrease from session 4 to 7, and a significant increase from session 7 to 10. In addition, it was hypothesized that parental intrusiveness would change according to a non-linear, 2-piece model (Hypothesis 5), where a flat slope would remain until session 5, after which a significant decrease in intrusive behavior would be seen.

Results of the current study provided support for the first aim. More specifically, support for Hypotheses 1 and 2 were demonstrated. Mothers who were randomized into ABC showed steeper rates of change in parental sensitivity and intrusiveness by the end of the 10 intervention sessions when compared to a control condition. However, Hypothesis 3 was not supported; there were no significant differences between conditions for the overall amount of change in positive regard at the end of the 10 intervention sessions. Instead, results suggested that both ABC and the control condition's slopes across the 10 sessions remained relatively flat.

Results of the current study provided partial support for the second aim of the current study regarding the rate and shape of change in parental sensitivity across the 10 sessions of ABC, as well as that change was a nonlinear process. Hypothesis 4 was partially supported; significant increases in sensitivity were found within the first piece of the 3-piece model (i.e., from sessions 1 to 4). However, results did not provide support for a significant decrease in sensitivity in piece 2 (session 4 to 7) or a significant increase in sensitivity in piece 3 (session 7 to 10). Moreover, comparisons between the slopes of each of the three pieces revealed that the first piece of the 3-

piece model showed a steeper rate of change than the second piece. Further, results suggest that parental sensitivity followed a nonlinear pattern of change given that the most change in sensitivity occurred within the first piece of the 3-piece model.

In contrast to Hypothesis 5's prediction that the first piece of the 2-piece model would show a flat slope until session 5 and then significant decreases in intrusiveness would be found from sessions 5 to 10, the first piece of the 2-piece model showed a significant decrease in parental intrusiveness whereas the second piece showed a flat slope. Further, comparisons between the slopes of the 2 pieces revealed that the first piece had the steeper slope or rate of change in parental intrusiveness. Thus, results showed support for a nonlinear pattern of change across the 10 intervention sessions of ABC, although the specific timing of when change would occur was not initially predicted. One possible explanation for these unexpected findings is that as mothers are becoming more sensitive, they are engaging in more appropriate behaviors with their children and subsequently behaving in less intrusive ways.

Findings from the current study add to the growing evidence that ABC is efficacious in improving parenting behaviors among high-risk caregivers (Bick & Dozier, 2013; Meade, Dozier, Weston-Lee, and Haggerty, 2014), and that brief interventions are effective in changing these parenting behaviors (Bakermans-Kranenburg, van Ijzendoorn, & Juffer, 2003). Furthermore, results from the current study are in line with previous research on therapies with children and families that found the most change occurs early in treatment (Eddy, Dishion, & Stoolmiller, 1998; Moras, Telfer, & Barolow, 1993). Finally, the current findings echo other researchers'

claim that change is not always a linear process (Collins, 2006; Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007) and has implications for treatment providers and developers (Hayes, Hope, Heimberg, & Juster, 2008). Clinicians can use the current findings as a point of reference for when parenting behavior is generally expected to change. If change is not seen within the first few sessions, adjustments to the therapeutic approach can be made if necessary.

4.1 Strengths, Limitations, and Future Directions

The current study had several strengths that many studies of treatment efficacy do not often have. Of note, the current study used an intensive longitudinal design to collect session-by-session data with 259 coded videos. This not only allowed for an exploration of within-person change across time rather than focusing on average change once the intervention was completed, but also an opportunity to explore the temporal process by which change in parenting behavior occurred and when change occurred. In addition, both random assignment and the use of a control intervention provide stronger support that the intervention differences at the end of the 10 sessions were due to ABC intervention effects rather than due to common factors between both interventions (i.e., duration, time with an interventionist, etc.). Furthermore, the current study was successful in changing parenting behaviors among a very high-risk sample of mothers, highlighting the utility of this home-based intervention. Finally, the current study used an observational coding method of assessing caregiving behavior rather than a self-report measure. This approach allowed for a more reliable assessment of change in parental behavior across each session than a self-report

measure of parenting behaviors and assured the constructs that were being assessed were coded similarly across families.

Although there are several strengths to the current study, there are also important limitations. Even though a large number of videos were collected and coded for each mother, the current study was still limited by a small sample size of mothers that participated in each intervention. This constrained the ability to look at whether there were differences between completers versus non-completers and responders versus non-responders. In addition, the current study was unable to investigate possible moderators of change to explain these differences.

In the future, the use of dismantling studies in combination with an intensive longitudinal design will help clarify what is leading to the change in parenting behavior. Additional studies should also investigate characteristics of caregivers that might preclude change in parenting behaviors such as psychopathology, attachment state of mind, and the number of negative life events that occur during intervention implementation.

4.2 Conclusions

Overall, the current findings add to evidence that Attachment and Biobehavioral Catch-up is efficacious in changing parenting quality among high-risk mothers. In addition, the greatest change in parenting behaviors was found to occur within the first few sessions of the intervention and provided preliminary evidence that change within ABC is a nonlinear process.

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Appendix
IRB APPROVAL LETTER



RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
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DATE: November 21, 2014

TO: Mary Dozier, PhD
FROM: University of Delaware IRB

STUDY TITLE: [511457-6] Differential DNA Methylation as a Function of a Parenting Intervention: A Randomized Clinical Trial

SUBMISSION TYPE: Continuing Review/Progress Report

ACTION: APPROVED
APPROVAL DATE: November 21, 2014
EXPIRATION DATE: November 25, 2015
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # (9)

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.