# The Early Start Denver Model: Outcomes and Moderators of an Intervention for Toddlers with Autism

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**Abstract**

Effective treatment for young children with autism spectrum disorder (ASD) requires identification and development of effective treatments that address the unique needs of toddlers with ASD as young as 18 months old. The current study aims to expand the current state of the research on the Early Start Denver Model (ESDM) as an effective intervention for toddlers with ASD by examining both treatment outcomes as well as moderators of those outcomes. Three treatment outcomes were examined, each relating closely to the conceptualization and goals of the ESDM and highlighting the anticipated relationship between general areas of development and specific behaviors: 1) shared positive affect, 2) gesture use, and 3) receptive and expressive language). Moderators included initial levels of participant's social orienting skills, response to joint attention, and object use. The current study is a randomized, controlled trial that included forty-eight children diagnosed with ASD between 18 and 30 months of age who were randomly assigned to one of two groups: ESDM or referral to community providers for intervention commonly available in the community. Results included main effects of ESDM treatment for communication outcomes, specifically receptive language (after 1 and 2 years of intervention) and expressive language (after 2 years of intervention). Additionally, significant moderation of treatment effects was noted, particularly response to joint attention and object use moderating language outcomes and both high and low initial levels of object use moderating several child outcomes. Continued focus on which children with ASD and their families benefit from ESDM intervention as well as identification of crucial treatment components will be critical for the dissemination and delivery of the ESDM beyond the research setting to the community at large.

**I. Overview**

Given the development of better diagnostic tools and a greater level of professional awareness and knowledge, autism spectrum disorders (ASD) can now be identified among children ages two and younger (Chawarska, Klin, Paul, & Volkmar, 2007; Cox, Klein, Charman, Baird, Baron-Cohen, Swettenham, Drew, & Wheelright, 1999). Such advances in early identification are essential for access to and implementation of early intervention and, as a result, better outcomes for children with ASD (Harris & Handleman, 2000; Smith & Dillenbeck, 2006). For example, Goldstein (2002) suggests that the prevalence of nonverbal children with ASD is decreasing as early intervention becomes more accessible. While some researchers have examined variability in outcomes among children diagnosed as young as 30 months of age (Harris & Handleman, 2000; Landa, Holman, & Garrett-Mayer, 2007; Turner & Stone, 2007), there is a lack of published outcome data on intervention models or treatment effectiveness for children who begin intervention by or before 30 months. Recently, intervention approaches targeting toddlers with ASD have been developed (Chandler et al., 2002; Dawson et al., 2010; Green et al., 2002; Itzchak et al., 2008); however, a lack of published randomized studies of toddler interventions exists. In addition, some teaching procedures that are considered appropriate for older children (e.g., 40 hours per week of adult-directed treatment and repetitive drill practice while sitting at a table) are considered developmentally inappropriate for toddlers. For these reasons, it is important to investigate the effectiveness of early intervention methods that are appropriately designed for toddlers with ASD (Wallace & Rogers, 2010).

This dissertation is unique in that it is the first randomized controlled trial of early intervention with toddlers with ASD. Additionally, this paper addresses the need for information regarding specific factors and individual characteristics that determine differential response to intervention in this population. In regards to examining treatment effectiveness, the current study is unique both in its methodological rigor (i.e., longitudinal design including gold-standard diagnostic criteria, randomized group assignment, evaluation by naïve examiners, and fidelity monitoring for the implementation of a manualized intervention) and its target population (i.e., children with ASD as young as 18 months old). Results have important implications for future research related to the design, evaluation, and individualization of early intervention for toddlers with ASD. Further, this project is the first of its kind to examine moderators of early intervention in young children with ASD over a two-year period.

This paper first provides a brief overview of ASD including current diagnostic criteria as well as issues related to prevalence and early diagnosis. Next, the literature pertaining to the early core characteristics of ASD (i.e., reciprocal social behaviors and communication skills) is discussed. Then early intervention in ASD is reviewed, including two areas of research that may have important implications for treatment design and implementation, namely brain development and environmental influences on learning. Next, a summary of the ESDM intervention is presented and a brief overview of the ESDM treatment goals and moderators are discussed. Finally, the methods and results are presented, followed by a discussion of the findings.

## II. Autism Spectrum Disorders: Brief Description

Autism Spectrum Disorders (ASD) is a term used to describe a group of neurodevelopmental disorders including Autistic Disorder, Asperger's Syndrome, and Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS). ASD is estimated to occur at a rate of approximately 1 in 88 (CDC, 2012), compared to prevalence reports in the 1960s and 1970s estimating 5 in 10,000 (Newschaffer et al., 2007). The apparent increase in prevalence has led to much public and scientific debate as to the possible causes. Some suggest that vaccines and thimerosol, a mercury containing preservative in vaccines, may be responsible for the rising rates of the disorder. However, to date, there has been no scientific evidence to support this link (Miller & Reynolds, 2009). Instead increased prevalence rates appear to be related to a number of other factors including the broadening definition of ASD (particularly at the less severe end of the spectrum) and an increasing use of the diagnosis to receive federally mandated intervention programs (Newschaffer et al., 2007; Rutter, 2005). Additionally, earlier identification and diagnosis of ASD among children two years old and younger may help explain the increase in prevalence rates (Fombonne, 2009). Across the years, gender rations of ASD have remained consistent. ASD affects three to four males to every one female (4:1), and research indicates that when females do have a diagnosis of ASD they tend to be more severely affected in terms of cognitive impairments and severity of ASD symptoms (Fombonne et al., 1998).

The current diagnostic criteria for ASD include impairments in three core areas of functioning: reciprocal social interactions, communication skills, and restricted and/or repetitive interests and behaviors *(DSM-IV-Text Revision;* American Psychiatric Association, 2000). The onset of these symptoms typically occurs before the age of three years old. Examples of social deficits in ASD include a lack of developmentally appropriate peer relationships, limited pleasure in shared interactions, and difficulties with nonverbal interaction skills including inconsistent eye contact and a limited range of facial expressions. In the area of communication skills, individuals with ASD often demonstrate delays in language that are not compensated for by gesture use, difficulties with reciprocal conversation, stereotyped or idiosyncratic language, and limited imitative social play as well as impairments in functional and creative play. Finally, examples of repetitive behaviors and interests in ASD include intense or abnormal interests, insistence on adhering to routines or rituals, stereotyped or repetitive motor mannerisms (e.g., hand flapping), and a preoccupation with parts of objects.

ASD is extremely heterogeneous in its presentation. The constellation of symptoms for any given individual can vary widely and is often influenced by chronological age and developmental level. For example, epidemiological studies indicate that 65% of individuals diagnosed with ASD have comorbid intellectual disability while the remainder have general cognitive abilities in the average to above average range (Fombonne, 2003). Additional and notable variability exists in the area of language abilities. While some individuals with ASD are verbally fluent and meet their language developmental milestones on time, 30-50% of children with ASD are reported to have significant impairments in language and/or remain nonverbal into adulthood (Howlin, Goode, Hutton, & Rutter, 2004). However, additional research suggests that the proportion of nonverbal children with ASD is less than 20% for those children who are referred for evaluation of ASD at early ages (Lord et al., 2004), illustrating the importance of early detection and diagnosis.

In the United States, the average age of diagnosis for ASD ranges from 3 years to 5 years, 8 months depending on sample characteristics and geographical location (e.g., Autism and Developmental Disabilities Monitoring Network, 2009; Barbaro & Dissanayake, 2009; Mandell et al., 2010; Shattuck et al., 2009). Individual characteristics that may contribute to an earlier diagnosis include being male, having an IQ score at or below 70, and having a history of a developmental regression (Shattuck et al., 2009). Despite an average age of diagnosis in the preschool years, retrospective parent report often indicates that initial concerns arise by 15 to 18 months of age (Howlin & Asgharian, 1999; Wiggins, Baio, & Rice, 2006) and studies of home videotapes reveal that symptoms of ASD may be evident by 12 months of age (Adrien et al., 1991; 1992; Baranek, 1999; Osterling & Dawson, 1994; Werner et al., 2000). Additionally, prospective studies of high-risk infant siblings of individuals with ASD reveal new insights about the identification and developmental time course of core symptoms of ASD (e.g., Zwaigenbaum et al., 2005). Results from these studies will be critical in facilitating earlier identification and diagnosis of ASD as well as providing key evidence for effective treatment design and implementation. In the next section, the core characteristics of ASD will be discussed with an emphasis on their respective developmental time courses.

## III. Early Core Characteristics of Autism Spectrum Disorders

As mentioned above, the current diagnostic criteria for ASD include impairments in social interaction, communication, and repetitive or restricted behaviors or interests. Because the focus of this review is on young children with ASD, an emphasis will be placed on characteristics in the domains of social interaction and communication, which are the most prominent at young ages in this population (Bryson, Zwaigenbaum, & Roberts, 2004; Ozonoff et al., 2010; Stone et al., 1994). Areas of development within these two domains include social reciprocity, play skills, gesture use, and receptive and expressive language, all of which are components of the ESDM curriculum and are considered essential to the diagnostic assessment for ASD in children younger than 2 years old (Zwaigenbaum et al., 2009).

### A. Social Interaction and Reciprocity

Social impairment is an enduring feature of ASD with important implications for other areas of development including gesture use, language acquisition, and adaptive functioning (Mundy et al., 1999; Sigman & Ruskin, 1999). Deficits in social skills have many manifestations including limited shared attention, expression of positive affect, eye contact, reciprocal social smiling, social interest, social approach, and emotional responsiveness and imitation (Dawson & Adams, 1984; Dilavore et al., 1995; Greenspan & Wieder, 1997; Kasari, Sigman, & Yirmiya 1993; Mundy et al., 1986; Travis & Sigman, 1998; Zwaigenbaum et al., 2004). In the following sections, different areas of social development will be presented and reviewed in regards to both typical development and development in ASD.

*i. Social Orienting*

Within the first six weeks of postnatal life, typically developing infants orient and attend to social stimuli, particularly toward people and their associated sounds, movements, and facial features (Morton & Johnson, 1991; Rochat & Striano, 1999). Through attending and orienting to faces, infants develop more sophisticated skills including the ability to turn their heads when their names are called (Rochat & Striano, 1999), and to discriminate among several facial expressions as well as between familiar and unfamiliar faces (Barrera and Maurer, 1981; Blasi et al., 2011; Fantz, 1961; Goren et al., 1975; Johnson et al., 1991; Johnson & Morton, 1991; Oster, 1981; Walker-Andrews, 1997; Young-Browne et al., 1977).

Young children with ASD demonstrate deficits in spontaneously orienting to naturally occurring social stimuli in their environment. According to retrospective studies using home videotapes, 8 to 12 month old infants later diagnosed with ASD were much less likely than typically developing infants of the same age to orient to faces (Bernabei et al., 1998; Mars et al., 1998; Osterling & Dawson, 1994) and to their names (Baranek, 1999; Mars et al., 1998; Osterling & Dawson, 1994; Osterling et al., 2002; Werner et al., 2000). Additionally, Dawson and colleagues (2004) showed that 3 to 4 year old children with ASD more frequently failed to orient to both non-social and social stimuli than did children with either development delays or typical development of the same age, but impairments were more severe for social stimuli.

Two major theories exist to account for the impairment in orienting to social stimuli in children with ASD. Some researchers suggest that ASD involves a general impairment in attentional functioning (Bryson et al., 1990; Courchesne et al., 1994; Dawson & Lewy, 1989a, 1989b), which can contribute to an inability to rapidly shift attention between different stimuli (Courchesne et al., 1995), including complex and variable social stimuli (e.g., facial expressions, speech, gestures). Children with ASD may have difficulty attending to, processing, and representing such unpredictable stimuli (Dawson, 1991; Dawson & Lewy, 1989a, 1989b; Gergely & Watson, 1999). Others suggest that children with ASD fail to assign reward value to social stimuli (Dawson et al. 2001; Mundy & Neal, 2001), which reflects a disturbance in the motivational mechanisms that normally draw an infant's attention to social stimuli (Rochat & Striano, 1999).

It has been argued that this failure to orient to social stimuli represents one of the earliest and most basic social impairments in children with ASD and, by depriving them of appropriate social stimulation, social orienting impairments may contribute to later-emerging social and communicative deficits, including the expression of shared affect (Dawson et al., 1998; Mundy & Neal, 2001).

*ii. Shared Affect*

Affective displays represent one of the earliest forms of social communication. For example, shortly after birth, newborns are capable of imitating adult facial expressions and the rate of this facial imitation increases when adults tune into and follow the infants' cues (Meltzoff & Moore, 1977). Such interactive reciprocity or synchrony between infants and caregivers is well-established by the time an infant is 6 months old and is often characterized by shared affect in the form of mutual gazing, smiling, vocalizing, and physical touch (Field, 1990; Sigman et al., 2004; Stern, 1985; Stern et al., 1985; Tomasello et al., 2005). The majority of these shared interactions involve positive emotions (Malatesa & Haviland, 1982), making it not surprising that smiling is one of the earliest and most frequent social behaviors displayed by infants in the first 6 months of life and is used to both initiate and maintain early social interactions (Bukatko & Daehler, 2001; van Beek et al., 1994; Kaye & Fogel, 1980; Venezia et al., 2004; Weinberg & Tronick; 1994; Yale et al., 2003).

Infants later diagnosed with ASD, however, demonstrate reduced social smiling (Adrien et al., 1992; Cassel et al., 2007; Zwaigenbaum et al., 2005) and shared affect (Adrien et al., 1992) by 12 months of age. While these children are not void of emotional expression and, in particular, positive affect, their use of affective expression during coordinated interactions or in response to the emotion of others is an area of deficit (Bieberich & Morgan, 1998; Greenspan & Wieder, 1997; Kasari et al., 1990; Loveland et al., 1994; Snow et al., 1987; Stone, 1997; Trevarthen & Daniel, 2005; Yirmiya et al., 2006). For example, Dawson and colleagues (1990) examined behaviors of children with ASD compared with typically developing children matched on receptive language during face-to-face interactions with their mothers during a snack scenario. Children with ASD did not differ from the typically developing children in the number of positive affect displays or the frequency of gazes at their mother's face. However, significant differences were found in the reciprocal and interactional aspects of these episodes. Children with ASD showed significantly less coordination of positive affect and gaze, and they were much less likely to respond to their mother's smile than typically developing children (Dawson et al., 1990).

Differences in affect sharing also extend to negative emotions in children with ASD. In a study by Corona and colleagues (1998), the emotional responsiveness of children with ASD was compared to mental age-matched children with intellectual disability on measures of attention, behavioral reactions, facial affect, and cardiac response. The study involved a distress paradigm in which the experimenter pretended to hurt herself and displayed either neutral or distressed affect. Both groups of children looked more at the experimenter's face and displayed more negative affect and concern in the distress situation than the neutral situation. However, the children with ASD looked at the experimenter's face much less and did not exhibit a change in heart rate in either condition. These results were in contrast to the children with intellectual disability who displayed both an orienting response and a decrease in heart rate during the distress condition (Corona et al., 1998).

The lack of reciprocal shared affect demonstrated by children with ASD could result in compensatory behaviors of parents or caregivers in order to elicit the coordination of affect and attention from their children (Lemanek et al., 1993). For example, when parents of children with ASD interact with their children they may use more attention-getting behaviors, increase their physical proximity, or use more non-verbal prompts than parents of children with developmental delay, language delay, or typically developing children (Lemanek et al., 1993). Caregivers of children with ASD may also exhibit a higher frequency of control strategies than other caregivers (Kasari et al., 1988; Sigman et al., 1986). Despite the method that a parent uses to get their child with ASD's attention and shared affect, researchers suggest that the amount of coordination between the parent's social bids and the child's focused attention is not only key to eliciting shared affect, but may also longitudinally impact their child's development of joint attention (Kasari, Sigman, Mundy, & Yirmiya, 1990; Mundy, Kasari, & Sigman, 1992; Vaughan et al., 2003) and language (Adamson & Bakeman, 1985; Dawson et al., 1990; Siller & Sigman, 2002).

*iii. Joint Attention*

Joint attention skills are defined as the ability to "coordinate attention between interactive social partners with respect to objects or events in order to share an awareness of the objects or events" (Mundy et al., 1986, p. 657). Joint attention differs from shared affect, described above, in that it refers to behaviors occurring within triadic interactions (i.e., coordinating attention between a person and an object) rather than dyadic interactions (i.e., attention to a person only). Joint attention behaviors are also differentiated from other forms of triadic communication that involve communication for purely instrumental purposes, namely requesting desired actions or objects (Mundy et al., 2003). In typical development, infants begin to engage in joint attention anywhere from 6 to 12 months of age (Carpenter et al., 1998; Corkum & Moore, 1998; Mundy & Crowson, 1997; Scaife & Bruner, 1975). Joint attention abilities include two separate behaviors: 1) following the attention of another (e.g., following another's eye gaze, head turn, or point), which is referred to as *responding to joint attention* (RJA; Mundy, Hogan, & Doehring, 1996; Seibert, Hogan, & Mundy, 1982); and 2) spontaneously initiating and/or directing coordinated attention of another using eye gaze and/or gestures (e.g., pointing or showing), which is referred to as *initiating joint attention* (IJA; Mundy et al., 1996; Seibert et al., 1982).

The attainment of joint attention skills is a critical milestone in early development and is imperative to social and language learning opportunities (Bakeman & Adamson, 1984; Baldwin, 1995). In the first years of life, joint attention may involve overt aspects of visual attention, such as showing a parent a toy. As a child ages, however, joint attention skills become more elaborate and involve subtle aspects of shared attention, such as ideas, intentions, and emotions (Mundy & Thorp, 2007; Rogers & Dawson, 2010). Additionally, several researchers examining joint attention in typically developing children have shown a relationship between joint attention skills and development in the areas of language (Baldwin, 1995; Carpenter et al., 1998; Kwisthout et al., 2008; Morales et al., 2000; Mundy & Crowson, 1997), social skills (Vaughan Van Hecke et al., 2007), theory of mind (Tomasello, 1995), and even neural development (Kwisthout et al., 2008).

Joint attention skills are often impaired in children with ASD (Mundy & Sigman, 1989). Between 10 to 11 months of age young children with ASD demonstrate emerging deficits in joint attention behaviors that persist into later childhood and beyond (Osterling, Dawson, & Munson 2002; Presmanes et al., 2007; Swettenham et al., 1998; Young et al., 2003). RJA and IJA have distinct developmental profiles and correlates in children with ASD. For example, as children with ASD become older, IJA and RJA abilities appear to diverge. While RJA deficits may emerge in the first year of life, by two years of age some children with ASD demonstrate basic gaze following ability (Chawarska, Klin, & Volkmar, 2003) and RJA abilities may continue to improve in older children with ASD or for those with higher cognitive levels (Leekam et al., 2001; Mundy et al., 1994; Sigman & Ruskin, 1999). Impairments in IJA, however, appear to persist as children with ASD get older (Mundy et al., 1994; Sigman & Ruskin, 1999). Mundy and Thorp (2007) provide a neural explanation for this divergence of joint attention skills based on the different areas of the brain involved in social initiation versus social response. The spontaneous initiation of social attention and coordination that is characteristic of IJA may recruit executive and social-motivational processes more so than RJA behaviors, which typically involve responding to another person's signal to shift attention (Mundy, 1995; Mundy et al., 2000). Interestingly, this developmental divergence in joint attention behaviors is also reflected in the clinical measures used for diagnosing and screening ASD. For example, the Autism Diagnostic Observation Scale (ADOS; Lord et al., 1999) is considered the 'gold standard' for assessing and diagnosing ASD across ages, developmental levels, and language skills. When administering the ADOS, the module used depends on the child's expressive language level and chronological age. Module 1 is typically used for children who are nonverbal or who inconsistently use phrase speech, and includes both IJA and RJA items in its diagnostic algorithm. Module 2, however, is used for children who use phrase speech, but are not verbally fluent, and includes only IJA in its diagnostic algorithm (Mundy & Thorp, 2007).

Research examining the relationship between joint attention behaviors and other developmental constructs provides additional support for conceptualizing IJA and RJA as distinct abilities. For example, IJA is more strongly related to individual differences in social symptom severity in preschool children with ASD than RJA (Mundy et al., 1994) and is more predictive of a child's tendency to spontaneously initiate social interactions seven to ten years later in life (Lord et al., 2003; Sigman & Ruskin, 1999). In contrast, RJA has been shown to be more strongly related to concurrent and future receptive and expressive language abilities (Luyster et al., 2008; Murray et al., 2008; Paul et al., 2008; Schietecatte et al., 2011; Sigman & Ruskin, 1999; Tomasello & Todd, 1983), to predict change in socialization and daily living skills as measured by the Vineland Adaptive Behavior Scales (Hutman et al., 2011), and to predict later ASD diagnosis in 14 month old siblings of children with ASD (Sullivan et al., 2007). Due to the relationship between RJA and these areas of development, all of which are included as targets of the intervention model examined for the current proposal (i.e., the ESDM), the remainder of the review on joint attention abilities will address RJA specifically in greater detail.

As discussed above, RJA deficits in ASD start to appear in the first year of life as measured through behavioral observations of (Chawarska, Klin & Volkmar, 2003). At the neural level, the basic gaze-following behaviors of RJA may involve the "social brain" (Adolphs, 2001), which is comprised of neural clusters in the temporal and parietal lobes and includes the amygdala, fusiform gyrus, prefrontal cortex, and superior temporal sulcus (Adolphs, 1999, 2001; 2003; Brothers, 1990). Recently, Pelphrey and colleagues (2011) have proposed that ASD involves an early and initial failure to develop the specialized functions of one or more of the neuroanatomical structures that make up the "social brain," one such function being social information processing. Additionally, Mosconi and colleagues (2009) demonstrated a relationship between the amygdala and RJA abilities in 4-year-old children with ASD. Using magnetic resonance imaging, they reported that children with larger amygdala volumes had increased deficits in RJA abilities.

From a social cognitive perspective, the development of RJA may be closely related to the development of theory of mind and the ability to understand others' feelings, thoughts, and intentions (Bretherton, 1991; Tomasello, 1995). In a recent study, Schietecatte and colleagues (2011) demonstrated that intention understanding uniquely contributed to RJA skills in 3-year-old children with ASD after controlling for the children's respective IQ scores on the Mullen Scales of Early Learning (Mullen, 1995). Whether intention understanding is a prerequisite for RJA (Aldridge et al., 2000; Carpenter et al., 2001; d'Entremont & Yazbek, 2007) or active engagement in RJA behaviors provides the experiential learning context to promote information-processing circuits involving intention understanding (Brooks & Meltzoff 2005; Yirmiya et al., 1998) is still a debate. Although imaging studies reveal that different cortical systems may be activated for gaze following and the interpretation of intentions (Baron-Cohen et al., 1999; Mundy et al., 2000; Russell et al., 2000), Mundy and colleagues (2009) suggest that RJA and intention understanding develop concurrently and involve the integration of these two different neural networks. Additional developmental studies suggest that gaze following may not initially reflect social-cognitive activity, but that it comes to do so over time (Brooks & Meltzoff, 2005; Moore, 1996; Woodward, 2003).

Considering the behavioral, neural, and cognitive aspects of RJA as described above, it is important to understand the implications that impairments in this area may have on additional areas of development. For example, deficits in RJA may deprive children with ASD opportunities for social learning, thereby contributing to early social and language delays (e.g., Sigman & Ruskin, 1999; Yoder et al., 2009). Researchers examining intervention for children with ASD show promising results in ameliorating RJA deficits by promoting shared visual attention, a foundational skill on which social coordination and shared experiences with others is built (Sullivan et al., 2007). Additionally, researchers studying RJA suggest that it is a highly responsive social behavior that may be relatively easy to influence through external stimulus contingencies. For example, Leekam and colleagues (2001) demonstrated that gaze-following skills improved in forty percent of participants (young children with ASD) when contingent external rewards were provided (i.e., illuminated targets appeared in response to correct gaze shifts). In another study of preschool-aged children with ASD receiving an intervention specifically targeting RJA (Jones et al., 2006), results demonstrated increased RJA in several contexts including at school with teachers and at home and in the community with parents. Additionally, parents in the study reported that both the quantity and quality of their child's interactions improved (Jones et al., 2006).

These observations suggest that children with ASD may be sensitive to modifications of non-social external contingencies that facilitate RJA development. Additionally, research on neural substrates related to attention and social cognition indicate that the early facilitation of RJA may be an important goal for interventions targeting social cognitive impairments in young children with ASD (Vaughan & Mundy, 2007). For example, Bono, Daley, and Sigman (2004) demonstrated that children who responded more correctly and consistently on RJA trials had increased benefits from more intense interventions (i.e., more social learning opportunities) than did children with less consistent RJA skills. Additionally, RJA may augment the capacity of children with autism to appreciate stimulus-reward associations and, therefore, display enhanced speed and maintenance of learning within a behavioral intervention paradigm (Mundy & Thorp, 2007; Rogers & Dawson, 2010).

In summary, RJA deficits in ASD represent a core deficit that influences both social and linguistic development. As evidenced above, however, interventions targeting RJA can have direct effects on improving RJA skills as well as long-term effects in other areas of development. Using the ESDM intervention, the current study aims to examine the role of RJA as a potential moderator of similar areas of development, including the treatment outcomes of shared positive affect, gesture use, and receptive and expressive language. An additional moderator of interest is object use, which is described below.

*v. Play and Imitation*

In typical development, children pass through a hierarchy of play skills, from simple manipulation of objects to more complex, higher order play (Hughes, 2009). Baranek and colleagues (2005) describe four developmental levels of play including exploratory play, relational play, functional play, and symbolic play. Exploratory play is described as play in which children engage with objects to explore and learn more about their surroundings; relational play involves the manipulation of objects with no particular meaningful purpose; functional play is “the appropriate use of an object or the conventional association of two or more objects, such as a spoon to feed a doll, or placing a teacup on a saucer” (Sigman & Ungerer, 1981, pg. 320); and finally, symbolic play is “complex,” “representational” play that involves “object substitution” (Baranek et al., 2005). In recognition of the many ways to define and measure the construct of play, the current proposal will examine object use, similar to functional play. In typical development, functional play provides a context for infants to learn how to use objects appropriately through early social interactive behaviors including imitation and joint attention (Landry & Loveland, 1988; Mundy, Sigman, & Kasari, 1990).

A large amount of literature demonstrates notable deficits in several types of play for children with ASD. Such deficits include reduced object exploration (Pierce & Courchesne, 2001), increased repetitive use of objects (Ozonoff et al., 2008), limited variety of play-acts on objects (Baranek et al., 2005; Stone et al., 1990; Williams et al., 2001), delays in symbolic play development (Ungerer & Sigman, 1981), and fewer novel play-acts (Charman & Baron-Cohen, 1997; Williams et al., 2001). A number of studies demonstrate that deficits in object imitation contribute to impairments in play for young children with ASD (e.g., Charman et al., 1997; 1998; DeMyer et al., 1972; Stone et al., 1997). For example, Stone and colleagues (1997) indicated a longitudinal relationship between imitation of functional and symbolic actions with objects and the development of play skills one year later in 2 years olds with ASD. However, Rogers and colleagues (2003) did not find a correlation between object imitation and a concurrent measure of play skills in children with ASD after controlling for developmental age, whereas a correlation did exist for children with developmental disabilities. These findings suggest that a relationship most likely does exist between the ability to imitate actions with objects and the development of higher level play behaviors in young children with ASD; however, the relationship may be accentuated when measured longitudinally or when the possible mediating effects of developmental age are examined (Ingersoll, 2008). Additionally, deficits in imitation in young children with ASD may hinder the development of peer play, since the majority of early peer interactions involve reciprocal imitation with toys (Eckerman & Didow, 1996; Eckerman & Stein, 1990; Hanna & Meltzoff, 1993). In a study examining the imitation of peer play in preschoolers, Stone and Lemanek (1990) found that parents of children with ASD reported significantly less imitation of peer play than parents of children with developmental delay, despite comparable developmental levels.

In addition to deficits in imitation, impairments in following the attentional directives of others toward objects and/or failing to engage others in their use of objects may limit the amount of guidance children with ASD receive on how to use objects correctly and functionally (Bruckner & Yoder, 2007; Kasari, Freeman, & Paparella, 2006). Such deficits in the functional use of objects may further limit the opportunities that children with ASD have to practice fundamental social learning skills at an early age (Bruckner & Yoder, 2007; Crais et al., 2009; Doctoroff, 1996; Williams et al., 1999). For example, Bruckner and Yoder (2007) demonstrated that limited use of objects in children with ASD was concurrently and longitudinally (e.g., 6 months) predictive of deficits in response to joint attention, motor imitation, and coordinated attention between objects and people. Additional evidence suggests deficits in object use in children with ASD further impact the areas of language comprehension (Ungerer & Sigman, 1981; Wing et al., 1977) and expressive language (Charman et al., 1997; Lyytinen et al., 2001; Ungerer & Sigman, 1984). For example, Bates and Dick (2002) report that word production does not begin until a child begins to functionally use objects, even when this behavior is delayed by months or even years. This pattern has been demonstrated for Williams Syndrome and Down syndrome (Singer Harris et al., 1997), and for young children with ASD (Happé & Frith, 1996). Additionally, children who are significantly delayed in both the functional use of objects and initial word production tend to show further delays in language at later stages of development (Thal et al., 1997).

Despite substantial deficits in imitation and play, young children with ASD may be capable of increased play behaviors and higher level play skills under structured experimental situations (i.e., enriched scaffolding opportunities) or when play is deliberately elicited or prompted with objects or gesture cues (Ingersoll & Schreibman, 2006; Jarrold 2003; Riguet et al., 1981; Stone et al., 1990). For example, Tiegerman and Primavera (1981) investigated the influence of three different interactional strategies on object manipulation in 4 to 6 year old children with ASD. The first strategy involved imitating the child's actions using a duplicate of the child's object, the second strategy involved a different action using the duplicate object, and the third strategy involved a different action on a different object. Tiegerman and Primavera (1981) found that the frequency and duration of object manipulation increased using the first strategy, when the experimenter directly imitated the children's behavior. Toys used in this study included a toy telephone, a toy car, a baby doll, and a rattle (Tiegerman & Primavera, 1981).

Early intervention, therefore, may be an essential tool in helping promote the functional use of objects in young children with ASD, providing them with quality opportunities for social and language learning, as well as setting them on positive behavioral and neurological trajectories (Mundy & Neal, 2001; Rogers & Dawson, 2010). For example, in two studies of early intervention in young children with ASD, object interest moderated treatment effects on child communication gains (Carter et al., 2011; Yoder & Stone, 2006).

In summary, social impairments are enduring features of ASD that emerge in the first years of life and include difficulties in social orienting, shared affect, joint attention, and object use. The longitudinal impact of these deficits is substantial and can be seen in the areas of cognition, social skills, language, and adaptive behavior. In the following section of this proposal, a second domain of impairment in ASD will be discussed: Language and Gesture Use.

**B. Language and Gestures**

In typical development, communication skills emerge in the first few weeks of life and provide the foundation for later language learning and speech acquisition. At this early stage in development, newborns recognize their mother's voice, coordinate eye gaze with movements, express affect, and participate in vocal turn taking (Fernald, 1992; Johnson et al., 1991; Messinger & Fogel, 1998; Spelke & Owsley, 1979). Continuing through the first year, infants engage in nonverbal communication to request, protest, share experiences, and exchange ideas with others (Bates, 1976; Carpenter, Nagell, & Tomasello, 1998). Through these interactions, they learn both the functional and social value of communication on which the future development of language is based (Adamson & Bakeman, 1991; Bloom, 1993; Wetherby, Prizant, & Schuler, 2000).

In individuals with ASD, impairments in language and communication comprise a critical dimension of the ASD phenotype and are extremely variable among those diagnosed (Lord et al., 2004). In the current proposal, *communication* is defined as "any act by which one person gives to or receives from another person information about that person's needs, desires, perceptions, knowledge, or affective states. Communication may be intentional or unintentional, may involve conventional or unconventional signals, may take linguistic or nonlinguistic forms, and may occur through spoken or other modes" (National Joint Committee for the Communication Needs of Persons With Severe Disabilities, 1992). Two subsets of communication include *language* and *speech*. *Language* is defined as "a set of shared rules that allow people to express their ideas in a meaningful way" (NIDCD, 2011). Language may be expressed verbally or by writing, signing, or making other gestures (e.g., symbolic gestures, eye blinking, or mouth movements). *Speech* is defined as "talking, which is one way to express language. It involves the precisely coordinated muscle actions of the tongue, lips, jaw, and vocal tract to produce the recognizable sounds that make up language" (NIDCD, 2011).

The current diagnostic criteria for ASD describe several aspects of language and communication impairment including difficulties in reciprocal conversation, stereotyped and restricted use of language, idiosyncratic language, and limited gesture use. There is evidence that difficulties in this area begin at an early age. Prospective and retrospective studies confirm that linguistic development in ASD is often delayed and represents one of the first reasons parents of children with ASD go to doctors with concerns (Landa & Garret-Mayer, 2006; Short & Schopler, 1988; Yirmiya et al., 2006; Yoder et al., 2009; Zwaigenbaum et al., 2005; 2009). Additionally, informal observations in homes as well as clinical observations in research settings suggest that 6-month old high-risk siblings later diagnosed with ASD exhibit delays in early language comprehension as well as delays in verbal and pre-verbal expressive skills (e.g., vocalizing less than other infants) (Landa & Garrett-Mayer, 2006; Thurm et al., 2007; Zwaigenbaum et al., 2005). In the following sections, the areas of gesture use, receptive language, and expressive language in ASD will be discussed in further detail.

*i. Gesture Use*

Gestures represent a form of nonverbal communication that combines motor acts (e.g., the use of the whole body, fingers, hands, or face) with the underlying intent to give or exchange information or ideas (Crais, Douglas, & Campbell, 2004). Through the use of gestures, preverbal infants are able to share interests, emotions, request help, and make demands (Bates et al., 1975; 1979; Capone & McGregor, 2004). As seen in Table 1, gestures develop in a consistent and

Table 1. Gestures categorized by communicative function.

| Function | 9-12 months | 12-15 months | 15-18 months | 18-24 months |
|---|---|---|---|---|
| Behavior Regulation | *Request Actions*<br>-Reaches to be picked up<br>-Does an action to get it to happen again (e.g., bounces up and down for "horsie") | *Request Actions*<br>-Reaches while opening and closing hands (e.g., being picked up, wants windup toy wound)<br>-Gives an object to an adult to get help (e.g., have it opened, fixed) | *Request Actions*<br>-Points to get someone to do something (e.g., open door, carry them to another room)<br>-Takes hand of adult to guide adult's hand or body to do something (e.g., towards tummy to get tickle) | |
| | *Request Objects*<br>-Points to obtain an object<br>-Reaches for an object<br>-Makes contact with an adult's hand to gain object | *Request Objects*<br>-Looks at object, then adult, then object again | *Requests Objects*<br>-Reaches while opening and closing hand to get an object | |
| | *Protest*<br>-Uses body to signal refusal/protest (e.g., arching body away when held in adult's arms)<br>-Pushes away an object with hand(s) | | *Protest*<br>-Shakes head "no" | |
| Social Interaction | *Representational Gestures*<br>-Waves "bye-bye"<br>-Imitates others clapping | *Representational Gestures*<br>-Shows functions of objects (e.g., brush hair with brush)<br>-Hugs objects<br>-Claps for excitement/ accomplishment (e.g., claps after putting blocks in bucket)<br>-"Dances" to music (e.g., bounces in seat from side to side with arms bent like dancing) | *Representational Gestures*<br>-Smacks lips like eating | *Representational Gestures*<br>-Shrugs shoulders or puts hands face-up for "All gone" or "Where did it go?"<br>-Blows kisses to others<br>-Signals "shh" w/fingers to lips<br>-Nods "yes"<br>-Pretends to sleep with hands together by head<br>-Uses conventional gesture of excitement (e.g., "high five" or "touchdown") |
| | *Seek Attention*<br>-Bangs objects to get attention (e.g., flapping arms, kicking legs)<br>-Grabs adult's hand to gain attn | | | *Seek Attention*<br>-Shows off (e.g., sticks out tongue, makes a funny face to get a laugh) |
| | *Social Games*<br>-Shows interest/anticipation in social games (e.g., moves body in anticipation, holds up hands for adult to manipulate)<br>-Participates by imitating an adult (e.g., begins to clap)<br>-Initiates social games (e.g., puts blanket over head for peek-a-boo) | | | |
| Joint Attention | *Comment*<br>-Shows objects<br>-Gives objects | *Comment*<br>-Points to object/event | *Comment*<br>-Points to an object in response to an adult's request, such as "Show me the apple" or "Where's the doggie?" | *Comment*<br>-Uses gesture as clarification of word/word approximation (e.g., child says "pane" and then points to airplane when not understood) |
| | | | *Request Information*<br>-Points to object or event to gain information (e.g., points to picture in book for adult to name it) | |

Note. Adapted from Crais et al., 2009; gestures listed were seen in 12 study children who were White, English-speaking, monolingual, and middle class.

predictable order during typical development. Iverson and Thal (1998) categorized these gestures into two primary categories: deictic and representational. Deictic gestures establish reference to objects or events in the environment and depend on the context for interpretation (e.g., pointing to a dog running, reaching for a ball; Bates, 1976; Iverson & Thal, 1998). The earliest deictic gestures emerge between 7 and 9 months of age depending on the setting (e.g., laboratory versus home) and the methodology used (e.g., naturalistic observation, parent report, standardized assessment; Crais et al., 2004). Some of these early deictic gestures, described as *contact* deictic gestures (McLean et al., 1991), include placing an adult's hand on an object to make a request (e.g., winding up a Jack-in-the-Box toy or blowing more bubbles) or pulling at an empty hand to obtain something (Bates et al., 1979; Crais et al., 2004). Around 10 to 12 months of age, children begin to use *distal* deictic gestures such as pointing at or reaching for objects at a distance (McLean et al., 1991). Crais and colleagues (2004), however, note that a few distal deictic gestures (e.g., reaching toward objects or to be picked up) actually emerge together with contact deictic gestures, possibly because they are used in identical contexts.

At approximately 12 months of age representational gestures emerge, also referred to as symbolic or iconic gestures (Acredolo & Goodwyn, 1988, 1996; Capirci, Iverson, Pizzuto, & Volterra, 1996; Caselli, 1990; Nicoladis, Mayberry, & Genesee, 1999). Representational gestures are gestures that convey meaning of as well as reference to an object, event, or social convention (Crais et al., 2009). Object-related representational gestures signify some feature of the object such as sniffing a flower, brushing hair with brush, or hugging a doll (Iverson & Thal, 1998). Representational gestures can also include pantomimes that signify actions (e.g., threading a needle, flapping one's arms to represent a bird's flight, and blowing to create bubbles) and signs that facilitate social interactions (e.g., waving, raising a finger to one's lip to indicate "be quiet;"

nodding "yes;" Crais et al., 2009; Xu et al., 2009). Goodwyn and Acredolo (1993), as well as others, propose that representational gestures constitute clear language symbols and encode meaning in much the same way as spoken language (Studdert-Kennedy; 1987).

During the second and third years of a child's life, pointing and gestures in general become increasingly integrated with spoken language (i.e., supplementing verbal messages; Alibali & Goldin-Meadow, 1993; Butcher & Goldin- Meadow, 2000; Capirci et al., 1996; Iverson et al., 1994; Nicoladis et al., 1999; Sowden et. al, 2008). Nicoladis and colleagues (1999) found that children 24 to 42 months of age typically use gestures with speech rather than gesture alone, and they do so at levels comparable to adults. Furthermore, Iverson and colleagues (1994) and Capirci and colleagues (1996) reported that pointing makes up a significant proportion of young children's gesture repertoires in the second and third years of life and accompanies speech more often than any other deictic gesture.

It is through the use of such gestures for communicative purposes that important building blocks for later language development are established and children learn the necessary means to indicate their needs and desires to others. It is no surprise then, that gestures and gesture-word combinations are predictive of later expressive language abilities in typical development (e.g., Capirci et al., 1996; Morford & Goldin-Meadow, 1992; Namy et al., 2000). Specifically, Rowe and Goldin-Meadow (2009) demonstrated that the number of different meanings conveyed in gestures by children at 18 months of age predicted vocabulary at 42 months of age, and gesture-speech combinations at age 18 months of age predicted sentence complexity at 42 months of age. Gestures, therefore, play an active role in language learning by giving children opportunities to practice specific language constructions before they can be produced in speech (Rowe & Goldin-Meadow, 2009). Additionally, gestures are often used in episodes of joint attention in which children's gestures (e.g., pointing) elicit verbal responses from parents that may further facilitate language learning within social interactions (Goldin-Meadow, 2003; Goldin-Meadow et al., 2007).

There is an agreement in the literature that children with ASD show rather severe delays and deficits in gestural communication. Several researchers have reported delays in pointing, showing, waving, and shaking one's head (Loveland & Landry, 1986; McHale, Simeonsson, Marcus, & Olley, 1980; Mars et al., 1998; Osterling & Dawson, 1994; Stone & Caro- Martinez, 1990; Stone et al., 1997; Wetherby et al., 1998; Zwaigenbaum et al., 2005), and others indicate deficits in integrating gestures with vocalizations or eye gaze to the same extent as typically developing children of similar mental ages (Stone et al., 1997; Tomasello & Camaioni, 1997; Wetherby et al., 1998). While studies indicate that children with ASD engage in reaching and requesting gestures, unlike typically developing children, they are more likely to rely on contact gestures (e.g., leading, pulling, or manipulating another's hand) than distal gestures such as pointing (Crais, Watson, & Baranek, 2009). If children with ASD do point, it often serves the function of requesting help or attaining an object of interest, whereas typically developing children also point to initiate social communicative acts such as directing attention for purely social purposes and commenting on objects or events of interest (Baron-Cohen, 1989; Tomasello & Camaioni, 1997). Additionally, individuals with ASD often develop and depend on idiosyncratic, unconventional, or maladaptive behaviors to communicate in the absence of more conventional gestures or symbolic communication. For example, they may scream, hit, engage in self-injury, and/or flee as a means of 1) gaining access to a preferred item, ritual, or activity; 2) escaping or avoiding a non-preferred demand; or 3) gaining attention from others (Fox, Dunlap, & Buschbacher, 2000).

Several studies have examined gesture use in addition to other factors that may underlie receptive and expressive language acquisition in children with ASD (see Table 2). In consideration of the relationship described above between gesture use and language development in typically developing children, it is not surprising that research reveals a similar trend for young children with ASD. Specifically, those young children with ASD who demonstrate increased levels of gesture use often have better language outcomes (Capone & McGregor, 2004; Goodwyn et al., 2000; Landa, 2007). Additionally, many of the other predictors of language development that have been studied occur in the context of interactions with others and incorporate aspects of nonverbal gesture use, such as imitation (e.g., motor actions), joint attention (e.g., pointing), and requesting behaviors (e.g., reaching or pointing). Therefore, improving joint attention skills, imitation, vocalizations, or gesture use in children with ASD may contribute to increased levels of social engagement, leading to more language learning opportunities, and eventually better language outcomes (Namy, Acredolo, & Goodwyn, 2000; Weismer et al., 2010).

In summary, children with ASD often have notable impairments in gesture use including delays in the onset and frequency of gesture use as well as the lack of integration of gesture use with other forms of communication (e.g., eye contact, vocalization). Additionally, gestures and gesture-word combinations are predictive of later receptive and expressive language abilities for children with ASD. Therefore, intervening in the area of gesture use early in development can have significant effects not only on the current onset and frequency of gesture use (Goodwyn et al., 2000; Goodwyn & Acredolo, 1993; McGregor & Capone, 2001), but also on later language acquisition (Row & Goldin-Meadow, 2009). It is important to note, however that the predictive value of gestures may differ depending on the age at which they are measured, emphasizing the importance of applying a developmental framework to the design and interpretation of longitudinal studies, particularly intervention efficacy trials (Howlin, Goode, Hutton, & Rutter, 2004).

Table 2. Concurrent and longitudinal predictors of receptive and expressive language development in children with ASD.

| | Receptive Language | | Expressive Language | | RL/EL Combined | |
|---|---|---|---|---|---|---|
| **Concurrent Predictors** | | | | | | |
| | Gestures | Luyster et al., 2008 | RL | Paul et al., 2008 | Joint Attention | Dawson et al., 2004; Sigman & Ruskin, 1999 |
| | Nonverbal Cognitive Ability | Luyster et al., 2008 | Nonverbal Cognitive Abilities | Luyster et al., 2008 | Initiating Joint Attention | Toth et al., 2006 |
| | Response to Joint Attention | Luyster et al., 2008 | Gestures | Luyster et al., 2008 | Nonverbal cognitive abilities | Weismer et al., 2010 |
| | | | Imitation (motor) | Luyster et al., 2008 | Frequency of Vocalization | Weismer et al., 2010 |
| | | | | | Imitation (motor) | Toth et al., 2006; Weismer et al., 2010 |
| **Longitudinal Predictors** | | | | | | |
| | Gestures | Wetherby et al., 2007 | Gestures | Capirci et al., 1996; Namy et al., 2000, Yoder, 2006 | Nonverbal cognitive abilities | Thurm et al., 2007 |
| | Consonant Production | Wetherby et al., 2007 | Joint Attention | Sigman & Ruskin, 1999 | Joint Attention | Charman et al., 2003; Mundy, Sigman, & Kasari, 1990; Thurm et al., 2007 |
| | Pretend Play | Wetherby et al., 2007 | Initiating Joint Attention | McDuffie, Yoder, 2006; Yoder, & Stone, 2005 | Response to Joint Attention | Sigman & McGovern, 2005 |
| | Stacking Blocks | Wetherby et al., 2007 | Imitation (motor) | McDuffie, Yoder, & Stone, 2005 | Imitation (motor) | Charman et al., 2003; Thurm et al., 2007 |
| | Inattention Behaviors | Bopp et al., 2009 | Imitation (vocal) | Smith et al., 2007 | Imitation (vocal) | Thurm et al., 2007 |
| | Social Unresponsiveness | Bopp et al., 2009 | Inattention Behaviors | Bopp et al., 2009 | Gestures | Mitchell et al., 2006 |
| | | | Social Unresponsiveness | Bopp et al., 2009 | Functional Play | Sigman & McGovern, 2005 |
| | | | Initial EL | Smith et al., 2007; Wetherby et al., 2007 | Requesting Behaviors | Sigman & McGovern, 2005 |
| | | | RL | Sigman & Ruskin, 1999; Wetherby et al., 2007 | | |
| | | | Stereotypic and Repetitive Behavior | Paul et al., 2008 | | |
| | | | Diversity of Object Play | Yoder, 2006 | | |
| | | | Pretend Play with Objects | Sigman & Ruskin, 1999; Smith et al., 2007 | | |

*i. Receptive and Expressive Language*

In typical development, infants reach notable milestones in both the comprehension and expressive use of language by approximately 12 months of age (see Table 3). First words emerge at this age and language comprehension may first be evident within familiar social routines or games (e.g., Pat-A-Cake or "Show me your nose!") expanding to more novel, spontaneous situations or interactions into the second year of life (Bruner, 1975). Between 12 to 18 months of age, expressive and receptive language increases to include names of objects and familiar people, greetings and goodbyes, relationships between objects (i.e., "all gone" or "more"), and the expression of ideas (e.g., "uh oh"; Fenson et al., 1994). By 18 months, expressive vocabularies reach an average size of approximately 100 words (Fenson et al., 1994; Tager-Flusberg, Paul, & Lord, 2005) and continue to increase into the third year of life. A controversy exists over whether or not this growth in vocabulary in the second year of life constitutes a "word explosion," in which the rate of acquisition increases, or is simply a gradual, steady increase in vocabulary over time (Hoff, 2005). Regardless of the rate at which a child's vocabulary grows, during this period of language acquisition, children learn words without explicit instruction or association (Nazzi & Bertoninici, 2003). As they enter their third year of life, children begin to combine words, develop conversational abilities, and reliably ask and answer questions (Chapman, 1981; Tager-Flusberg, Paul, & Lord, 2005). Continuing into the preschool years (i.e., ages 2 to 5 years), language development is marked by additional increases in both receptive and expressive vocabularies, as well as word combinations. Approximations in grammar also emerge during this period of development and include verb endings, prepositions, possessives, and plurals (Hoff, 2005). These advances in verbal communication enable a child to express more complex ideas,

Table 3. A summary of milestones in typical expressive language development.

| | 12 to 15 months | 18 months | 24 to 36 months | 3 to 4 years | 4 to 7 years |
|---|---|---|---|---|---|
| Semantics<br>(the meaning of words) | | | | | |
| Avg EL Vocab Size: | 10 words | 100 words (±105) | 300 words ( ±75) | 900 words | 2,500 words |
| Avg RL Vocab Size: | 50 words | 300 words | 900 words | | 8,000 words |
| Comprehension Strategies: | Attending to objects named and engaging in appropriate use of objects | Acting on objects as described by adult, interpreting sentences as requests for child actio n | Interpreting sentences according to knowledge of probable even ts | Supplying most probable missing information in answer to difficult questions | Over-reliance on word order to process sentences that use unusual word order, such as passives |
| Syntax<br>(the rules that govern the ways words combine to form phrases, clauses, and sentences) | First productions are single- word *holophrases;* one word carries the force of a whole sentence | First word combinations express basic semantic relations with consistent word order<br><br>Avg age of first word combinations: 18 mos (normal range: 14 to 24 mos). | Avg MLU at 24 mos: 1.92 (±0.5)<br>Avg MLU at 30 mos: 2.54 (±0.6)<br>Avg MLU at 36 mos: 3.16 (±0.7) | Grammatical morphemes become more consistent. Mature forms of negatives and questions develop.<br><br>Avg MLU at 4 years: 4.4 (±0.9) | Use of complex sentences increases from less than 10% to more than 20% of all utterances.<br><br>Avg MLU at 5 years: 5.6 (±1.2) |
| Phonology<br>(the study of speech sounds with reference to their distribution and patterning) | Most productions have CV or CVCV form (e.g., "ba" or "mama"). Front stops and nasals are most frequent consonants. | Back stops, fricatives, and glides are added to the con- sonant inventory. CVC syllable shapes begin to be used.<br><br>50% of consonants are produced correctly. | 9 to 10 different consonants are used in initial position; 5 to 6 in final; stops at all places of articu- lation are used.<br>Two-syllable words and initial consonant clusters are used by a majority of children.<br><br>70% of consonants are correct; speech is 50% intelligible. | Consonant blends are used. Some phonological simplification processes may persist.<br><br>Most sounds are produced correctly; speech is nearly 100% intelligible | Phonological processes are no longer used; a few distortions on difficult sounds (/s/, /l/, /r/) may persist.<br>Phonological analysis skills are learned for reading and spelling.<br><br>Almost all sounds are produced correctly. |
| Pragmatics<br>(the aspects of language that cannot be considered in isolation from its use; language as it is used in a social context) | Requests, comments<br>Combination of gestures with speech-like vocalizations | Requests, comments<br>Words predominate; gestural/vocal communication decreases | Requests, comments<br>Ask questions, convey new information, word combinations predominate | Talk about past and future events increases<br>More options for politeness are acquired<br>New communicative functions (projecting, narrating, etc.) | Language is used to predict, reason, and negotiate |
| Avg rate of communications: | 1 per minute | 2 per minute | 5 per minute | | |

EL = Expressive Language; RL = Receptive Language; MLU = mean length of utterance (usually taken as a hallmark measure of grammatical development); CV = consonant vowel; CVCV = consonant vowel consonant vowel

*Note.* From Tager-Flusberg, Paul, & Lord, 2005 share their own experiences, and describe actions and events from the present, past, or future (Tager-Flusberg, Paul & Lord, 2005). Conversational skills also continue to develop and language becomes instrumental in symbolic play schemes, problem solving, and self-monitoring (Bates, 1976).

According to several researchers, children with ASD demonstrate impairments in receptive and expressive language early in development (e.g., Landa & Garret-Mayer, 2006; Yirmiya et al., 2006; Zwaigenbaum et al., 2005; 2009). For example, in the area of receptive language, retrospective parent reports indicate that children with ASD understood fewer phrases than developmentally delayed or typically developing children by age 24 months (Luyster et al., 2005). Prospective studies indicate similar impairments in early language comprehension. High-risk infant siblings later diagnosed with ASD showed decreased vocabulary comprehension and fewer phrases understood as measured by the McArthur Communicative Development Inventories (MCDI; Fenson et al., 1993) between 12 and 24 months of age (Mitchell et al., 2006; Stone et al., 2007). The presence of significant delays in language comprehension has implications for concomitant as well as future adaptive functioning and nonverbal social communication skills (Rutter et al., 1992; Tager-Flusberg, Paul, & Lord, 2005). For example, in situations outside of daily routines or familiar contexts (i.e., spontaneous and fast-paced social interactions) children with ASD often struggle with understanding the meaning and intention of a speaker (Rutter et al., 1992). A certain level of semantic and pragmatic knowledge is required for understanding and using these more subtle and convert messages during verbal exchanges, both of which are areas of deficit in ASD (Klin, 2000; Klin et al., 2002; Yirmiya et al., 1992). Studies looking at sentence comprehension strategies further indicate not only word comprehension difficulties in children with ASD, but also difficulties comprehending the situation and the probability that the events within the situation could actually occur (Gaddes, 1984; Paul, Fischer, & Cohen, 1988; Henderson, Clarke, & Snowling, 2011; Tager-Flusberg, 1984).

In addition to receptive language delays, some infants who later develop ASD demonstrate marked impairments in their ability to intentionally communicate with others and often use a limited range of vocalizations in the early stages of language development (Charman et al., 2003; Mitchell et al., 2006; Wetherby et al., 2000). Approximately one-third to one-half of individuals with ASD present with significant difficulties using speech as a functional and effective means of communication (Tager-Flusberg, Paul, & Lord, 2005). While the nature of these difficulties is a topic of ongoing research, findings to date indicate that oromotor planning and delays in phonological development may be contributing factors (Bryson, 1997; Lord & Paul, 1997; National Research Council, 2001). However, difficulties with the acquisition of expressive language in children with ASD are not solely related to challenges with an individual's oromotor competence and/or the mechanics of speech development, but are heavily embedded in early social interactions (Tager-Flusberg, Paul, & Lord, 2005). As described above, children with ASD have difficulty attaining and maintaining social reciprocity, which results in a substantial dearth of “teachable moments” for learning critical components of conventional expressive language (Rogers & Dawson, 2010).

Even when expressive language skills are adequate for conversation, children with ASD have notable difficulties participating in reciprocal, mutual dialogues involving shared topics (Carpenter & Tomasello, 2000; Tager-Flusberg, Paul, & Lord, 2005). They may ignore spontaneous bids for communication (Stone & Caro-Martinez, 1990; Wetherby et al., 1998), use and interpret words literally (Tager-Flusberg, Paul, & Lord, 2005), dominate the conversation with their perseverative or circumscribed interests (Klin & Volkmar, 1997), and rely on structured situations for word learning and conversational exchanges (Landry & Loveland, 1989). As a result, children with ASD often have difficulties with semantic aspects of language (i.e., the meaning of words) as well as the development of more creative and generative language (Prizant, Schuler, Wetherby, & Rydell, 1997).

Additionally, individuals with ASD who communicate verbally may also demonstrate notable deviances in the quality of their speech, such as monotone intonation patterns and unusual prosody (Fay & Schuler, 1980). They may also develop echolalia as a primary means of communication (Hoff, 2005; Prizant et al., 1997). The term *echolalia* refers to the immediate repetition (i.e., immediate echolalia) or delayed repetition (i.e., delayed echolalia) of the speech produced by others (Fay & Schuler, 1980; Prizant et al., 1997; Rydell & Prizant, 1995; Schuler & Prizant, 1985). While the use of echolalia in children with ASD may appear to lack communicative intent and limited meaning, as children with ASD gain more competence in their spoken language skills, echolalia may begin to be used more functionally and serve as a developmental bridge to more appropriate, intentional, creative, and spontaneous language (McEvoy, Loveland, & Landry, 1988; Prizant, 1983). However, for those individuals with ASD who continue to use echolalia into adulthood, a decrease in social communicative competence may be observed (Rydell & Prizant, 1995).

Another feature of language development in some children with ASD is a regression of language skills (Baird et al., 2008; Goldberg et al., 2003; Parr et al., 2011). Researchers examining language loss report that language regression is unique to, but not universal in ASD as compared with other developmental disorders (Lord, Shulman, & DiLavore, 2004; Pickles et al., 2009). Language regression, therefore, barring other medical explanations, may serve as a “red flag” for ASD. Generally, regression proceeds gradually when children still have relatively small expressive vocabularies and has been linked to poorer long-term outcomes in certain areas of development. For example, children with ASD who experience regression demonstrate greater impairments in subsequent language acquisition (Bernabei et al., 2007; Brown & Prelock, 1995; Hansen et al., 2008; Luyster et al., 2005) and in the development of play skills (Bernabei et. al, 2007). Additionally, these children may have more severe symptoms of ASD as measured by the Autism Diagnostic Interview-Revised (ADI-R; Lord et al., 1994) and the Autism Diagnostic Observation Schedule (ADOS; Lord et al., 1999), two diagnostic measures considered the 'gold-standard' for assessing and diagnosing ASD across ages (Giannotti et al., 2008; Meilleur & Fombonne, 2009). Other researchers, however, report no differences in communication and other adaptive behaviors (Jones & Campbell, 2010; Richler et al., 2006; Siperstein & Volkmar, 2004; Werner et al., 2005), or in ASD symptom severity between those children with ASD who experience a language regression and those that do not (Lord et al., 2004; Meilleur & Fombonne, 2009).

Long-term developmental effects of regression may differ depending on the specific details of the regression, including the level of language acquired before loss and the extent to which other skills are lost. For example, Pickles and colleagues (2009) reported that children who experienced language regression while still using single words had delayed acquisition of phrased speech, but their long-term language skills were not significantly lower than children with ASD who did not experience regression. For those children who experienced language loss after phrased speech acquisition, the effects on later cognitive and language trajectories may be greater with broader negative repercussions on subsequent development (Pickles et al., 2009). Meilleur and Fombonne (2009) found that when children with ASD have a loss of language accompanied by regression in other areas (e.g., motor skills, self-help, social engagement), they demonstrate greater severity of ASD symptoms, especially for repetitive behaviors, following the regression and into early adolescence. Overall, further research in the area of regression in ASD is needed to elucidate the relationship between specific aspects of regression and other long-term developmental outcomes.

*vi. Summary*

In summary, ASD is a neurodevelopmental disorder that profoundly affects development across multiple domains in the first two to three years of life. Altering both the rate of ongoing development as well as established patterns of behavior, ASD typically results in severe, long-term social-communication impairments (Rogers, 2009). Both retrospective and prospective studies have contributed vital information about the early development and detection of ASD, including the identification of the early core characteristics of the disorder, the possible factors involved in its onset, its developmental course, and the heterogeneity of symptoms.

For the purposes of the current proposal, the most prominent characteristics observed at young ages in ASD were reviewed, specifically impairments in the domains of social interaction and communication. In the domain of social interaction and reciprocity, young children with ASD often demonstrate deficits in critical early milestones that are imperative to social and language learning opportunities. For example, difficulties in social orienting, shared affect, joint attention, and object play have longitudinal implications for development in the area of communication including gesture use and receptive and expressive language (e.g., Charman et al., 2003; Mitchell et al., 2006). With disturbances in the early interactions with others, infants with ASD fail to learn the functional and social value of communication on which the future development of language in based.

Promising research demonstrates the effectiveness of certain intervention methods to remediate these areas of deficits including treatments targeting specific skills (e.g., imitation, play, and joint attention) as well as comprehensive treatments. Therefore, advances in early detection research not only helps elucidate the fundamental mechanisms underlying ASD, but also allows for earlier access and implementation of early intervention and, as a result, better long-term outcomes for children with ASD. With the goal of intervening at the point when symptoms are first detected, intervention approaches for infants and toddlers with ASD are a major focus of current research (Chandler et al., 2002; Drew et al., 2002; Green et al., 2002; Mahoney & Perales, e002; McGee et al., 1999).

**IV. Early Intervention in Autism Spectrum Disorders**

Studies of early intensive behavioral intervention for children with ASD demonstrate substantial improvements for a large subset of children when initiated at preschool age and continued for 2 to 3 years. Such behaviorally based interventions are associated with improvements in the domains of cognition, behavior, and language (Rogers & Vismara, 2008), suggesting a certain level of plasticity in these aspects of development, especially when intervention is started early (Drew et al., 2002; Harris & Handelman, 2000). Research on early brain development in ASD suggests that the way in which young children with ASD interact with their environment affects brain connections and neural responses, having long-term implications for both behavior and brain development (Dawson, 2008). Early intervention, therefore, is imperative in shaping brain structures to be receptive to the social world, and in doing so, preventing or mitigating the symptoms and severity associated with ASD (Redcay & Courchesne, 2005; Sigman et al., 2004; Wallace & Rogers, 2010). Despite advances in the early detection of ASD and the reliability of diagnosis in 2 years olds (Chawarska et al., 2007), there is a lack of published outcome data on intervention models or treatment effectiveness for children with ASD who begin intervention by or before 30 months of age. The following sections will review literature related to early brain development in typically developing children, the importance of a social context for learning, and implications for intervention design and implementation for young children with ASD.

**A. Brain Development and Environmental Influences on Learning**

In the past few decades, an extraordinary amount of progress has been made in understanding how the brain develops, and in particular, the unique changes that occur in both circuitry and neurochemistry during the prenatal and early postnatal periods of development. Research indicates that genes and the environment interact continuously to affect the maturation of the brain. Such maturation includes several processes including increased myelination, synaptic growth, neural circuit formation, cell migration, pruning, and metabolic capacity (Shonkoff & Phillips, 2000). Different areas of the brain mature at different rates, reflected in the development of specific behaviors and abilities over time including object grasping, speech, self-regulation, and problem solving. As neural connections become established, they are secured through repeated experiences and interactions with the social and physical worlds (Carter et al., 2005; Kolb, 1999). The literature describing such experience-dependent neuroplasticity demonstrates that experience, especially within social interactions, is related to cortical specialization (Johnson & Munakata, 2005; Kuhl, Tsao, & Liu, 2003), specifically the fine-tuning of specific perceptual systems, as well as cortical connectivity, either functionally or structurally, between cortical areas (Leech & Saygin, 2010).

An illustration of the phenomenon of cortical specialization is the development of grasping motor behavior in infants (Kolb, 1999). Soon after birth, infants are able to use both arms (using a scooping motion) to bring objects toward their bodies. By approximately 3 months of age, infants orient their hands toward a specific object and grasp it using their entire hand. Later this grasp is refined to a “scissors” grip (using the sides of the thumb and index finger), and then, by approximately 8 months of age, a more precise “tweezer” grip develops (using the tips of the thumb and index finger). At the neural level, the successive development of these gripping behaviors coincides with the myelination in corresponding areas of the motor cortex. The whole hand grasp, for example, is connected to myelination of a group of axons involved in hand motion, while the development of the tweezer grip coincides with myelination of another group of neurons in the motor cortex that control finger movements (Kolb, 1999).

The interplay between cortical specialization and cortical connectivity is seen in the area of social development. An infant’s physical environment is inseparable from social stimuli, thereby creating the relational context in which the majority of their learning takes place in the first months of life (Baillargeon, 1994; Johnson, Grossman, & Farroni, 2008). In typical development, infants are primed to orient and attend to social stimuli due to its salience for basic need fulfillment (e.g., gaining attention of parent when hungry) as well as social development and language learning (Johnson et al., 1991; Farroni et al., 2005). This learning is evident at the neural level. An infant’s auditory and visual systems are highly specialized and attuned to social stimuli such as faces and voices. For example, face preference in newborns is thought to be guided by subcortical brain structures (Pelphrey & Carter, 2008) and as the visual cortical areas mature, more sophisticated abilities emerge, such as facial identity recognition (Johnson, 2005). Newborns first recognize their mother’s face based on information from both the outer contour of her head and hairline, as well as the internal configuration of her eyes, nose, and mouth (Bushnell, Sai, & Mullin, 1989). At 6 weeks of age, however, infants are able to recognize their mother's face using only the configuration of internal features (de Schonen & Mathivet, 1990). The development of cortical connectivity between a newborn's visual and auditory systems is also evident within the first months of life. For example, newborn infants will reliably turn their heads in the direction of a sound source as well as visual stimulus (Muir & Clifton, 1985) and they prefer to listen to their mother's voice over other female voices (DeCasper & Fifer, 1980). When infants are three and a half months old, they demonstrate the ability to associate the sound of their mother's voice with her face (Spelke & Owsley, 1979), and gaze longer at their mother's face after only a brief exposure to it (Bushnell et al., 1989; 2001; Field et al., 1984). By 5 to 7 months of age, infants can match voices and faces on the basis of the speaker's age and gender (Walker-Andrews et al., 1991; Bahrick et al., 1998), and by 6 months of age, infants are able to learn the voice-face pairings of same-sex female strangers (Hernandez-Reif et al., 1994).

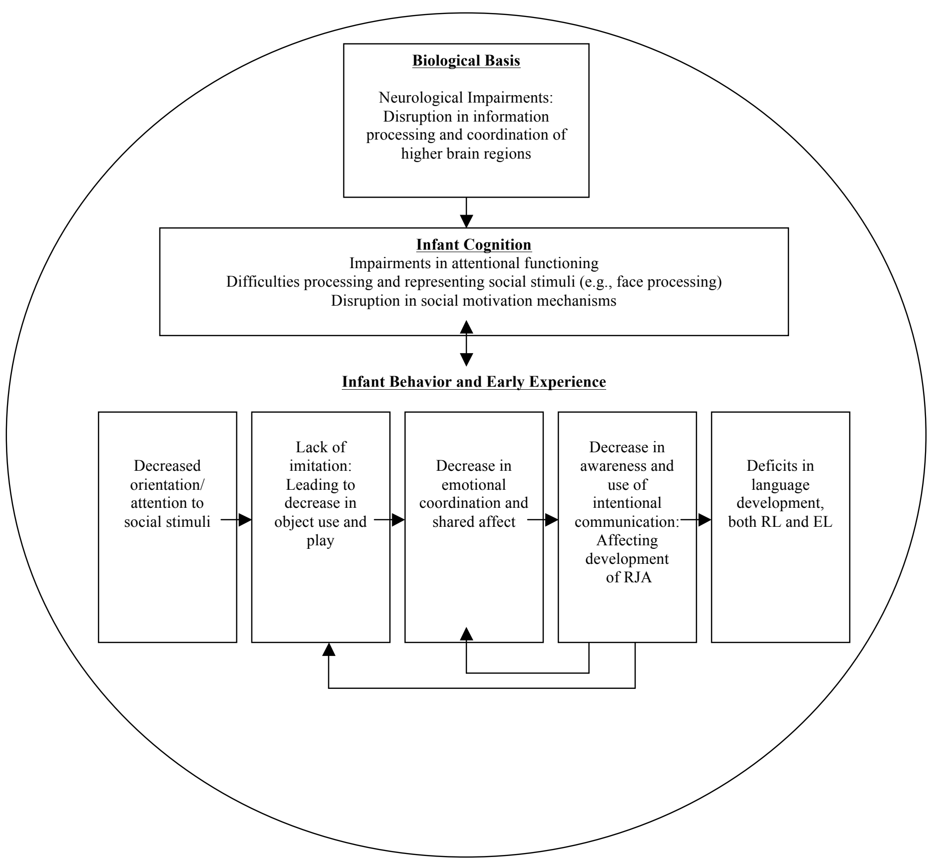
As these early behaviors are emerging, contingent brain activation takes place and shapes neural networks, leading to flexibility, generalization of knowledge, and expertise with continued experience (Eckerman & Didow, 1989; Ross, 1982; Rutter & Durkin, 1987). For example, at 2 months of age, the areas of an infant's brain that are activated when exposed to faces are similar to that documented as the core system for face processing in adults (Haxby, Hofman, & Gobbini, 2000). In particular, Haxby and colleagues (2000) observed activation in an area of the inferior temporal gyrus, which has been proposed to correspond with the fusiform face area in adults (Kanwisher, 2000; Kanwisher et al., 1997; Gauthier et al., 1999). Additionally, the inferior frontal and superior temporal gyrus are also activated in infants during face perception. Both these areas have been identified as part of the adult language network (Johnson, Grossman, & Farroni, 2008). Tzourio-Mazoyer and colleagues (2002) propose that the co-activation of face and future language networks seen in infants during face perception may be an evolutionary advantage to guide language learning while looking at the speaker's face in the context of social interactions. Additionally, Kuhl and colleagues (2003) demonstrated that exposure to speech is not necessarily sufficient to facilitate the development of speech and language learning. Instead, the key component for the development of typical speech perception is incorporating the infant's experience of language within an interactive, social context.

How do the phenomena of cortical specialization and cortical connectivity relate to ASD? As discussed above, cortical specialization involves neuronal and synaptic growth, allowing for connectivity and communication among different regions of the brain. Additionally, these networks undergo selective pruning, based partly on experience, becoming more efficient and responsive. Those connections that are utilized, therefore, become strengthened, while those that remain more idle are eliminated (Garber, 2007). In ASD, researchers suggest that the process of cortical specialization and the development of neural networks are compromised, resulting in abnormal connectivity and atypical synaptic synchronization, particularly in core brain regions involved in social and communicative development (Dinstein et al., 2011; Geschwind & Levitt, 2007; Mundy, 2003). Evident in the early stages of ASD development, poor neural synchronization is a notable neurophysiological characteristic of ASD and is often related to the severity of behavioral symptoms (e.g., joint attention; Geschwind & Levitt, 2007). Additionally, infants with ASD tend to prefer object- rather than people-related events. Therefore, it is hypothesized that as neural networks are stimulated by and become specialized for physical objects, an unusual construction of the world occurs and results in deficits in abilities typically promoted through social attention and interaction (e.g., shared emotion, reciprocal engagement, and language development; Mundy, 2003).

The disruption of complex information processing and the coordination of high-order brain regions in ASD occur early in life and bring about deficits in behaviors that require integration among these higher-order brain regions. Subsequently, different brain regions are recruited and, through experience, perpetuate ongoing brain changes over time (Bauman & Kemper, 1994; Geschwind & Levy, 2007). For example, imitation impairments present very early in children with ASD and these deficits may disrupt early establishment of "bodily synchrony" (Rogers & Dawson, 2010) and coordination (Meltzoff & Moore, 1977). Bodily synchrony is the first way in which infants and caregivers attune to each other's feelings and states. For example, when an infant shifts from an uninterested state to an attentive gaze, the mother, within seconds, responds with a corresponding shift from quiet attention to positive arousal and stimulation (Feldman, 2007). Impairments in this synchrony may affect the emotional coordination between caregiver and infant. Thus, early intervention that directly targets the development of socially engaged imitation, joint attention, and affect sharing could have potent effects on later language, play, and social outcomes (Bono, Daley, & Sigman, 2004; Sigman & Ruskin, 1999; Toth, Munson, Meltzoff, & Dawson, 2006).

In summary, current research on infant learning in the first year of life reveals that infants have the capacity to investigate and internalize information from both the physical and social worlds. While the physical world is generally predictable and reliable, the social world presents with information that goes beyond what is immediately observable from sensory input, including beliefs, intentions, and desires of others (Sigman, 2004). Through early social interactions and the simultaneous coordination of communication, behavior regulation, and affective expression, infants begin to understand how objects work, recognize the similarity between one's own actions and those of others, and remember events. These abilities are considered foundational skills and precursors to the development of joint attention and the social understanding of intentions (Sigman, 2004). Therefore, relating socially to others as an infant promotes optimal functioning throughout the lifespan, profoundly affecting an infant's perceptual, cognitive, language, and social development (Johnson, Grossman, & Farroni, 2008). Children with ASD, however, may have a specific deficit in their early sensitivity to the reward value of social stimuli (Mundy, 1995; Panksepp, 1979), making the social world less interesting and, therefore, less attended to. Such "self-imposed" (Mundy & Neal, 2001) social deprivation of children with ASD compromises their behavior and brain development, limiting the number of opportunities for them to learn language and social skills (see Figure 1; Dawson, 2008). Hopeful findings in

Figure 1. Social context for early learning in children with ASD.



the field of neuroscience reveal the remarkable plasticity of the young brain in response to early experience, particularly early intervention or stimulation (e.g., Bates & Roe, 2001; Madjan & Shatz, 2006). Thus, early intervention for young children with ASD is imperative in shaping brain structures to be receptive to the social world, thereby preventing or mitigating the symptoms and severity associated with ASD (Wallace & Rogers, 2010).

**B. Early Intervention in Autism Spectrum Disorders: Status of Current Research**

While considerable progress is being made in the area of early detection and diagnosis of ASD, there is currently a lack of empirically validated treatments for infants and toddlers with ASD younger than 3 years of age. Three studies recently conducted thorough reviews of the current state of early intensive interventions for young children with ASD and the ability of such interventions to enhance developmental outcomes. In 2002, the National Institutes of Health sponsored a meeting to address the methodological challenges of intervention research in ASD (Lord et al., 2005). At that time, a total of 30 published papers addressed intervention for children with ASD under the age of 6 years old. Almost all of the studies reviewed employed behavioral intervention methods (e.g., Lovaas, 1987), and a small number of studies used developmental approaches or targeted communicative intent (e.g., Ozonoff & Cathcart, 1998; Wetherby et al., 1997). Across many of these studies, substantial variability existed in the content, fidelity, and intensity of the interventions used, even more so than the methods that were implemented. The authors highlighted the need for established standards of research and randomized clinical trials in this area in order to evaluate intervention effectiveness for young children with ASD. Additional recommendations included modification of existing measures and creation of new outcome measures to better document goals and effects of treatment, innovative treatment designs and statistical techniques, inclusion of a diversity of study participants, and training workshops for ASD intervention researchers (Lord et al., 2005).

More recently, Kasari and Lawton (2010) explored current trends in early behavioral interventions during 2008 and 2009 that targeted deficits characteristic of ASD, excluding studies using interventions that focused only on challenging behavior or academics. In their review of 68 studies, they reported nearly a quarter increase in the number of intervention studies as well as improvements in experimental design (e.g., randomized controlled trials and group designs), intervention focus (e.g., ASD-specific deficits), and breadth of intervention strategies. For example, alternative approaches to applied behavior analysis (ABA) were used in some behavioral intervention studies and other studies implemented novel treatments that capitalized on individual children's interests such as Lego play, music, horseback riding, and computers. Despite noted progress in intervention research, Kasari and Lawton (2010) highlight the continued need for rigorous methodology in this area in order to isolate active ingredients of effective intervention for young children with ASD and to identify mediators and moderators of treatment.

Finally, Warren and colleagues (2011) conducted a systematic review of 34 studies of early intensive behavioral and developmental interventions in young children with ASD. Twenty-three of the studies used UCLA/Lovaas-based interventions and early intensive behavioral intervention (EIBI), 4 studies used comprehensive approaches (i.e., targeted multiple areas of functioning) for children below 2 years of age, and 7 studies used parent-training protocols. Of the 34 studies, 17 were case series and 2 were randomized controlled trials (RCTs). Warren and colleagues (2011) established their own rating system (i.e., good, fair, and poor quality) that was based on the following elements of evaluation: study design, diagnostic approach, participant ascertainment and characterization, intervention description, outcomes measurement, and statistical analysis. They rated one study as good quality, 10 as fair quality, and 23 as poor quality. UCLA-Lovaas-based interventions and the ESDM intervention benefited some children, particularly in the areas of language and cognitive skills. Less intense interventions that provided parent training may be beneficial for young children with ASD, specifically in the areas of social communication, language use, family functioning, and symptom severity. However, outcome data for these studies were frequently assessed short-term, with minimal long-term outcome data or follow-up. Overall, Warren and colleagues (2011) concluded that there is a lack of high-quality RCTs of early interventions for children with ASD and no studies that have directly compared effects of distinct, promising manualized treatment approaches. Additionally, while subgroups of children across studies demonstrated notable gains during intervention, Warren and colleagues (2011) determined that the specific participant characteristics that were associated with greater gains are still not well understood.

The review articles presented above provide a hopeful, yet realistic picture of the current state of research of early interventions for ASD. While notable progress has been made in this area of research over the last few years, there continues to be a lack of adequate evidence pinpointing specific behavioral intervention approaches that are the most effective for individual children with ASD.

**C. Key Components and Targets of Early Intervention in ASD**

What kinds of interventions are most appropriate for young children with ASD? In an attempt to determine which characteristics should be the basis for early intervention designs in ASD, Wallace and Rogers (2010) conducted a systematic review of 32 controlled, efficacious interventions for infants and toddlers with developmental disorders or developmental risks other than ASD. These target populations included infants born prematurely, those with developmental delays including Down syndrome, and those at risk for intellectual disability due to parent characteristics (e.g., parental poverty or parental intellectual disability). From this review, four specific intervention procedures used consistently across the studies were identified including: 1) parent involvement that consisted of ongoing parent coaching (specifically focusing on parental responsivity and sensitivity to child cues) and teaching parents to provide the interventions, 2) taking into consideration each infant's developmental profile and individualizing the intervention, 3) targeting a broad rather than narrow range of learning goals, and 4) beginning the intervention as early as the risk is detected and providing intervention that is both intense and longer in duration. In addition to these four characteristics of efficacious interventions, Wallace and Rogers (2010) highlight the importance of long-term follow-up in determining the value of an intervention. Overall, the review provides a foundation for moving forward in the design and assessment of efficacious interventions for infants and toddlers with ASD.

Additional researchers provide further guidance on the development and assessment of early interventions specific to ASD, many of which fall under the four procedures outlined by Wallace and Rogers (2010). For example, there is a consensus that family involvement, in the form of parent education or participation, is an essential aspect of early intervention (Dawson, 2008; Dawson & Osterling, 1997; Stahmer, Collings, & Palinkas, 2005; Woods & Wetherby, 2003). Additionally, researchers suggest the use of developmental, relationship-based interventions that are tailored to the individual child's emerging and established abilities (Dawson, 2008; Landa, 2007), and include a comprehensive curriculum targeting a range of skills (Anan et al., 2008; Dawson, 2008; Dawson et al., 2010; Itzchak et al., 2008; Landa, 2007; NIMH, 2004). Emphasis is placed on presenting information in a rewarding way and providing interactive experiences in which the skills may be frequently practiced in familiar, novel, and meaningful contexts in order to stimulate the flexible use of skills and to promote generalization (Dawson & Osterling, 1997; Landa, 2007). Intensive delivery of treatment (i.e., 25 hours a week for at least 2 years) initiated early in development is also encouraged (Dawson, 2008). Finally, Dawson (2008) advises the use of empirically validated teaching principles (e.g., Applied Behavior Analysis), behavioral strategies to reduce interfering behaviors (i.e., shaping, modeling, imitation), and a highly trained staff.

Despite the guideline to include a comprehensive, broad list of treatment goals within early intervention designs for young children with ASD, Kasari and Lawton (2010) reported that only 8.88% of the studies they reviewed (6/68) were comprehensive in scope. Most of these six comprehensive interventions were conducted at centers, used methods that relied on ABA principles, and included the following treatment components: short play sessions, discrete trial training, and/or functional communication training (e.g., Anan et al., 2008; Dawson et al., 2010; Itzchak et al., 2008). Those studies utilizing comprehensive interventions included a combination of the following treatment targets: stability of ASD diagnosis (Chawarska et al., 2009), intelligence (Dawson et al., 2010; Remington et al., 2007; Sherer & Schreibman, 2005), daily living skills (Dawson et al., 2010; Remington et al., 2007; Stahmer & Ingersoll, 2004), school placement (Smith, Groen, & Wynn, 2000), gesture use (Chawarski et al., 2009), joint attention (Chawarski et al., 2009; Kasari et al., 2008), imitation (Salt et al., 2002), emotion regulation (Gulsrud, Jahromi, & Kasari, 2009), symbolic play skills  (Kasari et al., 2009; Salt et al., 2002), emotional motivation and interpersonal responsiveness (Kim, Wingram, & Gold, 2009), receptive language (Dawson et al., 2010; Sherer & Schreibman, 2005); and expressive language (Drew et al., 2002; Koegel, Shirotova, & Koegel, 2009).

As research in the field of early intervention in ASD is advancing, procedures for intervention design and assessment, such as those listed above, are being developed in order to guide the quality and effectiveness of future research in this area. While studies suggest promising outcomes for subsets of children who participate in interventions that incorporate the procedures and comprehensive treatment targets listed above, there is still a critical need for replication and controlled studies of the factors that moderate treatment outcome.

**D. Early Intervention and Child Match: Moderators of Treatment**

As discussed above, ASD is a heterogeneous disorder in which many systems are affected at different stages of development. While a single intervention method may not be optimally effective or sufficient for all children with ASD (Beglinger & Smith 2005; Sherer & Schreibman, 2005), the specific factors and individual characteristics that determine differential response to intervention is an essential area of research that is currently not well understood. There are several types of variables that are likely to be involved in treatment response in ASD including pretreatment cognitive abilities (Bibby et al., 2002; Eikeseth et al., 2002; Goldstein, 2002; Howlin, Mawhood, & Rutter, 2000; Venter, Lord, & Schopler, 1992), nonverbal IQ scores (Paul et al., 2008; Thrum et al., 2007); age at treatment onset (Harris & Handleman, 2000); social responsiveness (Beglinger & Smith, 2005; Sallows & Graupner, 2005; Sherer & Schreibman, 2005; Sigman & Ruskin, 1999); imitation skills (Sallows & Graupner, 2005); language ability (Luyster, Kadlec, Carter, & Tager-Flusberg, 2009; Sallows & Graupner, 2005; Smith et al., 2007; Wetherby et al., 2007), object interest (Carter et al., 2011); and play (e.g., functional, symbolic, and/or varied play; Rogers et al., 2003; Sherer & Schreibman, 2005; Yoder, 2006). In light of the possible moderating effects of these variables on individual response to treatment, it is essential that future research studies incorporate rigorous methodology to closely monitor moderators of treatment outcome (Kasari & Lawton, 2010). Particularly, randomized controlled trials are needed that include longitudinal outcomes of treatment efficacy as well as the analysis of moderators of treatment response (Lord et al., 2005; Warren et al., 2011).

**F. Summary: Early Intervention in ASD**

Studies of early intensive behavioral intervention in ASD demonstrate substantial improvements for a large subset of children with ASD when initiated early in development and continued longitudinally. Despite advances in the early detection of ASD and the reliable diagnosis in 2 years olds (Chawarska et al., 2007), few empirical studies describe intervention models for children with ASD who begin treatment by or before 30 months of age. The importance of early intervention in this population, however, emerges from findings in the field of neuroscience that demonstrate the plasticity of the young brain in response to early experience, particularly early intervention or stimulation (e.g., Bates & Roe, 2001; Madjan & Shatz, 2006). Thus, early intervention for young children with ASD plays an influential role in the development of brain circuits, particularly those circuits involved in processing social information, having long-term mitigating effects on the symptoms and severity associated with ASD (Wallace & Rogers, 2010). The next section will review the Early Start Denver Model (ESDM), a unique, longitudinal intervention for young children 18 to 30 months of age with ASD.

**V. The Early Start Denver Model**

The Early Start Denver Model (EDSM; Rogers & Dawson, 2010) represents a refined and adapted extension of the Denver Model (Rogers et al., 1986; 2000; Rogers & Lewis, 1989) and is designed to address the unique needs of toddlers with autism as young as 18 months old.

The ESDM uses knowledge about how typical infants develop to facilitate similar developmental trajectories in young infants at risk for ASD. Using an intensive delivery model of comprehensive intervention, the ESDM aims to simultaneously reduce the severity of ASD symptoms as well as accelerate children's developmental rates in all domains, particularly cognitive, social-emotional, and language domains (Rogers & Dawson, 2010). The foundation of the ESDM is a synthesis of several complementary approaches including the Denver Model (Rogers et al., 1986; 2000; Rogers & Lewis, 1989), Roger's and Pennington's (1991) model of interpersonal development in ASD, Dawson and colleagues' (2004) model of ASD as a disorder of social motivation, and Pivotal Response Training (PRT; Koegel et al., 1999; Pierce & Schreibman, 1997; Pierce & Schreibman, 1995). These different approaches are briefly discussed below.

**A. The ESDM: A Synthesis of Treatment Approaches**

*i. The Denver Model*

The Denver Model is a comprehensive, intensive early behavioral intervention for preschool-age children with ASD that was originally developed and evaluated by Rogers and colleagues to promote social and communication development (Rogers et al., 1986; 2000; Rogers & Lewis, 1989). Specifically, the technique of "sensory social routines" (i.e., dynamic, active interactions involving positive affect) was developed in order to teach children to communicate intentionally through initiating, maintaining, and ending social interactions. A sensory social routine occurs within the context of a shared, joint activity and involves reciprocal interactions including taking turns, imitating each other, communicating with words, gestures, or facial expressions, and building on each other's activity. Typical sensory social routines involve lap games (i.e., "Peekaboo"), song routines with motions (i.e., "Eensy Weensy Spider"), floor song games (i.e., “Motorboat”), finger plays (i.e., “Creepy Fingers”), and movement routines (i.e., “Airplane”; Rogers & Dawson, 2010).

Sensory social routines are incorporated into the ESDM as well as the following core features of the Denver Model: 1) an interdisciplinary team that employs a comprehensive, developmental curriculum; 2) a focus on interpersonal engagements; 3) development of fluent, reciprocal and spontaneous imitation of gestures, facial movements and expressions, and object use; 4) emphasis on both nonverbal and verbal communication development; 5) a focus on cognitive aspects of play; and 6) a partnership between the treatment team and parents (Rogers & Dawson, 2010).

*ii. Rogers’s and Pennington’s Model for Early Intervention in ASD*

Rogers and Pennington (1991) established a developmental model of ASD that was strongly influenced by the infant research done in the 1970s and 1980s, particularly the work of Daniel Stern (1985). In their model, Rogers and Pennington (1991) observed that impairments in early imitation skills in young children with ASD contributed to a cascade of social-emotional communicative deficits. For example, in the absence of imitation, a disruption in the early emotional coordination between an infant and caregiver occurs and negatively impacts further development of affective attunement and emotion sharing. It also profoundly affects the development of an infant’s awareness of and use of intentional communication (Yirmiya et al., 1989). A main focus of the ESDM is to address the development of these early social-emotional communicative behaviors by promoting imitation, joint attention, emotion sharing, and intentional communication within the context of emotion-rich relationships with partners who are both responsive and sensitive (Rogers & Dawson, 2010). These types of relationships with caregivers are crucial for the development of early social-emotional communicative behaviors (Carpenter & Tomasello, 2000; Stern, 1985).

*iii. Social Motivation Hypothesis (Dawson et al., 2004)*

As discussed previously, researchers suggest that the biology of ASD involves a fundamental deficiency in social motivation due to insensitivity of social reward. As a result, these children spend less time attending to and interacting with other people. Not only does this impairment affect the development of certain behaviors including imitation, emotional sharing, and joint attention, it also affects the neural systems underlying the perception of such social information displayed by others (e.g., Geschwind & Levitt, 2007; Mundy, 2003). Several strategies used in the ESDM, including sensory social routines and Pivotal Response Training (PRT; see below), are designed to increase the salience of social rewards for children with ASD and enhance social attention and motivation for social interaction (Rogers & Dawson, 2010).

*iv. Pivotal Response Training (PRT)*

Pivotal Response Training (PRT) is a teaching approach based in applied behavior analysis (ABA) that highlights child initiative and spontaneity and can be delivered in natural contexts (Koegel et al., 1999; Pierce & Schreibman, 1997; Pierce & Schreibman, 1995). PRT techniques were developed to optimize children's motivation to interact with others and engage in repeated learning opportunities. The motivational teaching strategies used in PRT are considered one of the empirically supported practices for building communication skills in children with ASD (Koegel, Robinson, & Koegel, 2009) and include: 1) the use of reinforcers that are directly related to child's goals and responses, 2) incorporating child choice in to teaching episodes, 3) interspersing previously acquired (or maintenance) tasks with acquisition tasks, 4) therapist reinforcement of child's attempts to perform desired behaviors at whatever level of accuracy the child can produce at the moment, 5) using activities that are highly motivating to the child, and 6) sharing control of the material and interaction with the child. PRT strategies are incorporated into the teaching approaches used in the ESDM, serving to increase social learning opportunities for children with ASD and to counteract the negative cascade of effects resulting from a lack of social interaction early in development (Rogers & Dawson, 2010).

The different treatment approaches discussed above focus on promoting social and communication development in young children with ASD using a developmental framework. A large part of these treatment methods involves optimizing children's motivation to interact with others by targeting early impairments in social attention and social reward, thereby influencing and accelerating children's development in all domains. The ESDM curriculum, treatment goals, and intervention techniques are based on a similar developmental understanding of the impairments of ASD (Rogers & Dawson, 2010).

**B. The ESDM Curriculum and Teaching Techniques**

The ESDM curriculum was developed by a team of professionals from several areas of expertise including developmental and clinical psychology, applied behavior analysis, early childhood special education, speech and language pathology, and occupational therapy. During a child's participation in the ESDM, representatives from these fields either remain on treatment teams or are available for consultation. Pediatricians are also consulted about health related concerns that can interfere with an individual child's ability to benefit from intervention (e.g., seizures, sleep, nutrition, or allergies). In the ESDM, the interdisciplinary intervention team helps promote consistency across sessions and models for parent and families the importance of addressing all of their child's needs (Rogers & Dawson, 2010).

When an individual child enters the ESDM, his/her current skill levels are evaluated using the ESDM Curriculum Checklist, a list of specific skills sequenced developmentally within the following domains: receptive communication, expressive communication, joint attention, imitation, social skills, play skills, cognitive skills, fine motor skills, gross motor skills, and self-care skills. Once a child's abilities are evaluated and determined, individual learning objectives are then written that are designed to be achieved in a 12-week period. Every 12 weeks, new learning objectives are determined based on a new assessment with the ESDM Curriculum Checklist (Rogers & Dawson, 2010).

In order to teach individual learning objectives, the ESDM incorporates applied behavior analysis (ABA) teaching principles that have received empirical support for improving skill acquisition in very young children with ASD (e.g., Green et al., 2002; McGee et al., 1999). Additionally, emphasis is placed on applying these principles in a naturalistic, social context within affectively-based relationships. One of the goals of the intervention, therefore, is to utilize the child's natural environment (typically in the home) and his/her existing relationships to promote socially rich context for learning. Specifically, family-child and therapist-child interactions are used to help the children attend to key information in their environment (e.g., faces, actions, emotions), so they can make sense of information that is essential for typical language and social development. As children reach preschool age, play-dates that facilitate child-child interaction and collaboration with preschools are incorporated (Rogers & Dawson, 2010).

Parent and family involvement is considered a best practice in early ASD intervention (NIMH, 2004) and is an essential component of the ESDM. In order to help a child develop to his or her greatest capacity, they need to experience the same or more learning opportunities as do children with no genetic risk factors or biological impairments that affect their early learning. Therefore, an interactive social environment must be created for them (Rogers & Dawson, 2010). Parents and caregivers participating in the ESDM are taught specific skills for engaging and interacting with their children throughout the day, and embedding treatment techniques into everyday life. For example, parents learn that following child's lead, as opposed to directing the child's attention, positively contributes to language development for children with ASD (Siller & Sigman, 2002). Additionally, the ESDM helps parents draw out and read their children's subtle cues so that they can respond sensitively and reinforce their children's spontaneous communication (Rogers & Dawson, 2010).

Six teaching techniques are particularly emphasized within the ESDM and include: 1) teaching trials that employ a clear A-B-C format, in which the antecedent instruction elicits the behavior and is followed by a consequence; 2) utilizing intrinsic reinforcers when they exist for a particular skill, pairing all nonsocial reinforcers with social attention, and delivering consequences skillfully and contingently; 3) shaping, chaining, prompting, fading, and error correction procedures; 4) Pivotal Response Training (PRT) techniques to enhance child motivation and spontaneity, improve language, and facilitate response generalization (Koegel & Koegel, 1999; Pierce & Schreibman, 1997; Pierce & Schreibman, 1995); 5) positive, affect-based relationships as a context for language and communication learning; and 6) if required, increased levels of visual support, structure, and repetition according to pre-specified decision-making rules and the rate of child progress (Rogers & Dawson, 2010).

**C. Evaluation of the ESDM and Targets of Treatment**

Currently there are eight papers published in reviewed journals that describe the effectiveness of either the Denver Model (Rogers et al., 1986; 2006; Rogers & DiLalla, 1991;

Rogers & Lewis, 1989; Rogers, Lewis, & Reis, 1987) or the ESDM (Dawson et al., 2010; Vismara, Colombi, & Rogers, 2009; Vismara & Rogers, 2008). The first four studies used a pre-post design, controlling for initial developmental rate. Results from these studies provided consistent evidence of stimulated development in the areas of language and social-emotional development for a large group of children with ASD in Denver Model classrooms (Rogers et al., 1986; Rogers & DiLalla, 1991; Rogers & Lewis, 1989; Rogers, Lewis, & Reis, 1987). The next three studies demonstrated the efficacy of both the Denver Model and ESDM using single-subject design research (Rogers et al., 2006; Vismara & Rogers, 2008; Vismara, Colombi, & Rogers, 2009). Additionally, Vismara and colleagues (2009) tested the ESDM parent training aspect of the model, demonstrating both effective implementation of the model by parents as well as improvement in child social-communicative development. The most recent outcome research for the ESDM includes a randomized-controlled trial carried out at the University of Washington (Dawson et al., 2010). Results indicate that the ESDM is effective for increasing children's cognitive and language abilities, fostering social interaction and initiations, decreasing the severity of ASD symptoms, and improving overall behavior and adaptive skills.

Although longer-term follow-up studies and replications are necessary to determine the long term benefits of this treatment approach, the consistency of the evidence across several types of delivery (e.g., classroom, parent-delivered, and intensive at-home delivery) suggests that the ESDM is efficacious in addressing a wide range of early symptoms of ASD and improving child outcomes, at least during the preschool period (Rogers & Dawson, 2010). Additional studies examining the moderators of the ESDM intervention, those specific factors and individual child characteristics that determine differential response to treatment, are still greatly needed (Rogers & Dawson, 2010).

The current paper aims to expand the current state of the research on the ESDM as an effective intervention for children with ASD by examining both treatment outcomes as well as moderators of those outcomes. Three treatment outcomes will be examined, each relating closely to the conceptualization and goals of the ESDM and highlighting the anticipated relationship between general areas of development and specific behaviors (Charman & Howlin, 2003; Drew et al., 2002; Lord et al., 2005). For example, the ESDM curriculum focuses closely on creating positive emotional states in children during social interactions in an effort to enhance the reward value of social interactions (Rogers & Dawson, 2010). In the current study we measure this construct through the specific child behavior of *shared positive affect*. The ESDM also aims to teach the building blocks of social interaction, one of which is intentional nonverbal communication. The ESDM curriculum builds nonverbal communication skills in two stages, focusing first on natural gestures and then on conventional gestures (Rogers & Dawson, 2010). Therefore, the second outcome of this study is *gesture use*. Finally, the ESDM emphasizes intensive teaching, delivering learning opportunities constantly in the midst of social exchanges, in order to fill in the learning gaps for children with ASD. Within these sensitive and responsive social exchanges, which employ rich language to narrate a child's interests and activities, improvements in language development through modeling and imitation are expected (Rogers & Dawson, 2010). The third outcome for the current study, therefore, is *receptive and expressive language.* Although these three outcomes align closely to the theoretical conceptualization of the ESDM, they are also practically meaningful for parents. Starting with shared positive affect and moving through gesture use and verbal communication, the current outcomes represent a developmental sequence toward increased social communication and, ultimately, trajectories of developmental progress. To date, no studies have examined the moderators of the ESDM intervention. In the current study, we will examine whether initial levels of children's *social orienting skills, response to joint attention, and object use* moderate the three ESDM treatment outcomes described above.

**D. Summary of the ESDM**

In summary, the ESDM emphasizes a multi-disciplinary perspective that incorporates interpersonal exchange and positive affect, shared engagement with real-life materials and activities, ongoing verbal and nonverbal communication, a developmentally based curriculum addressing all developmental domains, teaching practices based on the principles of applied behavior analysis (ABA), individualization of each child's program, and a strong parent-family role that is responsive to each child and family's unique characteristics (Rogers & Dawson, 2010). Additionally, research evaluating the effectiveness of the ESDM offers a rare opportunity to examine the long-term impact of early intensive intervention that targets core social and communication deficits in children with ASD as young as 18 months old. Such longitudinal studies initiated at a very young age may be helpful in understanding the relationship between different levels of change that are targeted as part of an intervention. For example, is it necessary that a child with ASD improve in joint attention in order to show improvement in language in response to intervention? (Lord et al., 2005). The current study systematically tests the ESDM intervention, examining the main treatment effect of the ESDM on the developmental outcomes of shared positive affect, gesture use, receptive language, and expressive language. We will also examine whether these ESDM treatment outcomes are moderated by initial levels of children's social orienting skills, response to joint attention, and object use.

**VI. The Current Research Paper**

Advances in the early identification of ASD are essential for access to early intervention and, as a result, better outcomes for this population. While some researchers have examined variability in outcomes among children diagnosed as young as 30 months of age (Harris & Handleman, 2000; Landa, Holman, & Garrett-Mayer, 2007; Turner & Stone, 2007), there is a lack of published outcome data, particularly from randomized controlled trials, on intervention models or treatment effectiveness for children who begin intervention by or before 30 months. The goal of the current study is to examine the efficacy of the ESDM for improving outcomes of toddlers diagnosed with ASD and to examine potential moderators of treatment outcome.

Participants in the ESDM study included 48 children between the ages of 18 and 30 months diagnosed with autistic disorder or pervasive developmental disorder-not otherwise specified (PDD-NOS). Children were randomly assigned to either the ESDM group or an assess-and-monitor (A/M) group. The study lasted two years. The ESDM group received yearly assessments, 20 hours/week of the ESDM intervention from University of Washington clinicians, parent training, and any other community services the parents chose. In addition, caregivers were encouraged to incorporate ESDM techniques into everyday routines (estimated to be 10 or more hours/week),. The A/M group received yearly assessments with recommendations and referrals for interventions from community providers in the greater Seattle area. All children were evaluated by experienced examiners naïve to intervention status at three time points: 1) Time 1 (pre-intervention), 2) Time 2 (1 year after the onset of the intervention), and 3) Time 3 (at either 2 years after the onset of the intervention or at 48 months of age, whichever yielded a longer time frame).

The current study is unique in that it is the first randomized controlled trial of early intervention with toddlers with ASD, and only the second paper to examine the efficacy of the ESDM intervention. Additionally, this project addresses the need for information regarding specific factors and individual characteristics that determine differential response to intervention in this population. In regards to examining treatment effectiveness, the current study is unique both in its methodological rigor (i.e., longitudinal design including gold-standard diagnostic criteria, randomized group assignment, evaluation by naïve examiners, and fidelity monitoring for the implementation of a manualized intervention) and its target population (i.e., children with ASD as young as 18 months old). It represents a rich source of longitudinal information that will have important implications for future research related to the design, evaluation, and individualization of early intervention for toddlers with ASD. Further, this project is the first of its kind to examine moderators of early intervention in young children with ASD over a two-year period.

A study describing the initial findings using this same sample was published in the journal *Pediatrics* (Dawson et al., 2010). The purpose of the proposed project is to evaluate different aspects of the ESDM intervention than those reported previously. The specific aims of the proposed project are as follows.

**A. Aims**

*Aim 1. To examine the main treatment effect of the ESDM on the developmental outcomes of shared positive affect, gesture use, and receptive and expressive language.*

The primary aim of the proposed project is to examine the main effect of ESDM treatment on the three outcomes listed above. Each of the proposed outcomes is closely related to the conceptualization and goals of the ESDM and its developmental approach. Starting with shared positive affect and moving through gesture use and language abilities, these outcomes represent a developmental sequence of increased social communication skills.

Aim 1a. Shared Positive Affect as a Treatment Outcome. As described earlier, social-emotional skills involve attention to and interest in social stimuli early in life, developing into acts of both affective initiation and response. One such skill that promotes child development in this area is positive affect (Grossman, 2010; Maccoby & Martin, 1983). Shared positive affect (SPA) occurs when both the child and another individual (e.g., parent or caregiver) are engaged in a positive and shared affective experience, taking the observable form of laughter, smiling, or affectionate touch. Additionally, research suggests that in the long term, SPA may be related to increased child compliance, moral development, social skills, frustration tolerance, and adjustment in kindergarten in typically developing children (Kochanska & Aksan, 1995; Kochanska & Murray, 2000; Laible & Thompson, 2000). Siller & Sigman (2002) reported that higher levels of parent/child synchronization and affective attunement, a form of SPA, led to superior joint attention and language development 1, 10, and 16 years later in 4 year old children with ASD.

In an effort to bring children with ASD back into the social loop and promote affective, reciprocal interactions, the ESDM provides intensive social enrichment during a developmental period when dyadic and triadic interactions are emerging. The ESDM curriculum focuses closely on creating positive emotional states in children during social interactions in an effort to enhance the reward value of social interaction and reshape children's responsivity to voices, faces, and eyes (Rogers & Dawson, 2010). Strategies include the use of very enjoyable sensory social routines, within the context of a social dyad, and also the use of highly preferred object routines that are accompanied by and embedded within strongly social interactions. The adult, either the therapist or parent, uses clear, genuine, and natural positive affect throughout the interaction that is matched to the child's needs and abilities. Additionally, the adult modulates and helps regulate the child's affect, arousal, and attentional state so that optimal learning and participation takes place. Creating these positive, interactive routines serves to capture the child's attention and to support information processing within a social-communicative framework (Rogers & Dawson, 2010).

Aim 1b. Gesture Use as a Treatment Outcome. The ESDM curriculum builds intentional nonverbal communication skills in two stages, focusing first on natural gestures (e.g., raising feet to another's hands as a request for continued physical play) and then on conventional gestures (e.g., pointing, waving, or head nodding). The preliminary focus on natural gestures helps children develop the necessary tools to 1) regulate their own behavior by learning how to convey their desires to others as a request or protest, 2) interact socially with others by obtaining or maintaining the attention of a social partner, and 3) share attention with a social partner about an object or an event in joint attention scenarios (Rogers & Dawson, 2010). The ESDM utilizes sensory and motor activities to initially elicit a child's natural gestures including reaching toward a toy of choice or actively pushing away an unwanted item. The emphasis of this early gesture teaching is setting up activities in which the child's natural actions can be elicited and responded to as communicative acts. In their ESDM manual, Rogers and Dawson (2010) give a wonderful teaching example with a young child named Landon who, at the beginning of treatment, used very little intentional communication. In the example, Landon is independently laying on the floor playing with his feet. The therapist capitalizes on this motor activity to stimulate and reinforce Landon's natural use of gestures. She begins by tapping his feet together while singing and smiling at him. He begins to engage with her and in order for her to continue with the game, she waits for him to communicate through his use of body movements or natural gestures (i.e., raising his feet to her hands or clapping). The therapist acts contingently on each gesture, creating a social learning opportunity out of an intrinsically motivating activity (Rogers & Dawson, 2010). Although a child's behaviors that constitute natural gestures may be very subtle and not intentional at the beginning of treatment, therapists and parents are taught to elicit, interpret, and reinforce behaviors within play routines as intentional communicative acts in order to establish stronger, clearer and more meaningful gestures. Additionally, the ESDM emphasizes the importance of waiting for children to initiate and use their own bodies to communicate. When parents and therapists do less prompting, children are given a chance to do more independent communication (Rogers & Dawson, 2010). The process of shaping is used to help subtle gestures evolve into clearer gestures.

The second stage of teaching nonverbal communication skills within ESDM focuses on conventional gestures such as head shakes for "no," nods for "yes," pointing, blowing a kiss, shoulder shrugs, and hand gestures indicating "stop." The ESDM emphasizes teaching these gestures once a child has a variety of natural gestures that he or she uses for social purposes (e.g., to regulate other's behavior, to initiate and continue dyadic social interactions, and to coordinate attention to an object or event with a partner; Rogers & Dawson, 2010). When teaching these gestures, therapists and parents are trained to ensure that the target gesture has meaning for the child, that is, that the child already expresses the communicative function in some way. Gesture learning takes place within preferred activities or social routines, and utilizes the techniques of imitation, modeling, and natural reinforcement (Rogers & Dawson, 2010).

<u>Aim 1c. Receptive and Expressive Language as a Treatment Outcome.</u> As described above, young children with ASD exhibit severe difficulties in receptive and expressive language.

However, these children are capable of making considerable gains in language skills when given the right support and intervention. Within the ESDM framework, language development is facilitated through the use of both nonverbal and verbal communication and is presented to the child directly and simply within meaningful communicative exchanges. The ESDM trains therapists and parents to constantly create opportunities for the child to intentionally communicate throughout the day. Using a variety of joint activities (e.g., vocal play, imitation, modeling, and shaping), the child progresses through the fundamentals of nonverbal behaviors to vocalizations to multi-word utterances. A key element to this process is following a developmental model of how typical children learn to use and understand spoken language, that is, learning functional language skills based on their own thoughts and feelings (Tager-Flusberg, 1993; Prizant & Wetherby, 1998; Yoder & Warren, 2001; Charman et al., 2001).

The ESDM posits that understanding language is imperative to using it and, therefore, expects receptive and expressive language to develop concurrently. This developmental sequence of language learning is reflected in its curriculum, in which receptive and expressive language are woven into every activity and are taught using naturalistic strategies (Rogers & Dawson, 2010). To promote receptive language development, children are taught the importance of verbal speech through listening and attending skills as well as responses to instructions. Specific intervention targets for receptive language development might include direct eye contact, orienting when one's name is called, response to joint attention, and responding to a direct verbal request with or without gestures (i.e., "sit down," "clean up," "give me [object]"; Rogers & Dawson, 2010). To promote expressive language development, the ESDM emphasizes intentional communication first through vocalizing and nonverbal behaviors (e.g., refusing an object by pushing it away, pointing to indicate a choice). Target skills then include the spontaneous use of consonants, word approximations, single words, and finally word combinations (Rogers & Dawson, 2010). With a focus on developing an understanding and use of several forms of language, the ESDM teaches children with ASD to clarify their own intentions and follow the intentions of a communication partner, enabling them to communicate without relying on the immediate context (Wetherby, Prizant, & Schuler, 2000).

*Aim 2. To examine whether the above ESDM treatment outcomes are moderated by initial levels of children's social orienting skills, response to joint attention and object use.*

A secondary aim of the proposed project is to address the need for information regarding specific factors and individual characteristics that determine differential responsiveness to intervention in young children with ASD. This study is the first of its kind to examine moderators in a longitudinal, randomized controlled trial of early intervention with toddlers diagnosed with ASD. There are several candidate variables likely to be involved in treatment response in this population, but many of the studies demonstrating these effects lack the methodological standards to parcel out effects due to treatment versus effects due to natural development over time (Lord et al., 2005). Particularly, randomized controlled trials, such as the current study, are needed that include longitudinal outcomes of treatment efficacy as well as the analysis of moderators of treatment response. As described in section *C. Statistical Analysis and Hypotheses*, each moderator will be used for all three outcome measures and the rationale behind these analyses will be discussed. In the following subsections, each moderator is presented briefly.

Aim 2a. Social Orienting as a Moderator of Treatment Effects. Young children with ASD often fail to spontaneously orient to naturally occurring social stimuli and this deficit is proposed to be one of the earliest indicators of reduced social motivation in ASD (Dawson et al., 2004; Dawson et al., 1998). Additionally, reduced social orienting leads to decreased engagement in the social world, which further contributes to a failure to develop expertise in processing of social information such as faces and language (Dawson, Webb, & McPartland, 2005; Dawson et al., 2005; Grelotti et al., 2002). Therefore, previous research supports the use of social orienting as a moderator of treatment effects in the current study, specifically the outcomes of shared positive affect, gesture use, and language ability.

Aim 2b. Response to Joint Attention as a Moderator of Treatment Effects. In the proposed study, we will examine RJA skills at Time 1 as a moderator of ESDM treatment response. Previous research indicates a concurrent and predictive relationship between RJA skills and language abilities (e.g., Luyster et al., 2008) as well as social skills (e.g., Hutman et al., 2011). Therefore, there is a precedent for examining RJA as a moderator of gesture use, receptive language, and expressive language. The moderating effects of RJA on SPA are less clear due to conflicting literature regarding the developmental sequence of RJA and SPA. Our hypotheses related to this moderating relationship are discussed below.

Aim 2c. Object Use as a Moderator of Treatment Effects. Object use has a relationship to and provides opportunities for joint engagement (around the activity that the child is focused on) and consequently for social development and language learning (Mundy & Neal, 2001; Rogers & Dawson, 2010). Previous research demonstrates that object interest moderates treatment effects on child communication gains (Carter et al., 2011; Yoder & Stone, 2006), but a lack of research exists that examines object use as a moderator of treatment effects on shared positive affect. In the current study, therefore, we will attempt to replicate previous findings indicating that object use moderates communication gains, specifically gesture use, receptive language, and expressive language. We will also explore the role of object use as a moderator of treatment effects on shared positive affect.

## B. Methods

### *i. Participants*

Forty-eight participants for the ESDM study were recruited through pediatric practices, Birth-to-Three centers, preschools, hospitals, and state and local autism organizations (over 90 agencies in all). Exclusion criteria included 1) a neurodevelopmental disorder of known etiology (e.g., fragile X syndrome), 2) significant sensory or motor impairment, 3) major physical or medical problems such as a chronic serious health condition, 4) seizures at time of entry, 5) use of psychoactive medications, 6) history of a serious head injury and/or neurological disease, 7) alcohol or drug exposure during the prenatal period, 8) prematurity, and 9) ratio IQ below 35 as measured by mean age equivalence score/chronological age on the visual reception and fine motor subscales of the Mullen Scales of Early Learning (MSEL). Children who developed seizures during the course of the study were not excluded. Inclusion criteria included 1) younger than 30 months old at entry, 2) meeting criteria for autistic disorder on the Toddler Autism Diagnostic Interview, 3) meeting criteria for autism or ASD on the Autism Diagnostic Observation Schedule, 4) meeting a clinical diagnosis based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria using all available information, 5) residing within 30 minutes of the University of Washington, and 6) willingness to participate in a 2- year intervention. At Time 1, 18 children in the A/M group and 21 in the ESDM group received a DSM-IV diagnosis of Autistic Disorder. Six children in the A/M group and 3 in the ESDM group received a diagnosis of PDD-NOS. This difference was not significant (Fisher's exact test, $p$ = .231). The ethnicities involved were Asian (12.5%), white (72.9%), Latino (12.5%), and multiracial (14.6%), reflecting the minority distribution of the wider Seattle area. The male-to-female ratio reflected the expected ratio in ASD of 3.5:1.

Retention rates were 100% (Time 2) and 100% (Time 3) for the ESDM group and 96% (Time 2) and 88% (Time 3) for the A/M group, which yielded a sample size of 24 in the ESDM and 21 in the A/M group at outcome. Therefore, data from all 48 participants, regardless of study endpoint, will be included in an intent-to-treat analysis using imputation to address the issue of missing data.

*ii. Procedures*

Forty-eight children between 18 and 30 months of age diagnosed with Autistic Disorder or PDD-NOS, were randomly assigned to 1 of 2 groups: (1) the ESDM group, which received yearly assessments, 20 hours per week of the ESDM intervention from University of Washington clinicians, parent training, ESDM parent delivery for 5 or more hours per week, and any additional community services the parents chose; and (2) the Assess-and-Monitor (A/M) group, which received yearly assessments with intervention recommendations and referrals for intervention from commonly available community providers in the greater Seattle region. Children were evaluated by experienced examiners naive to intervention status at Time 1 (pre-intervention), Time 2 (1 year after onset of the intervention), and Time 3 (at either 2 years after onset of the intervention or at 48 months of age, whichever yielded a longer time frame).

*1. Randomization*

Participants were stratified into 2 groups on the basis of composite IQ at entry (<55 and >=55) and gender to ensure comparable IQ and gender ratios between treatment groups. Within each of these strata, randomization was conducted by using random permuted blocks of 4. The intervention groups did not differ at Time 1 in severity of autism symptoms based on ADOS scores, chronological age, IQ, gender, or adaptive behaviors (see Table 4., Dawson et al., 2010).

Table 4. Clinical characteristics for ESDM and A/M groups at Time 1 (preintervention).

| | A/M Group *n*=24 | | ESDM Group *n*=24 | | F | MS | *P* |
|---|---|---|---|---|---|---|---|
| | Mean (SD) | Range | Mean (SD) | Range | | | |
| Age at study entry, mos | 23.1 (3.9) | 18-30 | 23.9 (4.0) | 18-30 | 0.48 | 7.52 | .490 |
| Gender | | | | | | | |
| Male (%) | 18 (75) | --- | 19 (79) | --- | | | |
| Female (%)19M, 5F | 6 (25) | --- | 5 (21) | --- | | | |
| Ethnicity | | | | | | | |
| Asian (%) | 3 (12.5) | --- | 3 (12.5) | --- | | | |
| Hispanic (%) | 2 (8.3) | --- | 3 (12.5) | --- | | | |
| Multi-Racial (%) | 3 (12.5) | --- | 4 (16.7) | --- | | | |
| White (%) | 18 (75) | --- | 17 (70.8) | --- | | | |
| Mullen Early-learning composite[a] | 59.4 (8.6) | 49-74 | 61.0 (9.2) | 49-77 | 0.40 | 31.69 | .530 |
| VABS Adaptive behavior composite[a] | 69.9 (7.3) | 60-86 | 69.5 (5.7) | 57-84 | 0.04 | 1.69 | .844 |
| ADOS severity score | 6.9 (1.7) | --- | 7.2 (1.7) | --- | 0.35 | 1.02 | .557 |
| ADOS diagnosis | | | | | | | |
| Autistic Disorder (%) | 18 (75) | --- | 21 (87.5) | --- | | | |
| PDD-NOS (%) | 6 (25) | --- | 3 (12.5) | --- | | | |
| RBS total | 21.5 (19.2) | 2-86 | 15.2 (10.8) | 1-40 | 1.93 | 468.75 | .171 |

No significant differences among variables measured at Time 1 ($p$ >.10 on all measures).
[a] Standard score (mean:100 [SD:15]).

*2. ESDM Intervention*

The ESDM is based on the Denver Model, a comprehensive intensive early behavioral intervention for preschool-age children with autism originally developed and evaluated by Rogers and colleagues (Rogers et al., 1986; Rogers & Lewis, 1989; Rogers et al., 2000). The Early Start Denver Model is designed to address the unique needs of toddlers with autism as young as 18 months. This model incorporates applied behavior analysis (ABA) teaching principles that have received empirical support for improving skill acquisition in very young children with autism (i.e., operant conditioning, shaping, and chaining; Green et al., 2002; McGee et al., 1999), but is delivered in a naturalistic, social, and affectively-based relationship context. The intervention is provided in the toddler's natural environment, typically in the home, within the context of family-child and therapist-child interactions. As children reach preschool age, play-dates that facilitate child-child interaction and collaboration with preschools are incorporated.

a. Role of Parents. Parents are an integral part of the intervention and play a central role in determining objectives, devising the curriculum, and refining teaching practices. Parents are part of each therapy assessment and their input is sought on all objectives. Additionally, parents receive ongoing parent training that is offered in the home twice a month. The goals of parent training include empowering parents via skill acquisition, promoting a positive parent-child relationship and sense of parent competency, and generalizing the skills each child has acquired to everyday family activities. Each parent is trained in ABA methods, with an emphasis on PRT-based strategies. Sensitivity to values, cultural background, resources, and challenges of each family are emphasized. Appropriate referrals to outside professionals are readily offered to parents who might be experiencing mental health problems, such as depression or marital difficulties. Parents agree to use strategies learned in parent training for a minimum of 10 hours per week in the context of everyday activities (i.e., feeding, bath time, and play) and to keep a log of time spent using strategies at home.

b. Delivery. The intervention is delivered in the child's home and totals 30 hours per week of individual intervention. Therapist assistants work individually with the child for 2 hour sessions, twice a day, 5 days a week. Parents deliver an additional 10 hours of intervention. ESDM intervention hours were systematically recorded. Although therapist-delivered intervention hours per week were made available to families, due to illness, vacations, etc., the actual mean was 15.2 (SD: 1.4). Parents reported using ESDM strategies an average of 16.3 (SD: 6.2) hours per week. Over the study enrollment period, the ESDM group reported an average of 5.2 hours per week (SD: 2.1) in *other* therapies (e.g., speech therapy, developmental preschool). These additional therapies were documented using an intervention history interview, which was administered every 6 months (Dawson et al., 2010). ESDM intervention sessions followed a typical structure with activities within each session alternating between object-based routines and sensory social routines. The therapist maximized child motivation and attention by varying activities between the table and the floor, and between quiet and active episodes.

c. Training and Qualification of Providers. Each family's therapy team consisted of case supervisors, a clinical psychologist, a speech-language pathologist, a developmental behavioral pediatrician, and therapy assistants. An occupational therapist provided consultation as needed. Case supervisors managed the individual child's program, had a minimum of a Master's degree in applied behavior analysis or early childhood education, and a minimum of 5 years experience providing early intervention to young children with autism. Each therapy team met monthly for two days in person with Drs. Sally Rogers and Geraldine Dawson. The team also met semi-monthly with Dr. Dawson and weekly with other case managers and the clinical psychologist for peer supervision and to review intervention objectives and strategies. The intervention was observed at least bi-weekly by the lead therapist and every 3 months by the speech-language pathologist. Therapy assistants held baccalaureate degrees in education or related fields and had some experience with either young children or with children with autism. Therapy assistants participated in a two-month, full-time training provided by the lead therapist, met weekly with the lead therapist, and were observed regularly to assess ongoing clinical competence. Training included didactic readings, homework, observations, hands-on training, and in vivo feedback with current participants in the study. Therapy assistants worked independently with toddlers once they met the rigorous criteria for clinical competency across three sessions and multiple children. Competency was defined as completing coursework, passing tests, mastering the intervention, demonstrating fidelity of 85% of maximum scores on the fidelity instrument, and maintaining ongoing fidelity.

d. Intervention Fidelity. A previously developed measure of therapist competence and protocol adherence for Roger's Denver Model of intervention was adapted to assess the fidelity of administration of the ESDM. Fidelity ratings focus on the use of behavioral teaching procedures, naturalistic teaching, and affective and communicative aspects of the session. A detailed fidelity coding manual was adapted from the Denver Model Therapy Rating Scale to operationally define items and provide behavioral anchors for each item, with a maximum score of 5 per item. The range of scores between 4 and 5 indicates competent delivery of the model within that session across activity episodes.

*iii. Intervention Groups*

a. ESDM Group. The ESDM group was provided with intervention by trained therapists for 2-hour sessions, twice per day, 5 days per week, for 2 years. A detailed intervention manual and curriculum were used (Rogers & Dawson, 2010). Each child's plan is individualized. One or both parents were provided with parent training from the primary therapist during semi-monthly meetings, during which the principle and specific techniques of ESDM were taught. Parents were asked to use ESDM strategies during daily activities and to keep track of the number of hours during which they used these strategies.

b. A/M Group. Children who were randomly assigned to the A/M group received comprehensive diagnostic evaluations, community referrals, and recommendations for intervention services at Time 1 and again at each of the two follow-up assessments. Families were given resource manuals and reading materials (i.e., magazines) at Time 1 and twice yearly throughout the study. Careful documentation of community-based interventions received by children in the study was made via an intervention history interview (the same interview used to document intervention for the ESDM group). Since enrollment, parents were administered the intervention history interview every three months to assess community-based interventions across a variety of settings. Information collected included 1) type of intervention (e.g., speech/language, occupational therapy, medical, alternative), 2) group vs. 1:1 intervention, 3) number of hours per week, 4) staff-to-student ratio, and 5) training level of service providers. This interview has been successfully used in two previously NIH-funded longitudinal studies conducted by our research team. Evidence from these studies indicates that children with ASD in the greater Seattle area, on average, receive fewer than 10 hours of structured intervention during the preschool period and less than this below 2 years of age. Except for Microsoft Corporation and the Armed Forces, insurance benefits do not cover intensive behavioral intervention and there is no systematic state funding provided for intensive intervention. Furthermore, for those families who can afford private pay, long wait-lists prevent families from quickly accessing available providers. During the 2-year period in which the study was conducted, the A/M group reported an average of 9.1 hours per week of individual therapy and an average of 9.3 hours per week of group interventions (e.g., developmental pre-school; Dawson et al., 2010). In the greater Seattle area, there are a number of Birth-to-Three centers that provide interventions, speech and language therapy, and occupational therapy. Developmental preschool programs vary, but typically include special education and related services. There are a number of private ABA providers in the community (Dawson et al., 2010).

*iv. Measures*

a. Participant Diagnostic Measures**.** Time 1 diagnoses were made on the basis of two gold-standard measures combined with a clinical best estimate diagnosis from a licensed psychologist based on the presence or absence of autism symptoms per DSM-IV-TR diagnostic criteria. First, the Autism Diagnostic Interview–Revised (ADI-R; Lord et al., 1994) is a semi-structured and standardized parent interview developed to assess the presence and severity of symptoms of autism in early childhood across three main symptom domains: social relatedness; communication; and repetitive, restricted behaviors. In the current study, the toddler version of the ADI-R was used. Second, the Autism Diagnostic Observation Schedule-WPS (ADOS; Lord et al., 1999) is a semi-structured standardized observation that involves the presentation of a variety of social occasions and 'presses' designed to elicit behaviors relevant to diagnosing ASD, including social relatedness, communication, and repetitive behaviors. The ADOS consists of four developmentally sequenced modules of which only one is administered depending on the examinee's expressive language ability. Each module includes a standardized diagnostic algorithm composed of a subset of social and communicative behaviors that result in a severity score. These severity scores can be calculated to compare autism symptoms across modules (Gotham, Pickles, & Lord; 2009), with lower scores indicating better functioning. Due to the age and language ability of the participants in the current study, all children were evaluated using either Module 1 or 2.

b. Outcome Measures**.** The outcomes of shared positive affect and gesture use were measured using the Communication and Symbolic Behavior Scales-Developmental Profile (CSBS–DP: Wetherby and Prizant, 2002). The CSBS-DP is a 20-minute procedure that evaluates verbal and non-verbal communication in children at risk for communication and language impairments. During the CSBS-DP, the child was seated at a table next to his/her parent and a familiar examiner whom he/she met and interacted with prior to the testing session. The child was presented with a variety of toys, one at a time, including a wind-up toy, a balloon, bubbles, a jar filled with cereal, a book, a Kermit doll and set of play utensils, blocks, and a bag filled with toys. The examiner documented whether the child displayed one or more of eight conventional gestures (e.g., reach, nodding head, waves, or gives) and any distal gestures. The CSBS-DP Standard Score for gesture use (based on a mean of 10 and SD of 3) will be used in the current study at Time 1 to measure initial gesture use of all participants and at Time 3 to measure treatment effects. The CSBS-DP also measures a child's use of shared positive affect during interactions involving six different toys. During these interactions, the examiner documents whether the child uses shared positive affect with the examiner or his/her parent. In the current study shared positive affect is represented by a single item (#2) and scores ranged from 0 to 6. Shared positive affect was measured at Time 1 and Time 3.

The outcomes of receptive and expressive language were measured using the Mullen Scales of Early Learning (MSEL; Mullen, 1995). The MSEL is a standardized measure of developmental and cognitive function for infants and preschool children from birth to 68 months of age. Four of the five subscales were administered including Fine Motor, Visual Reception, Expressive Language, and Receptive Language. T-scores for subscales have a mean of 50 (SD: 10). The Early Learning Composite score is a standard score with mean of 100 (SD: 15). The Mullen was administered to each child at Time 1, Time 2, and Time 3. For the purposes of the current study, the Expressive Language t-score and the Receptive Language t-score from all three time points will be used for analysis.

c. Moderators**.** Social orienting was measured using the Social Orienting Task based on the research of Garry Butterworth (e.g., Butterworth & Jarrett, 1991**).** In this task, the child was seated across from a familiar examiner. A second examiner delivered a series of stimuli from various points in the room. Stimuli were either social (e.g. calling the child's name, patting hands on thighs, snapping fingers, or humming) or nonsocial (e.g. timer ticking, phone beep, whistle, and car horn). Social and non-social stimuli were matched on duration (six seconds each) and loudness. The order and location (30 degrees to the right and left in front of the child, and 30 degrees to the right and left behind the child) of the stimuli were counterbalanced across subjects. The child's orienting responses (i.e., turning eyes and/or head in the direction of the sound) were assessed for both nonsocial (4 trials) and social stimuli (4 trials). The child received a score of "1" for each successful trial yielding scores ranging from 0 to 4 for nonsocial orienting and from 0 to 4 for social orienting. Parents were also asked to rate the child's degree of familiarity with each sound on a scale of 1 to 5 (with 1 being very unfamiliar and 5 being familiar). Social orienting was measured at Time 1 (preintervention) and Time 3 (2-year outcome). The current study examines social orienting as a moderator of treatment effects, therefore, only Time 1 scores of social orienting will be analyzed.

Response to joint attention was measured using the Response to Joint Attention Task (also based on the research of Garry Butterworth; e.g., Butterworth & Jarrett, 1991). During this task, the child was seated at a table across from a familiar examiner whom he/she met and interacted with prior to the testing session. Two colorful posters were located on the walls of the room. After gaining the child's attention, the examiner attempted to direct the child's attention to one of the posters by saying, "Look," using either a pointing gesture accompanied by a gaze shift (2 trials) or a gaze shift alone (2 trials). The child received a score of "1" for each successful trial, therefore, scores for this task ranged from 0 to 4. Response to joint attention was measured at Time 1 (preintervention) and Time 3 (2-year outcome). The current study examines response to joint attention as a moderator of treatment effects, therefore, only Time 1 scores of response to joint attention will be analyzed.

The moderator of object use was measured using the Communication and Symbolic Behavior Scales-Developmental Profile (CSBS–DP: Wetherby and Prizant, 2002). One component of this 20-minute assessment is the evaluation a child's appropriate use of twelve different toys (e.g., drinks with cup, pours, or stirs). On the CSBS-DP, object use is represented by a single item (#17) and scores range from 0 to 12. In the current study, object use was measured at Time 1 and Time 3 (2-year outcome), but only Time 1 scores will be used for moderation analysis.

**C. Statistical Analysis and Hypotheses**

*i. Data Management*

The current data set was examined for outliers using plots, histograms, and stem and leaf plots. No outliers were detected. Interaction terms for moderation analysis were created. Time 1 values of outcome variables and moderators were grand mean centered in order to remove high correlations between the random intercept and slopes, and high correlations between first- and second-level variables and cross-level interactions (Kreft & de Leeuw, 1998). Additionally, grand mean centering predictor variables may provide estimates and other effects that can be related back to the theoretical concerns motivating the current research question (Kreft & de Leeuw, 1998), which for the current study involves identifying specific factors and individual characteristics that determine differential responsiveness to intervention in young children with ASD.

*ii. Intent-to-Treat Design*

As mentioned above, an intent-to-treat analysis using imputation was used to address the issue of missing data. At Time 1, both A/M and ESDM groups had a sample size of 24 participants. Although retention rates were 100% for the ESDM group at Time 2 and Time 3, the A/M group had retention rates of 96% ($n$=23) at Time 2 and 88% ($n$=21) at Time 3. Intent-to-treat designs (i.e., analyzing all participants assigned and imputing missing data as necessary) are used to increase the internal validity of treatment studies (Moher, Schulz, & Altman, 2001). Multiple imputation (MI) is one of two recommended methods for analyzing data sets with missing data (Enders, 2010; Graham, 2009). For the current study, MI was used and involved two primary steps: 1) imputation and 2) analysis. For the imputation step, multiple (five) complete data sets were created using a regression-based procedure in SPSS. As recommended by Enders (2010), all available data were used to impute the missing values of six variables: (a) receptive language at Time 2, (b) expressive language at Time 2, (c) receptive language at Time 3, (d) expressive language at Time 3, (e) gesture use at Time 3, and (f) shared positive affect at Time 3. During the analysis step, statistical analyses were conducted on all imputed data sets including correlation analysis, repeated measure ANOVA, and multiple regressions. MI as a method for dealing with missing data has been found to be as accurate as the primary alternative, full information maximum likelihood (Enders, 2010; Graham, 2009), and may be more easily understood by psychologists and educators at this stage of these fields' development (Graham, Cumsille, & Elek-Fisk, 2003).

*iii. Statistical Analysis*

*Aim 1. To examine the main treatment effect of the ESDM on developmental outcomes, including shared positive affect, gesture use, and receptive and expressive language.*

The primary aim of the proposed project was to examine the treatment effects of the ESDM on developmental outcomes in young children with ASD. Outcome variables included gains in shared positive affect and gesture use via the CSBS-DP from Time 1 to Time 3, and receptive and expressive language via the Mullen from Time 1 to Time 2, and from Time 1 to Time 3. Treatment groups were dummy coded (0=A/M group, 1=ESDM group), and the main effect of treatment group assignment on child outcome variables was assessed by using repeated-measures analysis of variance (ANOVA), with a priori contrasts that compared Time 1 scores with Time 2 and Time 3 outcome scores. Analyses were conducted using SPSS version 20.0. The alpha level for significance for all analyses was set at .05.

At Time 1, the intervention groups did not differ in severity of ASD symptoms (based on the ADOS scores), chronological age, IQ, gender, and other variables (see Table 4). Therefore, none of these variables are considered confounding variables and were not be included as covariates in order to maximize power. An a priori regression power analysis was performed using the computer software program G*Power (Faul, Erdfelder, Lang, & Buchner, 2007). The analysis revealed that in order to detect significance with the current study sample size of 48 participants and obtain a power of .80, the minimum effect size needed is 0.17.

*Aim 2. To examine whether treatment outcomes are moderated by the following child characteristics at Time 1: social orienting, response to joint attention, and object use.*

A secondary aim of the proposed project was to increase understanding of the specific factors and individual characteristics that influence differential responsiveness to intervention in young children with ASD; specifically, we asked whether Time 1 social orienting, response to joint attention, or object use moderated the effect of treatment on gains in shared positive affect and gesture use from Time 1 to Time 3, and receptive and expressive language from Time 1 to Time 2 as well as Time 1 to Time 3. Consistent with recommendations for randomized clinical trials (McCartney et al., 2010) and in an effort to conserve statistical power, outcome variable gains were quantified as residualized gain scores. These scores were obtained by regressing the Time 1 measure of each outcome variable onto the later measure of the same variable (Carter et al, 2011). Analyses were conducted using SPSS version 20.0.

Linear regression was employed to determine whether Time 1 child SO, RJA, or object use moderated the effect of ESDM intervention on child outcomes at Time 2 and Time 3 (see Table 5 for variable values across study time points). Separate linear regression was used for each outcome variable (SPA, gesture use, receptive and expressive language). As recommended by Aiken and West (1991), interaction terms were created by grand mean centering the Time 1 moderator variables and multiplying them by the dummy-coded treatment status variables. All variables were entered in one step, including treatment group, grand-mean centered moderator variable (i.e., SO at Time 1), interaction term (i.e., group x SO), and grand-mean centered values of the DV at Time 1 (i.e., SPA at Time 1 when running regression for SPA at Time 3). The Bonferroni correction procedure was applied to control for Type I error.

When moderation was observed, the method recommended by Preacher and colleagues (2006) as well as Hayes and Mathes (2009; MODPROBE for SPSS) was used to identify higher and lower regions of significance. These empirically derived regions of significance specified the upper and lower values of the moderator at which the ESDM and A/M groups were significantly different from one another on a particular dependent variable (e.g., SPA, gesture use, RL and EL). Statistically significant interactions were interpreted only when children from both groups had values in the regions of significance, which represents a statistically conservative and practically meaningful approach to analyzing interactions (Carter et al., 2011; Preacher et al., 2006). As described in Carter and colleagues (2011), this approach is particularly relevant when applied within the context of a randomized controlled trial where it is useful to determine values of the moderator at which the treatment (in this case the ESDM) facilitates or attenuates any given outcome.

Table 5 Means, standard deviations, and ranges of outcome and moderator variables for A/M and ESDM groups across three study time points.

| Study Variables | Time Period | A/M Group | | | ESDM Group | | |
|---|---|---|---|---|---|---|---|
| | | Mean | SD | Range | Mean | SD | Range |
| Shared Positive Affect | T1 | 0.9 | 1.16 | 0-4 | 1.0 | 1.14 | 0-5 |
| | T2 | --- | --- | --- | --- | --- | --- |
| | T3 | 3.0 | 1.38 | 0-6 | 2.8 | 2.07 | 0-6 |
| Gesture Use | T1 | 5.2 | 1.79 | 3-8 | 5.1 | 2.24 | 3-11 |
| | T2 | --- | --- | --- | --- | --- | --- |
| | T3 | 6.9 | 1.96 | 3-10 | 6.8 | 2.30 | 3-12 |
| Mullen Receptive language[a] | T1 | 21.2 | 3.79 | 20-36 | 21.1 | 4.71 | 20-43 |
| | T2 | 31.3 | 10.80 | 20-53 | 38.9 | 15.17 | 20-67 |
| | T3 | 32.0 | 9.97 | 20-55 | 40.0 | 16.06 | 20-69 |
| Mullen Expressive language[a] | T1 | 26.0 | 8.58 | 20-56 | 24.5 | 7.21 | 20-47 |
| | T2 | 33.1 | 11.13 | 20-54 | 36.1 | 13.92 | 20-65 |
| | T3 | 30.6 | 8.73 | 20-43 | 36.6 | 13.37 | 20-69 |
| Social Orienting | T1 | 1.9 | 1.41 | 0-4 | 2.1 | 1.13 | 0-4 |
| Response to Joint Attention | T1 | 1.2 | 1.30 | 0-4 | 0.7 | 0.71 | 0-2 |
| Object Use | T1 | 3.2 | 2.83 | 0-9 | 3.2 | 2.00 | 0-7 |

T1 = Time 1; T2 = Time 2; T3 = Time 3
[a] T score (mean: 50 [SD:10]).

Correlations between outcome variables (at Time1, Time 2, and Time 3) and moderator variables at Time 1 are presented in Tables 6a, 6b, and 6c.

Table 6a. Correlation table depicting relationship between moderator variables at Time 1and outcome variables measured at Time 1.

| | SPA | GES | RL | EL | SO | RJA | OBJ |
|---|---|---|---|---|---|---|---|
| **SPA** | 1.00 | | | | | | |
| **GES** | .261** | 1.00 | | | | | |
| **RL** | .235** | .223** | 1.00 | | | | |
| **EL** | .195* | .155 | .450*** | 1.00 | | | |
| **SO** | .246** | .283*** | .141* | .342*** | 1.00 | | |
| **RJA** | .065 | .424*** | .016 | .115 | .361*** | 1.00 | |
| **OBJ** | .083 | .169* | .173** | .361*** | -.036 | -.012 | 1.00 |

Note. ****p*<.001, ***p*<.01, **p*<.05
SPA=Shared positive affect; GES=Gesture use; RL=Receptive language; EL=Expressive language; SO=Social orienting; RJA=Response to joint attention; OBJ=Object use.

Table 6b. Correlation table depicting relationship between moderator variables at Time 1 and outcome variables measured at Time 2.

| | RL | EL | SO | RJA | OBJ |
|---|---|---|---|---|---|
| **RL** | 1.00 | | | | |
| **EL** | .879*** | 1.00 | | | |
| **SO** | .329*** | .302*** | 1.00 | | |
| **RJA** | .060 | .065 | .361*** | 1.00 | |
| **OBJ** | .109 | .206*** | -.036 | -.012 | 1.00 |

Note. ****p*<.001, ***p*<.01, **p*<.05
SPA=Shared positive affect; GES=Gesture use; RL=Receptive language; EL=Expressive language; SO=Social orienting; RJA=Response to joint attention; OBJ=Object use.

Table 6c. Correlation table depicting relationship between moderator variables at Time 1 and outcome variables measured at Time 3.

| | SPA | GES | RL | EL | SO | RJA | OBJ |
|---|---|---|---|---|---|---|---|
| **SPA** | 1.00 | | | | | | |
| **GES** | .358*** | 1.00 | | | | | |
| **RL** | .175** | .543*** | 1.00 | | | | |
| **EL** | .210*** | .515*** | .854*** | 1.00 | | | |
| **SO** | .169** | .343*** | .237*** | .253*** | 1.00 | | |
| **RJA** | -.059 | .284** | .080 | .080 | .361*** | 1.00 | |
| **OBJ** | .094 | .292*** | .031 | .031 | -.036 | -.012 | 1.00 |

Note. ****p*<.001, ***p*<.01, **p*<.05
SPA=Shared positive affect; GES=Gesture use; RL=Receptive language; EL=Expressive language; SO=Social orienting; RJA=Response to joint attention; OBJ=Object use.

**D. Results**

*i. Aim 1: Treatment Outcomes*

Aim 1a: Shared Positive Affect. The ESDM curriculum specifically fosters the intrinsic reward and motivation of shared social experiences, thereby bringing infants back into social loop and enabling them to capitalize on learning opportunities available within a relational context. Therefore, it was hypothesized that at Time 3, the ESDM group would show greater improvements in SPA than participants in the A/M group. The main effect of ESDM intervention on SPA from Time 1 to Time 3 did not reach levels of statistical significance, $F(1, 283) = .826$, $p = .364$ (see Table 7). The mean SPA score for the ESDM group at Time 3 was $M = 2.8$ ($SD = 2.1$) as compared to $M = 3.0$ ($SD = 1.4$) for the A/M group (see Table 5).

Aim 1b: Gesture Use. Promoting the building blocks of social communication within a relational context, the ESDM supports the development of intentional nonverbal communication. At Time 3, it was hypothesized that the ESDM group would demonstrate greater levels of gesture use than the A/M group. The main effect of ESDM intervention on Gesture Use from Time 1 to Time 3 did not reach levels of statistical significance, $F(1, 283) = .116$, $p = .734$ (see Table 7). The mean gesture use score for the ESDM group was $M = 5.1$ ($SD = 2.2$) as compared to $M = 5.2$ ($SD = 1.8$) for the A/M group (see Table 5).

Aim 1c: Receptive and Expressive Language. The current proposal aimed to replicate the findings of Dawson and colleagues (2010). Dawson and colleagues (2010) reported no significant differences at Time 2 between groups on Receptive or Expressive language t-scores as measured by the Mullen Scales of Early Learning. At Time 3, however, they reported a significant difference between groups on these Mullen subscales with the ESDM group showing greater gains.

In the current study, the main effects of the ESDM intervention on expressive language from Time 1 to Time 2 did not reach significance, $F(1, 285) = .474$, $p = .492$ (see Table 7). The mean expressive language score for the ESDM group at Time 2 was $M = 36.1$ ($SD = 13.9$) as compared to $M = 33.1$ ($SD = 11.1$) for the A/M group (see Table 5). From Time 1 to Time 2, the main effects of the ESDM intervention on Receptive Language did reach significance, $F(1, 285) = 19.528$, $p < .001$. The mean receptive language score for the ESDM group at Time 2 was $M = 38.9$ ($SD = 15.2$) as compared to $M = 31.3$ ($SD = 10.8$) for the A/M group (see Table 5).

At Time 3, treatment group had a significant effect on both participants' receptive and expressive language scores ($F(1, 283) = 24.83$, $p < .001$, and $F(1, 283) = 5.76$, $p = .017$, respectively; see Table 7), which replicates the findings of Dawson and colleagues (2010). The mean receptive language score for the ESDM group was $M = 40.0$ ($SD = 16.1$) as compared to $M = 32.0$ ($SD = 10.0$) for the A/M group (see Table 5). The mean expressive language score for the ESDM group at Time 3 was $M = 36.6$ ($SD = 13.4$) as compared to $M = 30.6$ ($SD = 8.7$) for the A/M group (see Table 5).

*ii. Aim 2: Moderation Analysis*

Aim 2a: Social Orienting. Young children with ASD fail to spontaneously orient to naturally occurring social stimuli in their environment as evidenced by retrospective (e.g., Osterling & Dawson, 1994) and prospective studies (e.g., Mitchell et al., 2006). Additionally, social orienting is one of the earliest indicators of reduced social motivation in ASD (Dawson et al., 2004; Dawson et al., 1998). According to the social motivation hypothesis, infants at risk for ASD spend less time attending to and socially engaging with people because of reduced social motivation. Instead, these infants have a stronger focus on nonsocial stimuli such as objects (Zwaigenbaum et al., 2005). Therefore, reduced social orienting leads to reduced engagement in the social world, which further contributes to a failure to develop expertise in processing of social information such as faces and language (Dawson, Webb, & McPartland, 2005; Dawson et al., 2005; Grelotti et al., 2002). Given that altered early experience may act as risk processes in the development of ASD, the goal of intervention, specifically the ESDM, is to target these risk processes to provide a more enriched environment for the at-risk child. Therefore, we hypothesized that in the current study, participants with higher levels of social orienting at Time 1 would attend to and take advantage of social learning opportunities showing an augmented response to treatment, regardless of treatment condition. This moderation effect was expected in the areas of shared positive affect, gesture use, and language ability. Additionally, due to the emphasis on social learning and providing an enriched context to practice and develop those skills in the ESDM, we predicted that social orienting would be more strongly related to treatment outcome for children enrolled in the ESDM intervention rather than the A/M group.

SO at Time 1 moderated the treatment effects on RL and EL at Time 2 ($t(282) = 3.33$, $p = .001$; $t(282) = 3.30$, $p = .001$; respectively), and SPA and EL at Time 3 ($t(280) = 2.69$, $p < .01$; $t(280) = 2.45$, $p < .05$, respectively; see Table 8). Children who demonstrated greater SO skills at Time 1, exhibited greater gains in RL and EL at Time 2, and SPA and EL at Time 3 if they were randomized to the ESDM group rather than the A/M group. Counter to our expectations, Time 1 social orienting skills did not moderate the treatment effects of the ESDM intervention on gains in child Gesture Use or RL at Time 3, $t(280) = 0.62$, $p = .528$; $t(280) = 1.36$, $p = 0.18$; respectively.

Aim 2b: Response to Joint Attention. As discussed above, RJA abilities are associated with concurrent and future language abilities (Luyster et al., 2008; Murray et al., 2008; Paul et al., 2008; Schietecatte et al., 2011; Sigman & Ruskin, 1999; Tomasello &Todd, 1983), predict change in socialization and daily living skills as measured by the Vineland Adaptive Behavior Scales (Hutman et al., 2011), and predict later ASD diagnosis in 14 month old siblings of children with ASD (Sullivan et al., 2007). Therefore, in the current study we hypothesized that children with more developed RJA skills at Time 1 will show greater improvements in gesture use and both receptive and expressive language development. Additionally, we predict that this effect will be stronger in the ESDM group due the specific instruction of joint attention abilities in the ESDM curriculum. In terms of the relationship between RJA and shared positive affect, research suggests that SPA may develop before RJA abilities (Adamson & Bakeman, 1985, Vaughan et al., 2003). However, Kasari and colleagues (2008) suggest that affect sharing deficits may be improved through the use of interactions embedded in motivating activities and involving both a joint focus of attention and the following of the child's initiations. In consideration of these somewhat contrasting views of the developmental sequence of RJA and SPA, it was hypothesized that RJA would not moderate the effect of treatment on the outcome of SPA for either treatment group.

RJA at Time 1 did moderate the treatment effect on RL at Time 2, $t(282) = 2.97$, $p < .01$; and Gesture Use at Time 3, $t(280) = -2.01$, $p < .05$; see Table 8). Children who demonstrated greater RJA skills at Time 1 exhibited greater gains in Gesture Use if they were randomized to the A/M group. In contrast, those children who demonstrated greater RJA skills at Time 1, exhibited greater gains in RL at Time 2 if they were randomized to the ESDM group. Counter to our expectations, Time 1 response to joint attention did not moderate the treatment effects of the ESDM intervention on gains in child EL at Time 2 ($t(282) = 1.42$, $p = .157$), RL or EL at Time 3 ($t(280) = -0.56$, $p = 576$; $t(280) = 1.58$, $p = .114$, respectively). As we expected, RJA did not moderate SPA at Time 3, $t(280) = -0.48$, $p = .633$.

<u>Aim 2c: Object Use</u>. The current study examined if Time 1 levels of object use moderate the main effects of treatment on the three outcomes variables listed in Aim 1 at Time 3. As

discussed above, object use has a relationship to and provides opportunities for joint engagement (around the activity that the child is focused on) and consequently for social development and language learning (Mundy & Neal, 2001; Rogers & Dawson, 2010). Based on the literature reviewed for the current proposal and previous research that demonstrates object interest as a moderator of treatment effects on child communication gains (Carter et al., 2011; Yoder & Stone, 2006), we predicted that participants with higher levels of object use at Time 1 would be able to take advantage of social learning opportunities and show an augmented response to treatment, regardless of treatment condition, in the areas of shared positive affect, gesture use, and language ability. However, due to the emphasis on social learning and providing an enriched context to practice and develop those skills in the ESDM, we predicted that object use would be more strongly related to treatment outcome for children enrolled in the ESDM intervention rather than the A/M group. For example, the ESDM conceptualizes communication deficits in ASD from a developmental point of view, capitalizing on a child's spontaneous toy engagement as an opportunity for language learning by training therapists or parents to point to, show, or talk about objects the child is already attending to.

Object use at Time 1 moderated all child outcome variables except for EL at Time 3, thus including RL and EL at Time 2 ($t(282) = 5.66$, $p < .001$; $t(280) = 3.71$, $p < .001$; respectively) and SPA, Gesture Use, and RL at Time 3 ($t(280) = 2.82$, $p < .01$; $t(280) = 2.21$; $p < .05$, $t(280) = 4.48$, $p < .001$, respectively; see Table 8). Children who demonstrated less object use at Time 1 exhibited greater gains in SPA if they were randomized to the A/M group. In contrast, children randomized to the ESDM intervention who had greater object use at Time 1 exhibited greater gains in SPA. Additionally, those children who demonstrated greater object use at Time 1, exhibited greater gains in RL and EL at Time 2, and Gesture Use and RL at Time 3 if they were randomized to the ESDM group rather than the A/M group. Counter to our expectations, Time 1 object use did not moderate the treatment effects of the ESDM intervention on gains in child EL at Time 3 ($t(280) = 1.94$, $p = .053$).

Table 7. Statistics for Outcomes at Time 2 and Time 3 Using Repeated Measures ANOVA.

| | Group X Time (T1 vs. T2) | | | Group X Time (T1 vs. T3) | | |
|---|---|---|---|---|---|---|
| | F | MS | *P* | F | MS | *P* |
| MSEL | | | | | | |
| Receptive language[a] | 19.53 | 1999.21 | < .001 | 24.83 | 5704.32 | < .001 |
| Expressive language[a] | 0.47 | 70.92 | .492 | 5.76 | 1308.88 | .017 |
| CSBS | | | | | | |
| Shared positive affect | | | | 0.83 | 2.44 | .364 |
| Gesture use[b] | | | | 0.12 | 0.63 | .734 |

*Note*. T1=Time 1; T2=Time 2; T3=Time 3
[a] T score (mean: 50 [SD:10]).
[b] Standard score (mean:10 [SD:3]).

Table 8. Results of Moderated Regression Analysis (*t*-values).

| | SPA | Gesture | RL T2 | RL T3 | EL T2 | EL T3 |
|---|---|---|---|---|---|---|
| SO | 2.69** | 0.62 | 3.33** | 1.36 | 3.30** | 2.45* |
| RJA | -0.48 | -2.01* | 2.97** | -0.56 | 1.42 | 1.58 |
| OBJ | 2.82** | 2.21* | 5.66*** | 4.48*** | 3.71*** | 1.94 |

*Note*. ***$p$<.001, **$p$<.01, *$p$<.05. T2=Time 2; T3=Time 3; SPA=Shared positive affect; GES=Gesture use; RL=Receptive language; EL=Expressive language; SO=Social orienting; RJA=Response to joint attention; OBJ=Object use.

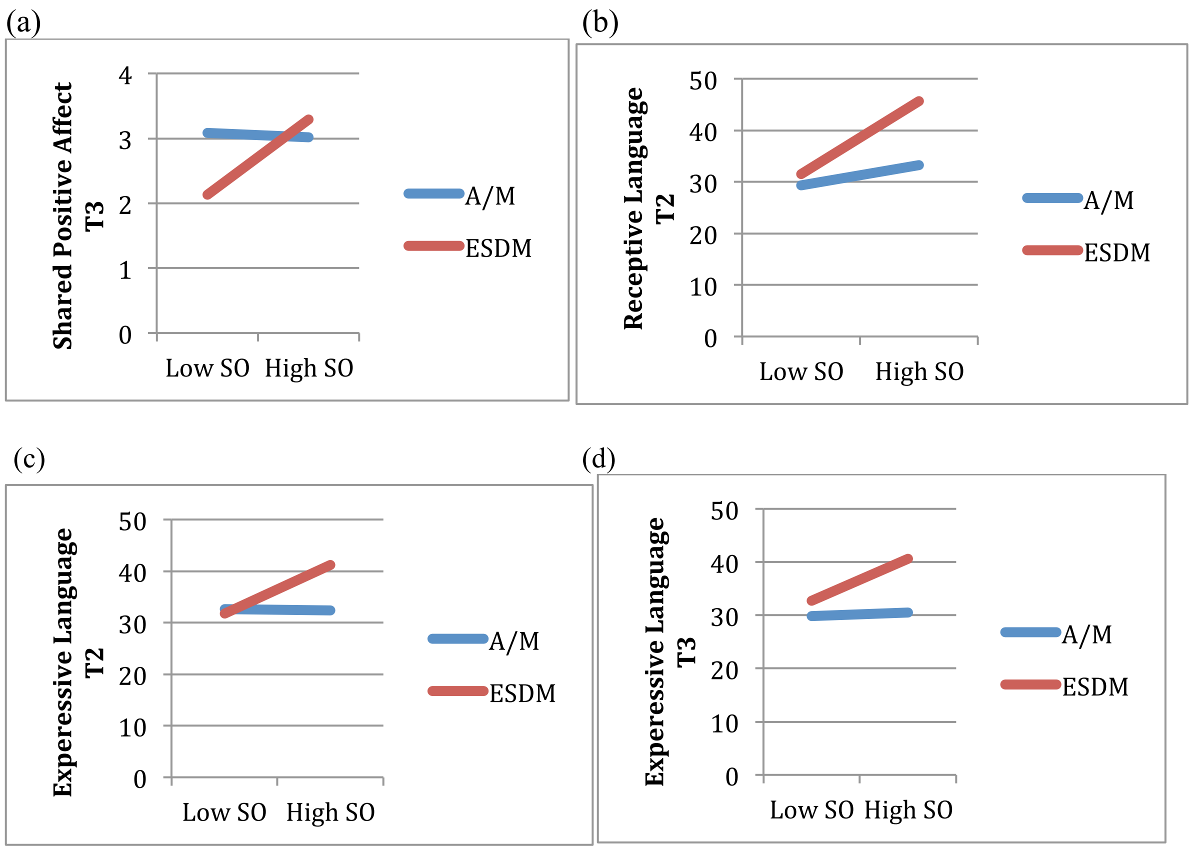



Figure 2. Graphs depicting treatment moderation by SO predicting outcomes of (a) SPA at Time 3, (b) RL at Time 2, (c) EL at Time 2, and (d) EL at Time 3. SO = Social Orienting; SPA = Shared Positive Affect; RL = Receptive Language; EL = Expressive Language.

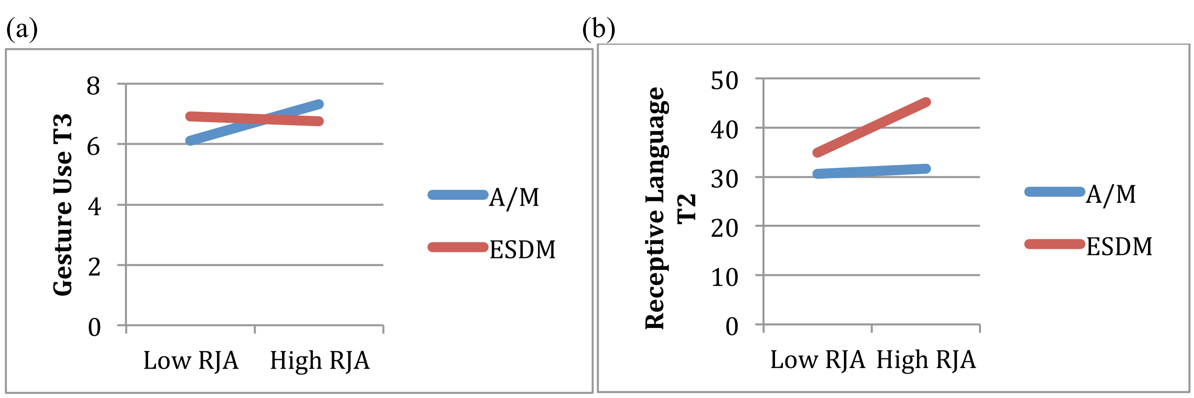



Figure 3. Graphs depicting treatment moderation by RJA predicting outcomes of (a) GES at Time 3 and (b) RL at Time 2. RJA = Response to Joint Attention; GES = Gesture Use; RL = Receptive Language.

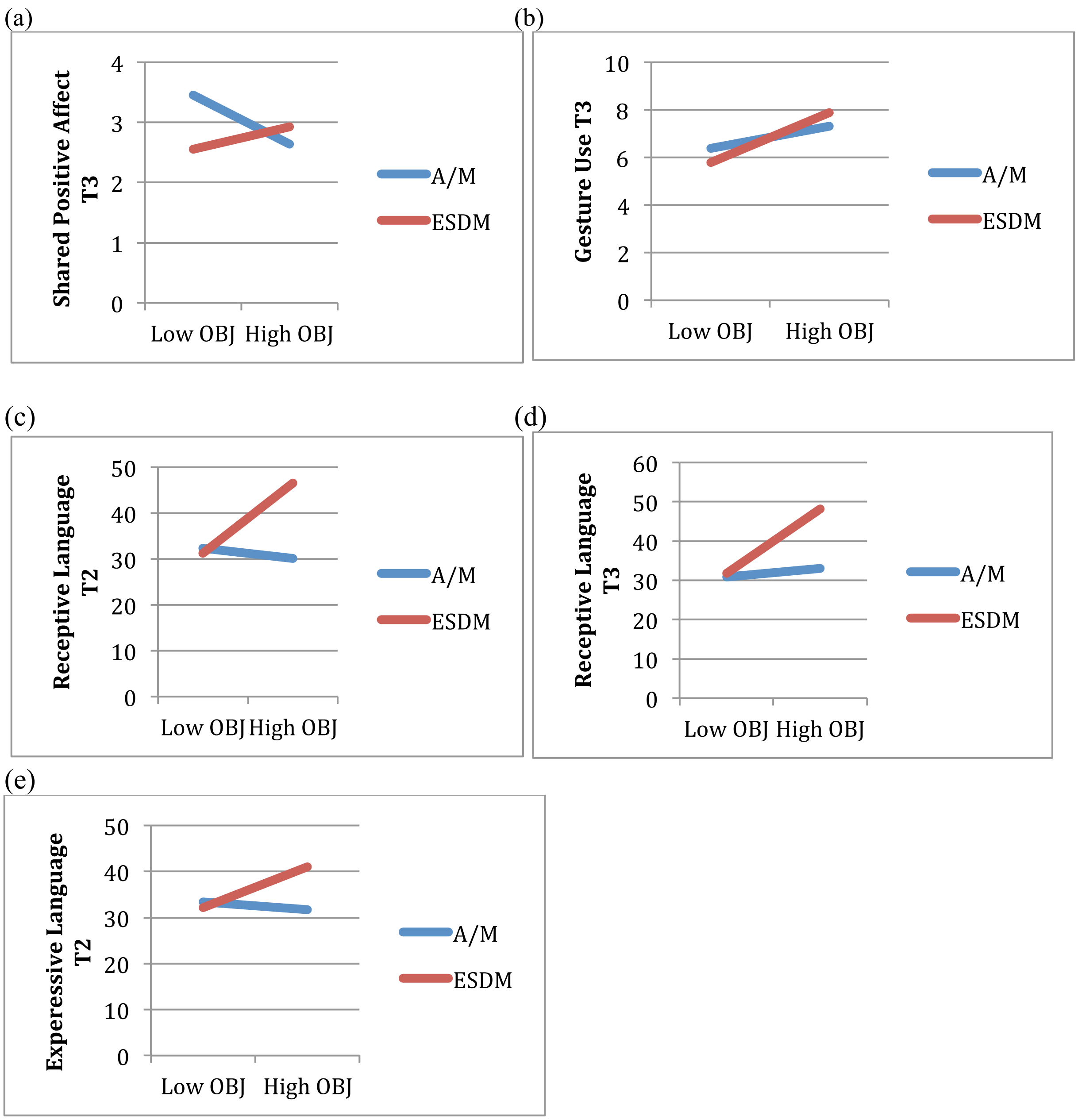



Figure 4. Graphs depicting treatment moderation by OBJ predicting outcomes of (a) SPA at Time 3, (b) GES at Time 3, (c) RL at Time 2, (d) EL at Time 2, and (e) EL at Time 2. OBJ = Object Use; SPA = Shared Positive Affect; GES = Gesture Use; RL = Receptive Language; EL = Expressive Language.

**E. Discussion**

Variability in treatment outcome is one of the most difficult issues facing those involved in treatment research and treatment implementation for children with ASD. Despite substantial empirical support for the effectiveness of some interventions (e.g., Goldstein, 2002; McConachie & Diggle, 2007), heterogeneity in outcome is observed across participants. Some children demonstrate marked improvement while others show nominal or no improvement. The current challenge, therefore, is to better understand the variables affecting treatment outcome and ultimately create methods of determining which specific intervention is best for a given child and their family. In the current study, we examined moderators of ESDM treatment effects, thereby addressing the need for information regarding specific factors and individual characteristics that determine differential response to intervention for toddlers with ASD. To our knowledge, this is the first randomized controlled trial of early intervention with toddlers with ASD, and the third paper to examine the efficacy of the Early Start Denver Model (ESDM) intervention within an RCT framework.

i. *Main Effects*. In the current study, children provided with the ESDM showed significant improvements in receptive language after one year of intervention, and significant improvements in receptive and expressive language after two years of intervention as compared with children who received community treatment. Main effects of treatment on language outcomes may be due to the ESDM's intentional focus on fostering a strong, intrinsically driven language system for children with ASD. A key element to this process is following a developmental model of how typical children learn to use and understand spoken language, that is, learning functional language skills based on their own thoughts and feelings (e.g., Tager-Flusberg, 1993). Within the ESDM curriculum, therapists and parents are trained to capitalize on opportunities for the child to intentionally communicate throughout the day. Using a variety of joint activities (e.g., vocal play, imitation, modeling, and shaping), the child progresses through the fundamentals of nonverbal behaviors to vocalizations to multi-word utterances. With such developmental considerations in which receptive and expressive language are woven into every activity and are taught using naturalistic strategies (Rogers & Dawson, 2010), consistent gains in language outcomes in the current study for children receiving ESDM are reflective of that emphasis.

One aim of the current study was to replicate the language findings reported by Dawson and colleagues (2010), a study describing the initial findings of ESDM treatment effects using this same sample. Findings after two years of intervention are consistent between the two studies, but Dawson and colleagues (2010) did not report a main effect of receptive language at Time 2 despite change scores in receptive language from baseline that fell just short of statistical significance (ESDM 17.8 points; A/M 9.8 points). Discrepant results between studies regarding receptive language gains after one year of intervention may be explained by the use of the intent-to-treat design employed in the current study and not by Dawson and colleagues (2010). As mentioned above, retention rates for the A/M group were 96% ($n$=23/24) at Time 2 and 88% ($n$=21/24) at Time 3. In order to address missing data and ultimately increase internal validity, multiple imputation was employed (Moher, Schulz, & Altman, 2001; Sterne et al., 2009). Multiple imputation involves creating several different imputed data sets and combining results for analysis, which may have given rise to changes in final results for a variable tending towards significance as reported by Dawson and colleagues (2010).

It is worthy to note a few points related to the language results in the current study. First of all, regardless of group, gains in receptive language and expressive language across the two-year treatment period are still below average. This is consistent with previous research indicating that children with ASD demonstrate impairments in receptive and expressive language early in development (e.g., Landa & Garret-Mayer, 2006; Yirmiya et al., 2006; Zwaigenbaum et al., 2005; 2009). For example, high-risk infant siblings later diagnosed with ASD showed decreased vocabulary comprehension and fewer phrases understood between 12 and 24 months of age (Mitchell et al., 2006; Stone et al., 2007). Also, approximately one-third to one-half of individuals with ASD present with significant difficulties using speech as a functional and effective means of communication (Tager-Flusberg, Paul, & Lord, 2005). Therefore, despite participation in the ESDM resulting in improved language gains during the toddler years, these young children with ASD are still behind their typical peers in the development of language. Continued follow up will be necessary to determine if language abilities approach average with more time, remain unchanged after two years of intervention, or eventually decline. As in research examining the emergence of ASD in high-risk infants, data on developmental trajectories of language may ultimately be more informative than profiles from any single point in time (Zwaigenbaum et al., 2007).

In light of trajectories, both the current study and Dawson and colleagues (2010) demonstrate a main effect for expressive language after two years of intervention but not after one year. One possible explanation may be the nature of delayed and/or deviant language development in children with ASD. Acquisition of expressive language in this population may be partly related to oromotor competence and/or the mechanics of speech development, but are heavily embedded in early social interactions (Tager-Flusberg, Paul, & Lord, 2005). As previously described, children with ASD have difficulty attaining and maintaining social reciprocity, which results in a substantial dearth of “teachable moments” for learning critical components of conventional expressive language (Rogers & Dawson, 2010). While typically developing children may learn words without explicit instruction or association during the second year of life (Nazzi & Bertoninici, 2003), young children with ASD may require the intensive teaching and delivery of learning opportunities for expressive language as provided by the ESDM. Such opportunities occur within the midst of social exchanges that employ rich language to narrate a child's interests and activities. To promote expressive language development, the ESDM emphasizes intentional communication first through nonverbal behaviors (e.g., refusing an object by pushing it away, pointing to indicate a choice) and then through vocalizing, spontaneous use of consonants, word approximations, single words, and finally word combinations. Perhaps in the first year of treatment, the Mullen expressive language scale, which consists of items such as answering questions and naming pictures, did not capture participants' gains in some of these early ESDM expressive language target skills.

Another explanation for no main effect of expressive language until Time 3 may be an increasing divergence between group gains for this outcome measure. The ESDM group showed similar expressive language standard scores after one and two years of treatment, indicating a steady rate of development, whereas the A/M group, on average, demonstrated a declining trend in expressive language at Time 3 after an initial increase at Time 2.

Counter to expectations, no main effect of treatment was found for gesture use or shared positive affect despite the fact that both are core target areas of the ESDM. It is of note that in the current study, these two outcomes were measured using scales with limited ranges of possible scores. Future studies examining these variables as outcomes using more specialized measures with a wider range of possible scores is necessary. For shared positive affect, our results are similar to Landa and colleagues (2011) who did not find between group differences in SPA using a six-month intervention targeting development of socially synchronous engagement in toddlers with ASD. Perhaps these null findings can be attributed in part to findings from Lemanek and colleagues (1993) that suggest that parents of children with ASD use compensatory behaviors to elicit the coordination of affect and attention from their children (i.e., use more attention-getting behaviors, increase their physical proximity, or use more non-verbal prompts). Such parental behaviors may mimic, to some degree, similar techniques taught to parents as part of the ESDM and may have influenced similar gains in SPA between groups.

For the outcome of gesture use, the A/M and ESDM groups showed very similar gains from Time 1 to Time 3. Although the ESDM curriculum includes reciprocal and spontaneous imitation of gestures, it is designed to improve IQ, language, and adaptive behavior. Previous research does indicate that young children with ASD who demonstrate increased levels of gesture use often have better language outcomes (Capone & McGregor, 2004; Goodwyn et al., 2000; Landa, 2007). Perhaps examining gesture use as a moderator of ESDM treatment effects rather than an outcome measure may shed light on the role of gesture use in the early social and communication development of children with ASD.

*ii. Moderator Effects*. As noted above, one of the major advantages of individualizing treatments for children with ASD is to take best advantage of early intervention. Additionally, with the capability of individualizing treatment early on, we can better capitalize on the developmental window for early intervention. The moderation analysis in the current study sought to determine the pretreatment behavioral characteristics associated with responsivity to ESDM versus A/M intervention.

*1. Moderators of SPA*. While there were no main effects of treatment on SPA, moderated effects were obtained. Results indicate that social orienting and object use moderated the treatment effects on gains in SPA. Specifically, children with higher levels of social orienting and/or object interest showed greater improvement after two years of treatment if randomized to the ESDM group. In contrast, children with lower levels of object use showed more gains in SPA if they were randomized to the A/M group. There are limited empirical data examining the role of social orienting as a moderator of child outcomes in treatment studies with children with ASD, yet it has been shown to be a key precursor to social and language development (Mundy & Neal, 2001); children must attend to social stimuli in order to observe, imitate, and learn from it.

To our knowledge, this is one of the first studies to examine moderators of SPA in children with ASD. Previous research has examined SPA as a main outcome of research evaluating the effectiveness of PCIT intervention (Solomon et al., 2008) and joint attention interventions (Gulsrud et al., 2007). Findings from the current study indicate that those children with higher levels of social orienting and object use were able to benefit from the several strategies imbedded into ESDM's sensory social routines that are designed to enhance social attention and shared affect. Perhaps children in the A/M group with lower levels of object use received intervention heavily focused on object-oriented interactions (i.e., ABA discrete trials, object labeling in speech therapy), in which coaching in the use of objects may have been directly taught. Such intervention, therefore, may have promoted object use skills within interactions involving some emotional coordination and shared affect.

*2. Moderators of Gesture Use*. While there were no main effects of treatment on Gesture use, moderated effects were obtained. Results indicate that treatment effects on gains in gesture use were moderated by RJA and object use. Namely, children randomized to the ESDM intervention who had higher levels of object interest at baseline demonstrated greater gains in gesture use, whereas children in the A/M group who had higher levels of RJA at baseline exhibited greater gains in gesture use. To our knowledge this is the first study to examine RJA as a moderator of treatment effects for gesture use. We hoped to elucidate what early skills may be contributing to gains in gesture use, given the role of gestures in the literature as a predictor of later language and ASD severity outcomes (Mitchell et al., 2006; Wetherby et al., 2007). Our findings indicate that toddlers with ASD participating in community treatments demonstrated greater gains in gesture use when they had higher levels of RJA. Perhaps community interventions tend to employ teaching techniques that capitalize on the use of coordinated attention. In contrast, participants in the ESDM group with high object use may have benefitted from the ESDM sensory and motor activities that incorporated the access and manipulation of objects to elicit natural gestures.

*3. Moderators of Receptive Language.* Main effects of treatment on receptive language were found at both Time 2 and Time 3. Receptive language outcomes were moderated by several variables for children randomized to the ESDM group. At Time 2, receptive language outcomes were moderated by high levels of social orienting, RJA, and object use. At Time 3, receptive language outcomes were moderated by high levels of object use. Our results are consistent with findings from previous studies demonstrating that receptive language outcomes were moderated by different levels of object play (i.e., pretend play and stacking blocks (Wetherby et al., 2007) and social attention and response (Bono, Daley, & Sigman, 2004; Bopp et al., 2009; Sigman & Ruskin, 1999; Thurm et al., 2007). For the latter, greater responsiveness to joint attention bids of modeled actions was associated with higher levels of receptive language (Charman et al., 2003; Mundy et al., 1990).

Within the ESDM, certain intervention targets for language may include activities incorporating early social communication skills (e.g., RJA, social orienting, and object use);

therefore, those children with higher levels of these skills may benefit more from the ESDM language curriculum. For example, specific intervention targets for receptive language development might include direct eye contact, orienting when one's name is called (social orienting), response to joint attention, and responding to a direct verbal request with or without gestures (i.e., "sit down," "clean up," "give me [object]"; Rogers & Dawson, 2010). Previous studies also demonstrate that gestures and initial language (i.e., consonant production; Wetherby et al., 2007) and frequency of vocalization (Weismer et al., 2010) moderate receptive language gains in young children with ASD. Future research examining the moderating role of these variables in the current study may shed additional clarification on which children may benefit from the ESDM intervention.

*4. Moderators of Expressive Language.* A main effect of treatment on expressive language was found at Time 3, but not at Time 2. For participants randomized to the ESDM, expressive language outcomes at Time 2 were moderated by high levels of social orienting and object use. At Time 3, expressive language was moderated by high levels of social orienting for the ESDM group. Our findings indicate that social orienting is a consistent moderator of expressive language gains for children receiving the ESDM. This finding replicates previous research indicating social attention and response moderates expressive language gains (Bopp et al., 2009). Object use, however, moderated only initial expressive language gains. Perhaps children's initial interest or use of objects provided an avenue by which ESDM therapists or caregivers could reinforce the child's social attention while also expanding the child's play behavior. Previous studies also indicate that object use or play moderates expressive language development as measured by diversity of object play (Yoder, 2006) as well as level of pretend play (Sigman & Ruskin, 1999; Smith et al., 2007). Future research is needed to discern whether different types of object use and play (i.e., functional versus imaginary) may differentially influence the development of spoken language. In contrast to the current results, Sigman and Ruskin (1999) demonstrated that joint attention moderated expressive language outcomes in 3 to 6 year old children with ASD when followed up 7 to 9 years later. Additional follow up with the current sample to investigate moderation of long-term expressive language gains may be warranted.

Variables not included in the current study that have been previously shown to moderate expressive language gains include motor imitation (McDuffie et al., 2012; Yoder, 2006; Yoder & Stone, 2005), vocal imitation (Smith et al., 2007), gestures (Capirci et al., 1996; Namy et al., 2000; Yoder, 2006), initial receptive language (Sigman & Ruskin, 1999; Wetherby et al., 2007), initial expressive language (Smith et al., 2007; Wetherby et al., 2007), and initial IQ (Thurm et al., 2007).

*iii. Conclusions.* Based on the results from the moderation analysis described above, children with certain developmental profiles may be more or less suited for the ESDM approach. Overall, the ESDM was more effective for children with higher Time 1 levels of SO, RJA, and object use. In contrast, children with lower object use at Time 1 showed more gains if randomized to the A/M group. Children with higher levels of social orienting, for example, may benefit from direct facilitation of social attention and language incorporated into the ESDM's sensory social routines and pivotal-response training. By directly targeting social orienting deficits and capitalizing on a child's initial level of social orienting skills, the ESDM intervention supports gains in reciprocal affective engagement and language development.

Our findings also indicate that children with higher levels of RJA may benefit more from the ESDM intervention, particularly its focus on addressing the early development of receptive language. Additional research examining interventions for children with ASD show promising results in ameliorating RJA deficits (Jones et al., 2006; Leekam et al., 2001; Sullivan et al., 2007) including increased levels of social engagement and eventually better language outcomes (Namy, Acredolo, & Goodwyn, 2000; Weismer et al., 2010). Some researchers suggest that in addition to longitudinal gains in child outcomes, improved RJA may augment the capacity of children with ASD to appreciate stimulus-reward associations and, therefore, display enhanced speed and maintenance of learning within a behavioral intervention paradigm (Mundy & Thorp, 2007; Rogers & Dawson, 2010).

The ESDM may also be more beneficial for children with higher levels of object use. Although the ESDM does not directly teach object play skills, they are included as part of sensory social and object-oriented joint action routines. Children in the ESDM group with higher levels of object use at baseline appeared to benefit from the language incorporated in those routines as well as opportunities for joint engagement and social exchanges. For example, the ESDM utilizes sensory and motor activities to initially elicit a child's natural gestures including reaching toward a toy of choice or actively pushing away an unwanted item. In this way, access to objects is used as a functional reward contingent on child nonverbal communication (Carter et al., 2011). Similar to language gains, ESDM participants with higher levels of object use at baseline appeared to benefit from gestures incorporated into these sensory and motor activities.

This finding is consistent with the guidelines outlined by Rogers and Dawson (2010) in the ESDM manual. The authors recommend that children participating in ESDM have a minimum level of skill in object use in order to respond well to many of the teaching techniques and objectives of the ESDM. As indicated by the results of the current study, therefore, the ESDM may benefit those children who are interested in objects and capable of carrying out some simple means-end actions (e.g., putting in or taking out, combining two objects in play) (Rogers & Dawson, 2010). Children with little interest in objects, however, may respond to "object spectacles" (Rogers & Dawson, 2010), toys that create physical or sensory effects (i.e., bubbles, balloons, pompoms, wind-up toys, maracas, bells, shakers, pinwheels).

Our results indicating moderation of language gains by higher levels of baseline object use conflicts with a previous study in which young children with ASD who had initially low levels of object interest developed superior communication skills while receiving a responsivity-based treatment relative to a contrast treatment (Yoder & Stone, 2006). The treatment that facilitated linguistic communication for children with low object interest also effectively taught object play skills; the contrasting treatment did not (McDuffie, Lieberman, & Yoder, 2012). Perhaps those children with low levels of object use at baseline did not benefit as fully from the language incorporated into object-oriented joint action routines as the children with stronger object use skills. As reported by Bates and Dick (2002), word production does not begin until a child begins to functionally use objects, even when this behavior is delayed by months or even years.

It is important to note that low levels of RJA skills, SO, and object use did not moderate receptive or expressive language gains at Time 2 or Time 3. These findings align with previous research indicating that infants with ASD who have limited social and communicative skills often demonstrate attenuated gains in later language development. The treatment effects of ESDM on language outcomes, therefore, are most pronounced for those toddlers with ASD who have a certain level of baseline skills. As a group, however, children who received the ESDM demonstrated greater gains in language development after two years of treatment then community interventions regardless of initial moderator values.

All of our findings must be considered within the context of the study's limitations and strengths. The sample size for each randomized group was relatively small, variability for baseline moderating variables was limited, and parent implementation was monitored only via parent report. Additionally, children in both the A/M and ESDM groups received outside treatments during this treatment study. Over the 2-year study enrollment period, the ESDM group reported an average of 5.2 hours per week (SD: 2.1) in outside therapies (e.g., speech therapy, developmental preschool). The A/M group reported an average of 9.1 hours per week of individual therapy and an average of 9.3 hours per week of group interventions (e.g., developmental pre-school; Dawson et al., 2010). The effect of other treatments on the children's progress cannot be ruled out. In terms of strengths, the current study is unique in its target population and methodological rigor including a longitudinal design, gold-standard diagnostic criteria, randomized group assignment, evaluation by naïve examiners, and fidelity monitoring for the implementation of a manualized intervention.

The ESDM is designed to address the unique needs of toddlers with ASD as young as 18 months old and uses knowledge about how typical infants develop to facilitate similar developmental trajectories in young infants at risk for ASD. The American Academy of Pediatrics (Johnson & Meyers, 2007) has recommended that all children be screened for ASD at 18 months of age, which necessitates the development of appropriate interventions for toddlers with ASD. Research evaluating the effectiveness of ESDM offers a rare opportunity to examine the long-term impact of early intensive intervention that targets core social and communication deficits in toddlers with ASD. The current study, therefore, provides a rich source of longitudinal information that demonstrates the effectiveness of the ESDM for improving language gains for young children with ASD and further elucidates certain child characteristics that moderate treatment response.

The moderation analyses in the current study were informed by previous research examining moderating variables of early intervention in children with ASD. The examination of moderators, however, remains a relatively new area of research despite its documented importance in intervention effectiveness and development in this population. In their review article, Wolery and Garfinkle (2002) recorded that fewer than 20% of ASD early intervention articles mentioned moderating variables and none of them conducted analyses to determine whether measures of mediating factors accounted for individual variability in outcomes. There are several types of variables that are likely to be involved in treatment response in ASD including pretreatment cognitive abilities (Bibby et al., 2002; Rogers, 1998; Harris & Handleman, 2000; Itzchak et al., 2008; Venter, Lord, & Schopler, 1992), nonverbal IQ scores (Paul et al., 2008; Thrum et al., 2007), age at treatment onset (Harris & Handleman, 2000), social responsiveness (Sallows & Graupner, 2005; Sherer & Schreibman, 2005; Sigman & Ruskin, 1999), imitation skills (Sallows & Graupner, 2005), pretreatment language ability (Luyster et al., 2009; Sallows & Graupner, 2005; Smith et al., 2007; Wetherby et al., 2007), object interest (Carter et al., 2011), and play (e.g., functional, symbolic, varied play; Rogers et al., 2003; Sherer & Schreibman, 2005; Yoder, 2006). Stoelb and colleagues (2004) examined biological moderators including dysmorphology, MRI results, head circumference, history of seizures or regression, sleep problems, and dietary supplements. Using regression analyses, only dysmorphology significantly predicted treatment change and also predicted which nonverbal children would develop language in the following year with 90% accuracy. History of regression predicted poorer gains (Stoelb et al., 2004).

As mentioned in Carter and colleagues (2011), children with ASD are unlikely to benefit from intervention unless maintenance of enhanced parenting practices occurs concurrently. The ESDM is an intervention approach in which parent training includes the generalization of their child's skills to everyday family activities as well as empowering parents via skill acquisition and promoting a positive parent-child relationship and sense of parent competency. Such parent training and involvement was likely an important ingredient of the success of the ESDM intervention in the current study. Future research examining treatment effects on parent and family variables (i.e., parent stress, psychopathology, support) as well as moderation analysis involving parent and family factors are warranted.

A growing area of research in the field of ASD indicates that parents of children with autism spectrum disorders (ASDs) are at risk for higher stress levels than parents of children with other developmental disabilities and typical development (Estes et al., 2009). This has important implications when the participation of parents is regarded as a best practice for early intervention in young children with ASD. Estes and colleagues (2013) recently examined the impact of a parent-delivered ESDM intervention (P-ESDM) on parent adjustment and stress. Parents in the P-ESDM group demonstrated no increase in stress versus a community sample over a 3-month period. Additional research examining what kinds of parent training parents are seeking out in the community and differentiating effects of skill-based versus coping-based (i.e., mindfulness, support, motivational interviewing, empowerment) training will be important in providing comprehensive and supportive interventions for children with ASD and their parents. Further, contextualizing treatment strategies and integrating individual differences among families in parent-delivered interventions may also impact treatment effectiveness and parent empowerment (Moes & Frea, 2002).

The current study examined social orienting, response to joint attention, and object use as moderators of treatment response. Additional child variables of interest include reinforcement value of social rewards, play skills, and baseline language skills, which require further investigation. Additionally, new approaches to early detection of infants at risk for ASD are focusing on neurophysiological risk indices (endophenotypes) with the hope that such measures will improve the ability to identify infants who will develop ASD (Dawson, 2008). Future research examining the relationship between such endophenotypes and treatment effects will contribute important information regarding the individualization of treatment and the impact of early intervention on brain function and organization.

Finally, future studies examining the many elements involved in ESDM treatment (i.e., parental coaching, parent follow through at home, individual administration, and several different aspects of treatment) is needed to discern which aspects of treatment are crucial for successful outcomes. Isolating these components has important implications for the realistic dissemination of the ESDM treatment in community-based delivery systems. Future studies that carefully examine the effectiveness of the ESDM intervention in such settings will be central to addressing the need for treatment in very young children diagnosed with ASD.

In summary, effective treatment for young children with ASD requires identification and development of effective treatments that address the unique needs of toddlers with ASD as young as 18 months old. In the current study, main effects of ESDM treatment were observed for communication outcomes, specifically receptive language (after 1 and 2 years of intervention) and expressive language (after 2 years of intervention). Additionally, significant moderation of treatment effects was noted, particularly RJA and object use moderating language outcomes and both high and low initial levels of object use moderating several child outcomes. Continued focus on which children with ASD and their families benefit from ESDM intervention as well as identification of crucial treatment components will be critical for the dissemination and delivery of the ESDM beyond the research setting to the community at large.

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