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Factors Associated with Enrollment into a Clinical Trial of Caregiver-Implemented Intervention for Infants at Risk for Autism Spectrum Disorder

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Introduction

Caregiver-implemented approaches to early intervention are evidence-based, community-viable, and potentially cost-effective, solutions to address developmental delays for young children with autism spectrum disorder (ASD) (Landa, 2018; Penner et al., 2015; Trembath et al., 2019; Wetherby et al., 2018). By capitalizing on everyday caregiver-child experiences, these approaches meet the need for intensity within the context of federal mandates for early intervention. Earlier identification of ASD has led to research on caregiver-implemented intervention strategies for infants younger than 24 months of age (Bradshaw, Steiner, Gengoux, & Koegel, 2015). Development of these very early caregiver-implemented interventions depends on parental engagement. Thus, identifying barriers to enrollment into caregiver-implemented intervention trials is an important focus of research. This study probes barriers to enrollment into a clinical intervention trial in the context of a prospective longitudinal study of infant siblings of children with ASD who have an increased likelihood of developing ASD compared to the general population.

Early intervention that begins in the first two years of life leads to significant gains across social, communication, cognitive, and play skills for infants and toddlers with or at risk for ASD (Bradshaw et al., 2015; Green et al., 2017; Landa, 2018; Schertz, Odom, Baggett, &

Sideris, 2018; Wetherby et al., 2014). Moreover, enhanced gains are associated with earlier age of treatment onset (Rogers et al., 2012). Naturalistic developmental behavioral interventions (NDBIs) now represent a promising treatment approach for infants and toddlers with ASD, and the majority of NDBIs emphasize the importance of caregiver involvement in intervention (Landa, 2018; Schreibman et al., 2015). In caregiver-implemented interventions, the therapist or clinician takes on the role of a “coach” who teaches the caregiver specific strategies that promote child skills. Caregivers are then encouraged to infuse these strategies into everyday interactions and routines with their child.

Caregiver-implemented interventions are grounded in established research on early child development and ASD treatment efficacy. In early typical development, parents and caregivers are the center of the infant’s social world. Caregiver-infant interactions comprise the context in which infants learn and develop communication, language, and self-regulation skills. Interventions that strategically capitalize on these caregiver-infant interactions most closely emulate the typical developmental pathway through which these skills emerge. Further, interventions delivered by caregivers in the child’s natural environment during normal routines promote generalization of learned skills (Coolican, Smith, & Bryson, 2010; Koegel, Koegel, & McNeerney, 2001). Caregiver-implemented intervention strategies are designed to be enacted during everyday routines, dramatically increasing the number of child learning opportunities and hours of active engagement. From a developmental perspective, parents are ideally suited to promote infant skills and active engagement within a socially enriched environment. Logistically, it is often not feasible for community agencies and service providers to dedicate the time and resources necessary for effective interventions implemented by clinicians. Thus, parents and caregivers are now viewed as critical components in early interventions for ASD, especially in the infant and toddler years.

Empirical evidence for the treatment of ASD in infants younger than 24 months is still emerging, but research to date suggests that caregiver-implemented interventions are effective in teaching parents intervention strategies and improving child outcomes (Bradshaw, Koegel, & Koegel, 2017; Carter et al., 2011; Drew et al., 2002; Green et al., 2017; Rogers et al., 2012, 2014; Steiner, Gengoux, Klin, & Chawarska, 2013; Wetherby et al., 2014, 2018). There is also some indication that caregiver-implemented interventions reduce parent stress (Bradshaw et al., 2017; Kasari, Gulsrud, Paparella, Hellemann, & Berry, 2015). In order to continue evaluating effectiveness of these very early interventions, parent enrollment into clinical trials is critical.

Despite promising evidence for the effectiveness of very early caregiver-implemented interventions for ASD in the prodromal period, rates of family enrollment into some early intervention trials has been surprisingly low (Siller, Morgan, Turner-Brown, Baggett, Baranek, Brian, Bryson, Carter, Crais, Estes, Kasari, Landa, Lord, Messinger, Mundy, Odom, Reznick, et al., 2013). Siller and colleagues (2013) reported that families frequently hesitated to enroll in early intervention studies, especially if their infant was younger than 24 months of age. Based on researcher observations, the authors speculated that hesitation to enroll was related to parents’ strong emotional reaction to their child’s ASD diagnosis and a potential lack of consensus between the parent and clinician regarding concerns. Additional

barriers included the lack of support from other family members and service providers and challenges with the time and resources required to participate in early intervention research.

In a randomized controlled trial (RCT) of a telehealth parent-mediated intervention program for ASD (Ingersoll, Shannon, Berger, Pickard, & Holtz, 2017), only 25.8% of families who were referred to the study after a diagnostic feedback session followed through with enrollment. The authors suggested that the timing of referral was a critical factor – offering enrollment into an intervention study during a time of high stress related to diagnostic feedback may interfere with, rather than promote, enrollment. In a feasibility study of early intervention for a community-based sample of 12-month-olds who screened positive for autism red flags (Baranek et al., 2015), only 41% of participants who screened positive agreed to move forward with the study and participate in a developmental evaluation to confirm full eligibility for the RCT. However, the majority of eligible participants (16 of 18) who completed the developmental evaluation agreed to enroll in the intervention RCT. Upon further investigation, Freuler et al. (2014) found that most families who enrolled in the RCT viewed enrollment as a vehicle for receiving intervention services, and only a minority of participants were unaware of their child's delays at the time of screening. This suggests that the decision to enroll was associated with consensus about child concerns. These two community-based studies are in contrast to an RCT involving infant siblings of children with ASD (Green et al., 2015) in which eligibility was determined by familial likelihood (i.e., sibling of a child with ASD) and not the presence of developmental delays or ASD red flags. In this RCT, 70% of eligible participants agreed to enroll. It is possible that when treatment eligibility is separated from observation of red flags and clinical or diagnostic feedback, consensus-building and degree of parental concern may be less of a barrier to parent participation. In addition, families who already have a child with ASD may be more likely to enroll in interventions for their younger child who is at increased familial risk.

Understanding of barriers to enrollment in RCTs for young children with ASD is still emerging, but extant research with non-ASD pediatric populations (i.e., children with other behavioral and mental health disorders) suggests that parents who decline enrollment into behavioral intervention are more likely to have lower income and lower levels of social support (Baker, Arnold, & Meagher, 2011; Heinrichs, Bertram, Kuschel, & Hahlweg, 2005). For example, among a low-income group of parents who chose not to enroll in a clinical trial of preventative parent training, respondents reported that they were too busy to participate, experienced scheduling conflicts, and had other family commitments (Garvey, Julion, Fogg, Kratovil, & Gross, 2006). In pediatric medical research trials, inconvenience of extra visits and appointments is often a top reason for declining to enroll in randomized clinical trials (Caldwell, Butow, & Craig, 2003). Together, this research suggests that factors associated with enrollment into clinical intervention trials involves a critical threshold of parental concerns or perceived child symptomology, balanced with the existing demands on family time, energy, and resources.

Intervention for young infants at the earliest possible sign of risk has the potential to reduce or prevent the gap in development compared to typically developing peers, even prior to diagnosis (Landa, 2018; Micheletti et al., 2020). Given that research and development on very early caregiver-implemented interventions for infants at risk for ASD are ongoing,

understanding and increasing family participation is critically important. The purpose of this study was to examine factors associated with enrollment into an RCT of caregiver-implemented intervention for families with 12-month-old infants who were exhibiting early red flags for ASD. In the context of a longitudinal study of infant siblings of children with ASD, we compare family demographics and infant clinical features across families who agreed to enroll into a caregiver-implemented early intervention trial for ASD and those who declined.

Methods

Participants

Our complete participant sample included 231 infants who were enrolled in a longitudinal study of infant development. Participants were either classified as high risk for ASD (HR, N=103) or low risk for ASD (LR, N=128). HR infants were defined as having an older, full biological sibling with ASD. Diagnosis of the older sibling was confirmed by clinician best estimate diagnosis of ASD via review of diagnostic reports from comprehensive community evaluations completed by a licensed psychologist or medical doctor and scoring within the clinical range on the Social Responsiveness Scale-2 (Constantino, 2012) and the Social Communication Questionnaire (Rutter, Bailey, & Lord, 2003). If evaluations were not sufficient, siblings were administered an Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) by research-reliable clinicians. Participants were classified as LR if they had no family history of ASD in 1st or 2nd degree relatives. Exclusion criteria for all participants were as follows: gestational age below 35 weeks, major hearing and/or visual impairment, seizure disorder, known genetic syndrome, and significant pre- or perinatal complications.

All participants were enrolled prior to six months of age and seen at multiple time points from 6 to 36 months of age. Shortly after the participant's 12-month birthday, all participants were administered an assessment battery to determine eligibility for a clinical trial of caregiver-implemented intervention. Measures and procedures for eligibility determination are described in detail below. Out of the 231 HR and LR infants, 57 (47 HR and 10 LR) infants were deemed eligible for the RCT and were invited to enroll. These children are part of an ongoing longitudinal study and collection of intervention outcome measures is currently underway. Thus, the researchers remain masked to treatment condition (i.e., whether participants who enrolled in the RCT were randomized to Group ESI or Individual + Group ESI, see below for treatment descriptions). Details and analyses related to treatment condition are not included this study.

Measures

Demographic Information.—Family demographic information was collected with a standard questionnaire given to caregivers upon entry into the longitudinal study. Information collected includes caregiver age, caregiver highest level of education and total years of education, caregiver employment status, total household income, home address, and sibling developmental information (e.g., diagnoses of ASD). This information was updated and reviewed at each visit to monitor changes in any of these variables.

Eligibility for Treatment.—Eligibility for treatment was determined using a comprehensive battery of five measures that spanned a variety of risk factors across multiple settings and informants, including genetic liability, parent report of symptoms, social-communication and play skills, and expert clinical observation of ASD red flags in the clinic and home. These measures included: 1) high-risk sibling status, 2) Early Screening for Autism and Communication Disorders (ESAC; Wetherby, Woods, & Lord, 2007), 3) Communication and Symbolic Behavior Scales Behavior Sample (CSBS; Wetherby & Prizant, 2002), 4) Systematic Observation of Red Flags (SORF; Wetherby & Woods, 2004)—Clinic, and 5) Systematic Observation of Red Flags (SORF; Wetherby & Woods, 2004)—Home. Participants who obtained a “positive screen” on one of the SORFs and an additional 2 measures were deemed eligible for intervention. Each measure and associated criteria for obtaining a positive screen are described below.

Early Screening for Autism and Communication Disorders (Wetherby, Guthrie, Petkova et al. 2015; Wetherby, Woods, & Lord, 2007). The ESAC is a parent-report screener for autism spectrum and communication disorders. It consists of 30 items that are either ratings (i.e., *not yet/rarely, sometimes, often*) or checklists of behaviors related to autism symptomology for infants and toddlers between 12–36 months of age. There are 7 additional open-ended questions that allow for parents to elaborate on their child’s behavior. The ESAC has good sensitivity, ranging from 0.78 to 0.86, and specificity, ranging from 0.81 to 0.84. The ESAC total score has a minimum of 0 and maximum of 60, with higher total scores indicating more ASD symptomology. In the present study, a positive screen on the ESAC was considered a score of 20 or greater. The ESAC also asks if the caregiver has concerns about their child’s development (*yes* or *no*). The response to this question was also included in analyses.

Communication and Symbolic Behavior Scales (CSBS) – Developmental Profile, Behavior Sample. The CSBS (Wetherby & Prizant, 2002) is a standardized, norm-referenced instrument designed to measure early communication development. It offers a behavior sample involving structured and unstructured activities that provide opportunity for observation of spontaneous social communication, speech, and early symbolic skills. The CSBS provides standard scores for three communication composites (Social, Speech, Symbolic), each of which are comprised of 2–3 cluster scores. Composite and cluster scores carry a mean of 10 and standard deviation of 3. A total score is also provided (mean of 100 and standard deviation of 15). For this study, a positive screen on the CSBS was 1 or more composite scores below the 10th percentile or two or more cluster scores below the 10th percentile.

Systematic Observation of Red Flags for ASD (SORF) – Clinic. The SORF (Dow, Guthrie, Stronach, & Wetherby, 2017) is an observational screening measure of ASD symptomology. It uses current diagnostic criteria (DSM-5, American Psychiatric Association, 2013) to assess for red flag behaviors for ASD in toddlers. There are 22 observational items based on the two core diagnostic domains: impairment in Social Communication and Social Interaction (SC) and Restricted Repetitive Behaviors (RRB). All items are scored by trained evaluators. Each item is rated on a scale of 0–3 according to

item-level definitions, with higher scores indicating greater atypicality. Generally, a score of 0 indicates no presence of atypicality or absence of the symptom, a score of 1 indicates some atypicality observed or unclear presence of the symptom, and a score of 2 or 3 indicates clear symptom presence. Items with a score of 2 or 3 on ten items from the SC domain and seven items from the RRB domain are counted to yield a Total Red Flags score. The Total Red Flags score has a range of 0 to 17. The SORF-Clinic was completed using the behavior sample collected during the CSBS-DP Behavior Sample (described above). Criteria for a positive screen on the SORF-Clinic was a Total Red Flags score of 8.

Systematic Observation of Red Flags (SORF) – Home.: The SORF (described above) was also scored on a behavior sample that was collected by a trained research coordinator in the child's home. During this behavior sample, caregivers were asked to interact with their infant as they normally would while engaging in 3–4 activities: snack, book reading, playtime, and other familiar routines and activities. The research coordinator filmed the behavior sample and did not interact with the child or caregiver during the recording. The SORF-Home was scored by trained evaluators. Criteria for a positive screen on the SORF-Home was a Total Red Flags score of 8.

Developmental Assessment.

Mullen Scales of Early Learning (Mullen, 1995).: The Mullen is clinician-administered developmental assessment for infants and children, from birth through 68 months. The Mullen assesses the child's abilities and provides standardized scores in five domains: Visual Reception, Receptive Language, Expressive Language, Fine Motor Skills, and Gross Motor Skills. Domain scores are represented in t-scores, which have a mean of 50 and standard deviation of 10. In this study, a Verbal Composite score was calculated by averaging t-scores for Receptive and Expressive Language and a Nonverbal Composite score was calculated by averaging t-scores for Visual Reception and Fine Motor.

Vineland Adaptive Behavior Scales, Second Edition, Survey Form (Vineland II) (Sparrow, Cicchetti, & Balla, 2005).: The Vineland II Survey Form is a semi-structured interview administered with a parent or caregiver that measures adaptive behavior across four domains of child behavior: Communication, Daily Living Skills, Socialization, and Motor Skills. Domain scores are represented in standard scores with a mean of 100 and standard deviation of 15. The Vineland-II Survey Form was administered by a trained and reliable research assistant.

Intervention Enrollment Procedure

Infants who met eligibility criteria based on 12-month measures were invited to enroll into an RCT of a caregiver-implemented intervention for ASD. Once infants were deemed eligible for the RCT, families were presented with feedback that their infant was displaying red flags for ASD and told that these red flags qualified them for an intervention study for at-risk infants. Families were aware that only infants who were exhibiting red flags for ASD at the 12-month visit were offered the intervention. The intervention study was then presented to families as an RCT comparing effectiveness of two intervention conditions of the Early Social Interaction (ESI) model, which is an evidence-based NDBI (Wetherby et al.,

2014): (1) group-ESI only (a weekly information, education, and support group meeting located at the clinic) and (2) individual-ESI (twice-weekly individual coaching sessions at home or in the community) in addition to group-ESI. Families were told that each intervention condition lasts for 9 months, with the option for additional monthly group booster sessions up to the child's third birthday. They were informed that this was not a crossover design and families assigned to one condition would not receive the other condition after their 9-month participation ended. Full descriptions of each intervention model were provided to parents verbally and summarized in a brochure, as described below.

Group-ESI.—Group-ESI consisted of weekly, 75-minute psychoeducational group meetings providing families information about social communication, emotional regulation, and play development. Group sessions also included education on how to promote active engagement and support by interacting with other infants and caregivers. Group sessions took place at the clinic in an activity-based playgroup setting designed to promote parent-child interaction. Sessions provided information in print documents, consultation with an interventionist while parents interacted with their child, and opportunities for parents to ask questions and interact with other families. Each playgroup consisted of up to 5 families and included both typically developing children from the community along with children enrolled in the group-ESI arm of the intervention study.

Individual-ESI + Group-ESI.—The Individual-ESI condition involved twice-weekly 75-minute home-based individual coaching sessions, offered in addition to group-ESI. During home sessions, a trained interventionist coached parents in a one-on-one setting on how to support their child's communication, social, and play skills in everyday activities and settings. This intervention included program planning, coaching on how to embed intervention supports and strategies into 25 hours/week of daily activities, and generalization to community settings.

All participants, regardless of intervention condition, were also asked to complete weekly and/or monthly questionnaires, monthly home observations, and two additional clinic-based assessments at ages 15 and 21 months, in addition to diagnostic evaluations at 24 and 36 months that all participants received. Monthly time commitment was described to parents as 6 to 8 hours for the group-ESI condition and 16 to 18 hours for the individual-ESI + group-ESI condition. Parents were enrolled into the intervention prior to knowing the randomization assignment.

Data Analysis

Demographic and clinical characteristics were calculated overall and by enrollment groups (enrolled vs. not enrolled) using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Binary logistic regression models were employed to evaluate bivariable associations between intervention enrollment and family demographics, infant developmental profiles, and sibling ASD symptomatology. Model results are presented as odds ratios (OR) with 95% confidence intervals (CI). In addition, receiver operating characteristic (ROC) curve values were calculated and used concurrently with odds ratios to identify the strongest predictors of study enrollment.

Statistical significance was evaluated at 0.05 level, and inferential analyses and statistical modeling were performed using SAS v9.4 (The SAS Institute, Cary, NC) and R v3.5 (Vienna, Austria).

Results

Among the 57 participants who were eligible for intervention and were invited to enroll in the clinical trial, 32 (56%) chose to enroll and 25 (44%) declined. Out of the 25 participants who declined enrollment into the intervention study, 21 (84%) remained in the larger longitudinal study and four participants (16%) were lost to follow-up and did not return for research study visits after the 12-month assessment. Data summaries and logistic regression models that examined demographic predictors of intervention enrollment are presented in Table 1. Risk status, infant sex, maternal years of education, maternal age, and ASD severity of the older sibling were not statistically associated with enrollment. However, maternal fulltime work status, household income, and distance to the clinic all emerged as significant predictors of intervention enrollment. Maternal employment status was defined by a dichotomous variable: employed fulltime (N=21) and not employed fulltime (N=35). Mothers who reported to be working part time (N=12), not working (N=19), students (N=2), and other (N=2) were combined and included in the not employed fulltime group. The odds of a family in which the mother was working fulltime enrolling into the intervention study were 71% less (OR=0.29 [0.09, 0.90], $p = .031$) than the odds of a non-fulltime mother enrolling. Family income presented a slightly more complicated picture such that families with a total household income between \$60,000-\$100,000 had odds that were 85% lower for enrolling into intervention compared to families who made less than \$60,000 ($p = .015$). In contrast, families with the highest income (>\$100,000) did not differ significantly from families with the lowest income (<\$60,000), albeit odds of enrollment for the highest earners were also lower relative to the lowest earners, by 62% ($p = .208$). Finally, living further from the clinic was associated with decreased odds of enrolling into intervention. Families who lived more than 30 miles from the clinic had the lowest enrollment rate, with odds of enrollment that were 88% (OR=0.12 [0.01, 0.66], $p = .014$) less than families who lived less than 10 miles from the clinic.

Child clinical features associated with intervention enrollment are presented in Table 2. Very few participants in the sample were already receiving early intervention services (n=5) and four out of these five participants chose to enroll into the RCT. Of the two parent report measures of infant behavior (the Vineland-II and ESAC), only Vineland Communication differentiated families who chose not to enroll into intervention from those who did. The average Vineland Communication score for infants who enrolled in intervention was 88.1 (SD = 13.5) compared to 96.6 (SD = 11.7) for infants who did not enroll. For every one-point increase in the Vineland Communication standard score, the odds of enrolling into intervention decreased by 5% (OR = 0.95 [0.90, 0.99], $p = .030$). Infant performance on the Mullen Expressive and Receptive Language Scales approached statistical significance in the regression model, with infants who enrolled averaging 37.0 (SD = 7.2) for the verbal scales compared to 41.0 (SD = 8.4) for infants who did not enroll. For every one-point increase in the verbal t-score (average of receptive and expressive language scales), odds of enrollment into intervention reduced by 7% (OR = 0.93 [0.87, 1.00], $p = .061$). This finding was

examined further by looking at receptive and expressive language t-scores separately. Average receptive language t-scores were 37.6 (SD = 8.82) for the infants who enrolled into intervention and 40.9 (SD = 8.98) for infants who did not. A slightly larger between-group discrepancy was observed in expressive language where infants who enrolled into intervention had an average of 36.4 (SD = 9.72) and infants who did not enroll had an average of 41.2 (SD = 10.5). Logistic regressions for these subscales were not significant (receptive language: OR = 0.96 [0.90, 1.02], $p = .163$; expressive language: OR = 0.95 [0.90, 1.01], $p = .087$). Infant performance on the CSBS did not impact the odds of enrolling into intervention. Similarly, parental concern reported on the ESAC and infant red flags for ASD as measured with the SORF-Clinic and SORF-Home did not have a significant effect on the odds of intervention enrollment.

Discussion

The findings from this study highlight a number of barriers to enrollment in an RCT of caregiver-implemented intervention for 12-month-old infants who are exhibiting significant red flags for ASD. Distance to the clinic, maternal fulltime work, and total household income all emerged as significant logistical and socio-demographic factors associated with intervention study enrollment. While distance to clinic had the largest effect on enrollment decisions, all three of these factors reflect a family's available time and resources. We hypothesize that the time and resources needed for participating in the RCT were perceived as too burdensome, ultimately deterring families from enrollment. Interestingly, the majority of families stayed in the longitudinal research study, which only required three visits to the clinic between 1–2 years of age, compared to weekly visits to the clinic for the RCT (i.e., about 36 additional visits between 1–2 years of age). This suggests that it was not participation in research, per se, that parents found too burdensome, it may have been specifically the time and resources needed to participate in the clinical trial that seemed to interfere with families' enrollment.

This RCT consisted of two intervention conditions, both of which required at least one weekly visit to the clinic. Families who lived further from the clinic had greater odds of declining study enrollment. Findings also showed that families making an income of \$60,000 or less and those making \$100,000 or more had higher odds of intervention enrollment. In contrast, middle-income families (combined household income of \$60,000–\$100,000) had significantly lower odds of enrolling. This finding may reflect the nature of jobs that place household incomes in this range, including roles with less flexibility in hours. It is possible that higher income families have more flexibility in job roles and work schedules that can accommodate a caregiver-implemented intervention study. Likewise, lower income families may have one parent who is not working, allowing them to dedicate the time needed to participate in the intervention, or it could reflect the family's need for services if they otherwise do not have access to or resources for intervention. This interpretation is also consistent with the finding that mothers who were working fulltime demonstrated lower odds of enrolling in the early intervention study. These data suggest that the inclusion of a clinic-based component in RCTs for young infants at risk for ASD may pose a barrier to study enrollment.

Indeed, there is a body of research suggesting that families with fewer resources are less likely to enroll in parent training treatment trials (Baker et al., 2011; Heinrichs et al., 2005), and that this association may be driven by competing time demands (Garvey et al., 2006). Our results are in line with this work and additionally suggest that the association between family resources and research enrollment may depend on perceived burden, which in the present study involved weekly clinic visits. These results have implications for access to services more broadly, where in-home intervention services may be more appropriate for middle-income families and those living in more rural areas.

Child clinical profiles at the 12-month visit across all participants depict clear red flags for ASD and mild to moderate delays in social communication, in the absence of global developmental delays. However, parents of infants who exhibited lower scores on adaptive communication and language had higher odds of enrolling in the study. No other infant clinical features significantly predicted enrollment, suggesting that symptom profiles of these very young children may not signal a strong need for intervention to parents. Near typical functioning in adaptive communication and language may drive caregivers to decline intervention study enrollment despite red flags for ASD and vulnerabilities in social-communication skills. Delay in language has historically been the first sign of ASD for parents of older children and it is possible that average language skills, even in children as young as 12 months, may diminish parental buy-in. Most parents in this sample have older children with ASD whose developmental course to diagnosis may be dissimilar from that of their younger infant. Despite expert clinical judgment of ASD risk, the absence of pronounced delays – especially compared to the older sibling with ASD, may indicate to parents that intervention is unnecessary. It is also possible that the dosage of the RCT (i.e., once weekly sessions) may have impacted parents' decision to enroll. State early intervention programs vary widely in the number of hours delivered to families, with the average landing at about 4–5 hours per month (IDEA Infant Toddler Coordinators Association, 2019; Wise, Little, Holliman, Wise, & Wang, 2010). This dosage is in line with that of this RCT but due to the clinic-based component, which requires additional travel time, the study may have been perceived as more intensive than typical state-delivered programs, and thus too burdensome. On the other hand, in states where 20+ hours per week is provided to children with ASD, an RCT at this dosage may have seemed negligible and signaled to parents that early intervention was unnecessary. In this way, components specific to the RCT and local context (i.e., clinic-based service delivery and dosage) may have uniquely impacted enrollment decisions.

As previously discussed, Ingersoll et al (2017) suggested that a family's experience of stress at the time of diagnosis may negatively impact enrollment in an intervention study. In this study, families received their first clinical assessment with developmental feedback at the infant's 9-month appointment. Then at 12 months, following a second clinical assessment, parents were given feedback about their child's development and made aware of their child's risk for ASD. Eligible families were subsequently invited to enroll in the early intervention study. At present, it is unknown how the emotional reaction to this feedback session influenced the families' decision to enroll. Future studies could disentangle the effects of clinical feedback from other factors, such as parent buy-in and perceived burden, on intervention enrollment.

Limitations

The findings of this study should be viewed in light of their limitations. First, the small size of the current sample may have led some analyses to be underpowered, possibly preventing us from uncovering additional factors associated with low intervention study enrollment. Second, this study did not include any direct measures of parental attitudes toward early intervention trials or reasons for declining enrollment. Additional studies using parent interviews, focus groups, and/or questionnaires (e.g., the Barriers to Treatment Participation Scale; Kazdin, Holland, Crowley, & Breton, 1997) will help to unpack parental decision-making and map pathways that may lead to strengthened parent-clinician consensus and enthusiastic study enrollment. This study did not collect a standardized measure of parental wellbeing (e.g., stress and strain) or information on participation in treatment services for older siblings with ASD, preventing us from understanding personal and family contextual issues associated with decisions to enroll in the RCT. Finally, while we are confident in the eligibility criteria that were carefully selected for this study, we do not have full outcome data for participants who declined intervention. Thus, we do not currently know about barriers to participation, engagement, and retention for those participants who agreed to enroll in the RCT. Because most participants remained in the large, longitudinal study, our longitudinal research will be able to systematically evaluate developmental trajectories and outcomes for children and families who did, compared to those who did not, enroll in the intervention study, once all intervention outcomes are ascertained. While a minority of families were already receiving outside intervention services at the time of the 12-month visit ($n=4$), and the majority of those families agreed to enroll in the RCT, it is outside the scope of the current study to evaluate whether families who declined enrollment proceeded to seek out community-based, in-home early intervention services. Future research should collect this data to determine if parents were resistant to the clinic-based aspect of the RCT or to intervention more broadly.

Conclusions and Future Directions

Emerging research in caregiver-implemented interventions for infants, prior to diagnosis of ASD, suggests that enrollment into early intervention RCTs is a challenge. Our study suggests that factors related to caregiver resources and child communication skills are some of the significant barriers to study enrollment. Intervention that requires parents to come to the clinic may lead families with limited time (full-time work and/or living far from clinic) to decline enrollment. Parents of infants with higher communication skills may also be more resistant to intervention enrollment. Overall, these findings substantiate a call for early intervention research that takes place at home in the natural environment to accommodate families with competing demands, in addition to the development and dissemination of community viable treatments by community providers. Research and practice conducted in the home environment may address these barriers to participation and allow for universally accessible intervention services for all families, regardless of SES and family context.

Future research should focus on understanding the complicated process of attaining and maintaining parental buy-in to the importance and implications of early red flags for ASD, in addition to how these factors translate to a vital opportunity to optimize children's outcomes via early intervention. This exploration should include several areas. First, it is

important to fully understand the impact of parent awareness and knowledge of social-communication milestones and ASD red flags on caregiver uptake of early intervention. Parents with children who were not showing dramatic delays in everyday adaptive communication skills at 12 months of age had lower odds of intervention enrollment, despite documented early signs of ASD and social-communication delays. This suggests the vital importance of educating parents and caregivers about early social-communication development, and of potential utilization of techniques to promote parent attitudinal and behavioral change. Second, our current data do not allow us to examine how parental buy-in is associated with likelihood of enrollment in intervention. Measuring the degree to which parents agreed with clinician concerns would yield invaluable information and may suggest that attainment of parent-clinician consensus is critical before anything else is targeted in the process of enrollment. Employing qualitative methodologies will help describe the complicated process of parental decision-making regarding very early intervention, including consideration of logistical or resource-related factors such as investment of time, transportation challenges, and cost.

Finally, studies that continue to demonstrate the impact of very early intervention on immediate and longer-term outcomes (into the school-age years) will further solidify the importance of early identification and intervention in the first year of life. We may hope to see that, like the effect in non-ASD populations (e.g., Nock & Kazdin, 2001), confidence in treatment leads to increased enrollment. Future work should monitor and report on rates of enrollment and participation in very early intervention trials and investigate potential barriers to enrollment, especially when intervention is conveniently offered in the home, as prescribed by federal mandates (IDEA 2004; amended PL Public Law 114–95, the Every Student Succeeds Act, 2015). Such findings will shed light on best practices for broad dissemination of early identification and intervention strategies.

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Table 1

Participant Demographics

Characteristic	All N=57 (100%)	Not Enrolled N=25 (43.9%)	Enrolled N=32 (56.1%)	Enrolled Odds Ratio [CI]	ROC
Risk for ASD					
Low risk	10 (17.5%)	5 (50%)	5 (50%)	Reference	0.522
High risk	47 (82.5%)	20 (42.5%)	27 (57.5%)	1.34 [0.32,5.64]	
Sex					
Male	39 (68.4%)	18 (46.2%)	21 (53.8%)	Reference	0.532
Female	18 (31.6%)	7 (38.9%)	11 (61.1%)	1.35 [0.43,4.20]	
Maternal highest level of education					
High School/GED/Associate's/Some college	11 (19.6%)	3 (27.3%)	8 (72.7%)	Reference	0.566
Bachelor's Degree	26 (46.4%)	12 (46.1%)	14 (53.9%)	0.46 [0.08,2.05]	
Graduate/Professional Degree	19 (33.9%)	9 (47.4%)	10 (52.6%)	0.44 [0.07,2.13]	
Maternal Years of Education (Mean, SD)	16.9 (2.15)	17.4 (2.48)	16.5 (1.81)	0.81 [0.62,1.06]	0.606
Maternal age (Mean, SD)	34.4 (4.78)	33.4 (4.08)	35.2 (5.20)	1.08 [0.97,1.21]	0.599
Maternal employment status:					
Mothers not employed fulltime	35 (62.5%)	11 (31.4%)	24 (68.6%)	Reference	0.646
Mothers employed fulltime ^a	21 (37.5%)	13 (61.9%)	8 (38.1%)	0.29 [0.09,0.90] *	
Total household income:					
<\$20,000 - \$60,000	15 (27.8%)	3 (20%)	12 (80%)	Reference	0.691
>\$60,000 - \$100,000	17 (31.5%)	11 (64.7%)	6 (35.3%)	0.15 [0.02,0.70] *	
>\$100,000	22 (40.7%)	9 (40.9%)	13 (59.1%)	0.38 [0.07,1.67]	
Distance between home and Marcus:					
10 miles or less	12 (21.4%)	3 (25%)	9 (75%)	Reference	0.723
>10–20 miles	13 (23.2%)	3 (23.1%)	10 (76.9%)	1.11 [0.15,7.98]	
>20–30 miles	18 (32.1%)	8 (44.4%)	10 (55.6)	0.44 [0.07,2.13]	
>30 miles	13 (23.2%)	10 (76.9%)	3 (23.1%)	0.12 [0.01,0.66] *	
Older Sibling ASD Severity (Mean, SD)					
SCQ Total	21.4 (6.42)	20.8 (6.45)	21.8 (6.53)	1.02 [0.92, 1.14]	0.524

Note. All values are reported as the number and percent of participants, unless otherwise noted.

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Mothers not employed fulltime included mothers who reported to be working part time (N=12), not working (N=19), students (N=2), and other (N=2). SCQ = Social Communication Questionnaire

⁺ $p < .1$
* $p < .05$,
** $p < .01$

Table 2

Clinical Characteristics at 12 Months

Characteristic	All N=57	Not Enrolled N=25	Enrolled N=32	Enrolled Odds Ratio [CI]	ROC
Receiving Early Intervention Services					
No	52 (91.2%)	24(46.1%)	28 (53.9%)	Reference	
Yes	5 (8.8%)	1 (20%)	4 (80%)	3.43 [0.36, 32.79]	0.543
CSBS (Mean, SD)					
Social Composite	6.61 (1.36)	6.60(1.50)	6.62(1.26)	1.01 [0.69,1.50]	0.496
Speech Composite	7.67 (0.95)	7.80(1.15)	7.56 (0.76)	0.76 [0.43,1.36]	0.543
Symbolic Composite	6.84(2.16)	7.24 (2.65)	6.53 (1.67)	0.85 [0.66,1.10]	0.554
Total Standard Score	79.6 (5.82)	80.3 (7.46)	79.0(4.15)	0.96 [0.88,1.06]	0.540
ESAC Total (Mean, SD)	21.7 (7.42)	20.2(7.12)	22.8 (7.57)	1.05 [0.98,1.13]	0.590
ESAC Parental Report of Concern ^a					
No	45 (78.9%)	20 (44.4%)	25 (55.6%)	Reference	
Yes	12 (21.1%)	5 (41.7%)	7 (58.3%)	1.12 [0.31, 4.07]	0.509
Mullen Scales of Early Learning (Mean, SD)					
Nonverbal T Score	53.3 (7.72)	53.2 (8.22)	53.3 (7.44)	1.00 [0.94,1.07]	0.524
Verbal T Score	38.8 (7.92)	41.0(8.36)	37.0 (7.20)	0.93 [0.87,1.00] ⁺	0.636
Systematic Observation of Red Flags – Clinic (Mean, SD)					
Social Communication Red Flags	7.14(1.89)	7.25 (1.98)	7.06(1.85)	0.95 [0.71,1.26]	0.519
RRB Red Flags	2.48 (1.50)	2.25(1.42)	2.66(1.56)	1.21 [0.84,1.74]	0.566
Total Red Flags	9.62 (2.63)	9.50 (2.60)	9.72 (2.68)	1.03 [0.84,1.27]	0.520
Systematic Observation of Red Flags – Home (Mean, SD)					
Social Communication Red Flags	7.06 (2.04)	7.42(1.43)	6.83 (2.34)	0.86 [0.64,1.16]	0.535
RRB Red Flags	1.06(1.20)	0.79 (0.85)	1.23 (1.36)	1.41 [0.82,2.43]	0.571
Total Red Flags	8.12(2.60)	8.21 (1.78)	8.07 (3.03)	0.98 [0.78,1.22]	0.476
Vineland Adaptive Behavior Scales (Mean, SD)					
Communication	91.5 (13.4)	96.6(11.7)	88.1 (13.5)	0.95 [0.90,0.99] [*]	0.686
Daily Living Skills	84.3 (8.86)	84.0(11.0)	84.5 (7.29)	1.01 [0.95,1.07]	0.471

Characteristic	All N=57	Not Enrolled N=25	Enrolled N=32	Enrolled Odds Ratio [CI]	ROC
Socialization	94.5 (8.74)	96.6(7.10)	93.1 (9.54)	0.95 [0.89,1.02]	0.619
Motor Skills	91.6(11.3)	89.4(11.1)	93.1 (11.3)	1.03 [0.98,1.08]	0.575
Adaptive Behavior Composite	88.4 (8.32)	89.7 (8.91)	87.5 (7.91)	0.97 [0.90,1.04]	0.614

Note. All values are reported as the number and percent of participants, unless otherwise noted.

^aThis represents the number of parents who responded “yes” to having concerns about their child’s development on the ESAC. CSBS = Communication and Symbolic Behavior Scales, ESAC = Early Screening for Autism and Communication Disorders

⁺ $p < .1$
^{*} $p < .05$,
^{**} $p < .01$