

RESEARCH ARTICLE

Infant Achievements Intervention Improves Caregiver Implementation Fidelity and Infant Social Communication Outcomes: A Preliminary Randomized Clinical Trial

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ABSTRACT

Randomized controlled trials (RCTs) focused on idiopathic social communication delay (SCD) in the first year of life are rare. We preliminarily tested the efficacy of an 8-week caregiver-implemented intervention for infants with idiopathic SCD. Infants (8–12 months) with SCD were block-randomized with caregivers to the Infant Achievements (IA) ($n = 18$) or Caregiver Education (CE) ($n = 20$) group in this assessor-masked RCT. Assessments were completed at baseline, post-intervention, and 8-week follow-up. IA caregivers received reflective, home-based coaching to implement naturalistic developmental behavioral intervention (NDBI) strategies. Primary outcomes: masked ratings of caregiver implementation fidelity, frequency of infant initiation of joint attention (IJA), and percent of coordination of joint engagement (CJE). Secondary outcomes: masked researcher-administered and scored Mullen Scales of Early Learning (MSEL) language and Visual Reception scaled scores; nonmasked caregiver-reported Communication and Symbolic Behavior Scales Caregiver Questionnaire (CSBS CQ) Social, Speech, and Symbolic composite scores and McArthur-Bates Communication Development Inventories Words Understood and Produced scores. Prespecified analyses followed an intent-to-treat approach using Generalized Linear Mixed Models for non-normally distributed outcomes and linear mixed-effects models for those with normal distributions. Significant group by time effects favored the IA group relative to the CE group on all primary outcomes at post-intervention (p 's ≤ 0.001), and for caregiver fidelity and IJA, at follow-up (≤ 0.03). Significant IA intervention effects were detected on secondary outcomes of nonverbal cognition (MSEL Visual Reception) and CSBS CQ Speech composite at post-intervention (< 0.01) and follow-up (≤ 0.02). IA equips caregivers to learn and generalize the implementation of child-responsive NDBI strategies and propels pre-linguistic social communication advances in SCD infants.

Trial Registration: [ClinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT034404505.

1 | Introduction

Although 1 in 6 children are identified with a developmental disability (Maenner et al. 2023), most diagnoses are not made until

after a child enters preschool, leading to missed opportunities for early, potentially transformative interventions. Preemptive interventions during infancy (Grzadzinski et al. 2021), a critical window of experience-dependent neuroplasticity (Knudsen 2004)

Summary

- What's known:
 - Caregiver-mediated intervention for toddlers with social communication delay (SCD) improves social communication outcomes.
- What's new:
 - Coaching caregivers of infants (ages 8–12 months) with SCD to implement Infant Achievements (IA) improves caregiver fidelity.
 - Infants in the IA group had better social communication outcomes, generalized and sustained through follow-up, compared to infants in the active control caregiver education group.
- What's relevant:
 - Intervention should be implemented during the first year of life if delays are detected rather than waiting to fail.
 - More research is needed to identify the active ingredients of infant social communication interventions.

could optimize developmental trajectories by capitalizing on infants' heightened perceptual sensitivity to socially relevant stimuli (Johnson 2017). Despite prospective longitudinal evidence that early language and social communication skills are strong predictors of long-term outcomes (Dillon et al. 2021), research on interventions for social communication delays (SCD) in infancy is sparse. This study addresses the gap in caregiver-implemented interventions for infants (≤ 12 months) with idiopathic SCD.

Infants at elevated likelihood (EL) for SCD or autism demonstrate disrupted social processing (Jones et al. 2017), and reduced dyadic synchrony (Yirmiya et al. 2006). Their ambiguous or less frequent signals may be challenging for caregivers to interpret, possibly attenuating development-enhancing input (Choi et al. 2020). Robust, clear cues from caregivers are critical for propelling social communication learning (Stallworthy et al. 2023). While caregivers play a pivotal role in infants' social communication development (Eggebrecht et al. 2017; Weisleder and Fernald 2013), they report limited knowledge about how to effectively engage with their infants who have social communication delays (Pfeiffer et al. 2024).

Evidence-based naturalistic developmental behavioral intervention strategies (NDBI; Schreibman et al. 2015) have been shown to improve social communication and benefit visual information processing outcomes in toddlers (Landa et al. 2011) and could be translated for caregiver implementation with SCD infants. Indeed, effective caregiver-mediated interventions tailored for infants are needed to empower caregivers to understand child behavior and development, establish developmentally appropriate expectations, and implement evidence-based strategies to support skill acquisition. A systematic review with meta-analysis of behavioral interventions for infants and toddlers identified one promising intervention strategy, instructing caregivers to reinforce child communication behaviors, which increased those child behaviors or strengthened links between caregiver parentese and frequency of child communicative behavior (Simacek et al. 2023). However, only six intervention studies focused on infants age ≤ 12 months, mostly *without* developmental concerns (Simacek et al. 2023). Two randomized controlled trials (RCTs)

were identified that enrolled infants age ≤ 10 months at elevated likelihood (EL) of developing autism due to having an older autistic sibling but not due to an identified SCD (Green et al. 2015; Jones et al. 2017). One RCT enrolled infants (age 9–14 months) showing autism-related traits (Whitehouse et al. 2019). All three provided caregiver-mediated intervention. Green et al. (2015) reported significant effects on researcher-coded caregiver non-directiveness during caregiver-infant interaction. Whitehouse et al. (2019) did not report significant effects on caregiver outcomes. Statistically significant treatment effects on infants were detected on caregiver-report measures (social adaptation, Green et al. 2015; communication, Whitehouse et al. 2019) or via neurocognitive social attention metrics (habituation times, frontal EEG theta power), where post-intervention results of EL autism infants approximated those from same-age peers at low autism likelihood (Jones et al. 2017).

Although the reviewed RCTs demonstrated the potential of caregiver-mediated intervention as a preemptive intervention for infants, the extent to which these findings can be generalized to infants showing early signs of SCD remains unclear, as only one of the three studies enrolled infants with autism-related traits; none included an active control condition. The current RCT with an active control addresses these gaps by examining the preliminary efficacy of an innovative caregiver-mediated infant intervention (Infant Achievements [IA]) for infants (aged 8–12 months) with SCD. We hypothesized that:

1. Caregivers coached in IA implementation would show significantly greater fidelity during infant interactions compared to caregivers in the active control (Caregiver Education; CE) group.
2. Infants with SCD in the IA group would demonstrate significantly greater gains in social engagement (frequency of initiation of joint attention, percent coordination of joint engagement; caregiver-reported social skills) and communication (Mullen Scales of Early Learning [MSEL] Receptive Language and Expressive Language scores; caregiver-reported communication, language, and speech skills), and nonverbal cognitive performance per the MSEL Visual Reception scaled score compared to infants in the CE group.

2 | Methods

2.1 | Ethical Considerations

This parallel RCT protocol was approved by the Johns Hopkins Institutional Review Board and registered with clinicaltrials.gov (NCT03404505; <http://www.clinicaltrials.gov>). Written informed consent was obtained from caregivers before participation. This study conformed to standards specified in the US Federal Policy for the Protection of Human Subjects.

2.2 | Participants

Between 2017 and 2020, a sample size of 32 caregiver-infant dyads (16 caregiver-infant dyads per intervention arm) was targeted for a total of 64 participants (i.e., 32 caregiver-infant dyads). With measures collected from the caregiver and infant

across three time points (baseline, post-intervention, and follow-up) in a sample of this size, power calculations indicated 80% (two-sided, $\alpha = 0.05$) power to detect an effect size of 0.51 (medium effect). Sixty-two families of infants between ages 8 to 12 months completed an initial telephone eligibility screening with a trained research assistant. Infant exclusion criteria were: history of head injury, seizure disorder, severe birth trauma, birth defects or genetic disorders, hearing or visual impairment; birth weight < 1500g; prenatal illicit drug or excessive alcohol exposure; living in foster care; residing > 40 miles from our institution; and primary language other than English. Infants met at least one of the following eligibility criteria by scoring: (a) ≥ 7 on the *Autism Observation Scales for Infants* (AOSI; Bryson et al. 2008); (b) ≥ 1 standard deviation (SD) below the mean on the *Mullen Scales of Early Learning* (MSEL) Expressive or Receptive Language scales (Mullen 1995); or (c) ≤ 10 th percentile on any of the three composite scores or total score of the Communication and Symbolic Behavior Scale Developmental Profile *Infant Toddler Checklist* (Wetherby and Prizant 2002; see Eligibility Measures, below). Thirty-eight families who completed an eligibility assessment met eligibility criteria and agreed to further participation. Most infants (24 of 38; 63%) met eligibility on two or more criteria, and 10 (26%) met criteria on all three measures (Table S1). Eligible participating families completed baseline measures prior to randomization. Sample demographics are presented in Table 1.

2.3 | Randomization

A box randomization procedure was used with block sizes of 2, 4, and 6, with block size concealed until group assignment was made. IA and CE conditions were randomly assigned within each block, and block size was randomly determined by an independent statistician. Of the 38 enrolled families, 18 were randomly assigned to CE and 20 to IA, with 16 CE and 17 IA families completing the study protocol (Figure 1). In both conditions, families received the intervention (IA group) or education (CE group) in their homes. For both groups, baseline, post-, and follow-up assessments occurred in our child development lab. Randomized families were not asked to stop any ongoing treatment (Table S2). Caregivers received \$25 incentives after eligibility testing and after follow-up testing upon study completion. Families kept the toys that they were given during each week of the intervention.

2.4 | Treatment Conditions

2.4.1 | Infant Achievements Condition

The primary caregiver of each infant received in-home coaching sessions ($M = 15.88$ sessions, $SD = 0.33$) by a developmental psychologist semi-weekly for approximately eight weeks ($M = 9.68$ weeks, $SD = 1.10$ weeks), using Practice-Based Coaching (Snyder et al. 2015). This approach consists of three cyclical components: focused observation, reflection plus feedback using video of caregiver-infant engagement, and shared goals and action planning (Snyder et al. 2015). Coaches modeled child-responsive engagement using a small, conceptually

TABLE 1 | Demographic and baseline measures for the caregiver education (CE) and infant achievements (IA) intervention groups.

	CE (N=20)	IA (N=18)	p
Age	10.14 (1.18)	9.24 (0.84)	0.01
Sex			0.30
Female	10 (50.0%)	6 (33.3%)	
Male	10 (50.0%)	12 (66.7%)	
Autism sibling			0.06
Yes	6 (35.3%)	11 (68.8%)	
No	11 (64.7%)	5 (31.2%)	
Race			0.25
Asian	1 (6.2%)	2 (11.8%)	
Black	1 (6.2%)	4 (23.5%)	
White	12 (75.0%)	7 (41.2%)	
Multiracial	2 (12.5%)	4 (23.5%)	
Ethnicity			0.74
Hispanic/Latino	4 (22.2%)	3 (17.6%)	
Not hispanic/latino	14 (77.8%)	14 (82.4%)	
Participating caregiver			0.40
Father	2 (10.0%)	4 (22.2%)	
Grandmother	1 (5.0%)	0 (0.0%)	
Mother	17 (85.0%)	14 (77.8%)	
Participating caregiver education			0.56
No college degree	7 (38.9%)	5 (29.4%)	
College degree	11 (61.1%)	12 (70.6%)	
Household income			0.55
Prefer not to answer	1 (5.9%)	3 (17.6%)	
\$60,000 and below	4 (23.5%)	4 (23.5%)	
Above \$60,000	12 (70.6%)	10 (58.8%)	
AOSI total score	5.11 (2.75)	6.94 (4.40)	0.13
MSEL			
Receptive language	39.05 (8.37)	36.44 (6.05)	0.28
Expressive language	37.15 (8.61)	38.61 (7.01)	0.57
Visual reception	58.15 (6.14)	52.78 (6.54)	0.01
CSBS ITC			
Social percentile	45.94 (28.71)	42.12 (34.96)	0.73
Speech percentile	54.67 (33.58)	32.24 (25.75)	0.03
Symbolic percentile	47.94 (31.80)	35.12 (27.14)	0.21

Abbreviations: AOSI, The autism observation scale for infants; CSBS ITC, Communication and Symbolic Behavior Scale Infant Toddler Checklist; MSEL, Mullen Scales of Early Learning.

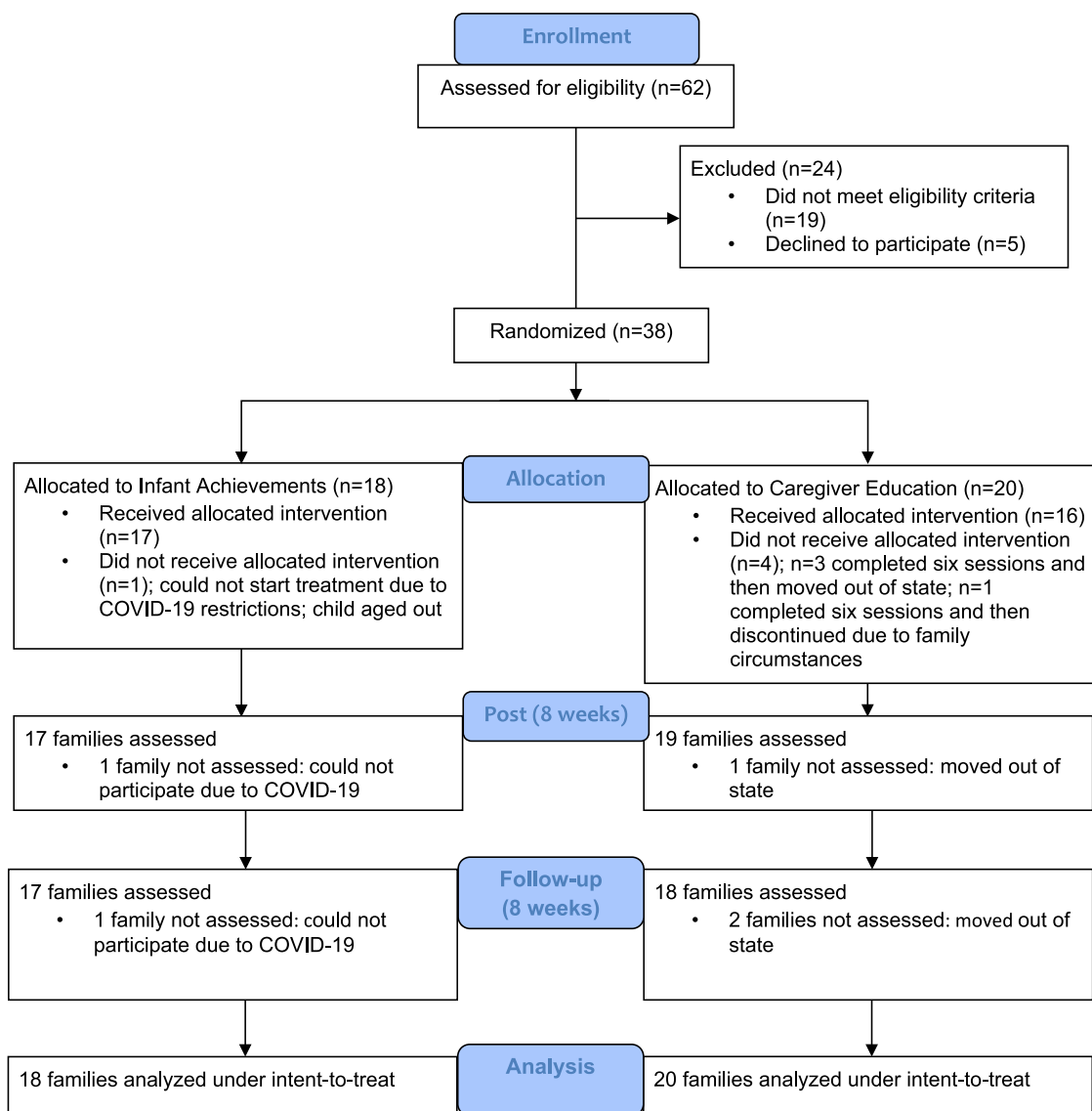


FIGURE 1 | CONSORT participant flow diagram.

and sequentially linked set of NDBI strategies. Caregivers were coached to follow the infant's lead using developmentally appropriate production (modeling or imitating the child) of child-contingent action or linguistic content (i.e., linguistic mapping), naming and describing what the infant was playing with, doing, or looking at, then to pause for the infant to initiate or respond, and finally, to provide a prompt or naturalistic reward. This 'package' of caregiver behaviors aligns with the NDBI antecedent-behavior-consequence sequence and with (Sameroff 2009). Since objects and routines influence the actions and communication between infants and caregivers (Custode and Tamis-LeMonda 2020), the following strategies were introduced in the first session and practiced and generalized during play with carefully selected toys that are both developmentally appropriate and motivating (Table S3): (a) dyadic, reciprocal play routines that maximize infant attention and encourage coordinated joint engagement, joint attention, and communication; (b) language (e.g., "ball", a consonant-vowel unit with an early-developing consonant) and gestures that caregivers would use

repeatedly, providing high-dosage focused stimulation; (c) and reciprocal social affordances.

Each week, coaches provided a different strategically selected toy that families could keep and use in subsequent sessions, allowing for a variety of developmentally appropriate play activities, reciprocal engagement, language, and gestures (Table S3). The motoric and cognitive affordances of these toys were expected to entice, or entrain, infant engagement (Lobo et al. 2014) and encourage caregivers to implement intervention strategies while encouraging their own creative strategies (Schatz et al. 2022).

2.4.2 | Caregiver Education Condition

CE caregivers received twice-weekly sessions with a trained study team member. During in-home once-weekly visits, a child development tutorial was delivered via iPad or laptop

computer. The tutorial integrated information from the empirical child development literature and publicly available evidence-based developmental information. Topic-aligned, high-quality videos from raisingchildren.net.au also were utilized. IA intervention strategies were not discussed; no coaching was provided. Weekly phone follow-up check-ins reinforced that week's tutorial concepts and addressed caregiver content-related questions. Families were given study-provided developmentally appropriate toys (different from IA toys) aligned with the weekly tutorial concepts (e.g., development of communication milestones, reading the child's cues, etc.) but were not instructed in how to use the toys with their child (Table S4).

2.5 | Coach Fidelity of Implementation

Coaches in both treatment arms were experienced research staff who were trained to fidelity of implementation in coaching caregivers. As shown in Table S5, IA coach fidelity was rated for 20 items spanning: (a) Adherence to Process (e.g., checking on goals, modeling toy use, reviewing videos with caregivers, providing feedback); (b) Adherence to Content (e.g., reviewing or discussing caregiver implementation strategies, collaboratively setting goals); and (c) Quality of Coaching (e.g., how positively and constructively the coach interacts with the caregiver). Adherence items were rated as 0 = not completed, 1 = completed. Quality items were rated on a 3-point scale as 0 = strongly disagree/disagree, 1 = neutral, 2 = agree/strongly agree.

CE coach fidelity was rated using a 12-item checklist with ratings of 0 = not completed, 1 = completed. As shown in Table S6, CE coach fidelity items focused on (a) Session Procedures (e.g., delivering the tutorial as scripted, reviewing the Daily Play Diary) and (b) Use of General Strategies (e.g., responding warmly to the caregiver, briefly addressing questions while avoiding direct coaching of infant-caregiver interaction). For both IA and CE coaching fidelity, ratings were summed and divided by the total possible score for percent fidelity. Inter-rater reliability for a randomly selected 20% of videos from all three data points using intraclass correlation coefficient (ICC 2-way mixed model; Bobak et al. 2018) was moderate at 0.71 (95% CI = 0.67–0.74) for IA coach fidelity and moderate at 0.71 (95% CI = 0.64–0.77) for CE coach fidelity. The primary coders were masked regarding which sessions were coded for reliability.

Implementation fidelity was high for both IA and CE coaches, with mean scores of 97.98% for IA (range = 85.71%–100%, SD = 3.09) and 97.03% for CE (range = 72.73%–100%, SD = 5.49). We aimed for at least 80% fidelity in both conditions—a threshold met for all ratings except for one CE coaching session at 72.73% (due to extenuating family circumstances). Coach fidelity of implementation was monitored regularly throughout the RCT by a study team developmental clinical psychologist. If any deviations in implementation were observed, coaches were retrained. A Welch two-sample *t*-test indicated no statistically significant difference between the two groups, $t(172.3) = 1.73$, $p = 0.086$, 95% CI [−0.14, 2.04], suggesting that overall coach fidelity of implementation was comparable across both treatment arms.

2.6 | Participant Characterization Measures

The Demographic Questionnaire (baseline), completed by caregivers, provided family background information (race, ethnicity, sex, caregiver education, household income).

The Treatment History Questionnaire (baseline, post-intervention, follow-up) was completed by caregivers, providing information regarding current and prior infant treatment (e.g., speech/language, occupational, physical therapy).

2.7 | Eligibility Measures

A clinical researcher, trained to fidelity for administration and inter-rater reliability for scoring, administered the first two measures and caregivers completed the third measure below to assess for infant SCD.

The Autism Observation Scale for Infants (Bryson et al. 2008) is an examiner-administered measure of early autism indicators (6–18 months). Higher scores indicate greater atypicality.

The MSEL (Mullen 1995) is a standardized, norm-referenced developmental test (0–68 months). The Expressive Language (EL) subscale assessed infants' vocalizations, babbling complexity, and word production. The Receptive Language (RL) subscale assessed infants' listening and coordination thereof with looking, recognition of words, response to name, etc.

The Communication and Symbolic Behavior Scales Developmental Profile Infant-Toddler Checklist (ITC; Wetherby and Prizant 2002) is a standardized, norm-referenced (6–24 months) caregiver questionnaire capturing prelinguistic social and communication skills. Seven scales comprise three composite scores that, combined, generate a total score. The Social composite includes Emotion and Eye Gaze, Communication (rate and communicative function), and Gestures scales. The Speech composite includes Sounds and Words scales (diversity of communicative sounds and words). The Symbolic composite includes Understanding (of language) and Object Use (symbolic and constructive play) scales. Eligibility criterion levels were set at > 1.25 SD below the mean (standard scores at or below 6 for the composite scores and 81 for the total scores; percentiles at or below 10).

2.8 | Outcome Measures

Baseline, post-intervention, and follow-up assessments of primary and secondary outcomes were conducted in a research setting at an urban, outpatient autism specialty center in the Mid-Atlantic region of the United States. Baseline assessments occurred within two weeks of eligibility screening ($M = 0.29$ weeks, $SD = 1.23$ weeks) and three weeks of treatment onset ($M = 2.31$, $SD = 1.18$). Post-intervention assessments occurred within three weeks of treatment end ($M = 3.08$ weeks, $SD = 4.80$ weeks). Follow-up assessments occurred within 8–10 weeks of the post-intervention assessment ($M = 11.50$, $SD = 6.22$ weeks). Three participants received delayed post-intervention and follow-up assessments due to institutional

COVID-19 restrictions, resulting in elevated SDs (see Pandemic Effects, below). All assessments were conducted by masked-to-condition examiners.

2.9 | Primary outcome measures

Video recordings of 10-min caregiver-infant play samples, using standardized toy sets, were coded, masked to condition and datapoint to assess caregiver IA implementation fidelity (Table S7) using 3- and 5-point Likert-type scales. Three items related to set-up for infant positioning and stability and ease of access to toys were rated on 3-point scales (1 = did not implement; 2 = partially implemented, 3 = fully implemented) with all remaining items rated on 5-point scales (anchors: 1 = did not implement; 3 = partially implemented, 5 = fully implemented). Total score was calculated; higher scores indicated higher fidelity. Cronbach's alpha for the Caregiver Fidelity scale was high at 0.90 (SD = 0.08). Inter-rater reliability for a randomly selected 20% of videos from all three datapoints using ICC 2-way mixed model (Bobak et al. 2018) was good at 0.82 (95% CI = 0.79–0.86). The primary coder was masked regarding which sessions were to be coded for reliability.

Duration of infant coordinated joint engagement (CJE) in caregiver-child play sample videos was coded using the *Joint Engagement Rating Scale (JERI)*, (Adamson et al. 2020) (Table S8) with Behavioral Observation Research Interactive Software (BORIS; Friard and Gamba 2016). The outcome variable, CJE, defined as the proportion of time when the infant and caregiver were actively engaged with the same object or event, and the infant was actively and consistently acknowledging the caregiver's participation or initiating engagement with the caregiver through coordinated gaze shifts. Coding for three dyads was not masked for primary coding, but coding for inter-rater reliability was completed by a masked coder. Inter-rater reliability was calculated for 20% of the coded videos; ICC (2-way Mixed Model) was excellent at 0.95 (95% CI: 0.93–0.96) (Bobak et al. 2018).

The *Communication and Symbolic Behavior Scales Developmental Profile (CSBS DP) Behavior Sample* (Wetherby and Prizant 2002) is a normed (9–24 months) examiner-administered, standardized procedure with presses for child communication initiation having strong reliability and validity (internal consistency 0.91, inter-rater reliability 0.76–0.99, test–retest reliability 0.85–0.91) (Eadie et al. 2010; Wetherby and Prizant 2002) and predictive validity when compared to the MSEL language and Early Learning Composite scores (0.61–0.75). The outcome variable was frequency of spontaneous initiation of joint attention (IJA) defined as infant communicative triadic gaze shifts between an object and adult, or declarative pointing, showing, or giving with eye contact (or directed gaze). Inter-rater reliability was calculated for 20% of videos with a good ICC (Bobak et al. 2018) of 0.83 (95% CI: 0.79–0.87).

2.10 | Secondary Outcome Measures

The *CSBS Caregiver Questionnaire (CSBS CQ)*; Wetherby and Prizant 2002), a standardized (6–24 months) 42-item measure

with strong test–retest reliability (0.77–0.86) and moderate predictive validity when compared to the MSEL language and Early Learning Composite scores (0.42–0.63), yielded three secondary outcome variables: Social (Emotion and Eye Gaze; Communication), Speech (Use of Sounds; Use of Words), and Symbolic (Understanding of language and gestures) composite standard scores ($M = 10$, $SD = 3$), which were dependent variables. While not registered with clinicaltrials.gov, this measure was added prior to the start of the study to obtain caregiver-observed pre-linguistic and early communication infant behavior.

The MSEL EL, RL (described above) (with strong internal consistency, median 0.80–0.82, strong test–retest reliability 0.82–0.85, moderate concurrent validity with Bayley Scales of Infant Development Mental Developmental Index 0.54–0.59; Mullen 1995) and Visual Reception (VR) subscales were administered at baseline, post-intervention, and follow-up. The VR scale assesses nonverbal cognitive processing and comprehension of visual information such as shapes, patterns, and spatial relations. Scaled scores served as dependent variables. While not registered with clinicaltrials.gov, VR was added prior to the start of the study to test the hypothesis that the play-based IA intervention supported non-verbal cognitive development. The VR scale had good internal consistency (median 0.79), strong test–retest reliability (0.85), and moderate concurrent validity with Bayley Scales of Infant Development Mental Developmental Index 0.58; (Mullen 1995).

MacArthur-Bates Communicative Development Inventories-Words and Gestures Form (CDI) (normed for 8–16 months) (Fenson et al. 2007) is a standardized caregiver-completed questionnaire measuring child language and nonverbal communication with strong test–retest reliability for word comprehension and gesture in 8- to 20-month-olds (> 0.80), lower for word production, likely due to floor effects. Predictive validity for the Words and Gestures forms between ages 10–16 months (T1) and Words and Sentences forms between 16 and 20 months (T2) was strong (0.69) for total word production. Number of words produced and words understood served as dependent variables.

2.11 | Effects of COVID-19 Pandemic on Research Protocol

One family assigned to the IA group was unable to start home intervention visits due to COVID-19 restrictions; their infant aged out prior to IRB-approved resumption of in-person study visits. Three families (IA = 1, CE = 2) transitioned from in-person to telehealth visits and had delayed post-intervention and follow-up assessments. Similarly, two families completed post-intervention evaluations, but follow-up evaluations were delayed until in-person restrictions were lifted. The trial ended after the final follow-up assessment was conducted.

2.12 | Statistical Analyses

Descriptive statistics of baseline characteristics included frequency (%) and means and SDs for categorical and continuous variables, respectively. Between-group differences in baseline

characteristics were evaluated using Welch's *t* test (continuous variables) and Fisher's exact test (categorical variables).

Analyses were conducted following an intent-to-treat approach in R version 4.4.0 (R Core Team 2024). Due to the sample size, male and female infants and their caregivers were pooled for analyses. To model non-normally distributed outcomes, we used Generalized Linear Mixed Models (GLMMs) tailored to the specific distributional characteristics of each outcome (Brooks et al. 2017). Caregiver fidelity (proportion) was analyzed using a GLMM with a beta distribution and a logit link function (Douma and Weedon 2019). For JERI CJE, a Bayesian GLMM with a binomial family and a logit link function was employed to handle the zero-inflated proportion data effectively (Zuur et al. 2009). Outcomes consisting of count data (CSBS IJA, CDI Words Understood, and CDI Words Produced) were analyzed using GLMMs with a negative binomial distribution and a log link function to account for overdispersion (Hilbe 2011), which can lead to underestimating standard errors and overestimating the significance of predictors. For normally distributed outcomes (MSEL VR, EL, and RL scores; and CSBS Speech, Social, and Symbolic composites) linear mixed-effects models were implemented using the *nlme* package (Pinheiro et al. 2017). Normality of residuals was assessed using quantile-quantile plots and the Shapiro-Wilk test. Homogeneity of variance across groups was evaluated with Levene's test. Linearity was further verified by plotting residuals against fitted values.

All models were consistent with an intent-to-treat approach as they included all participants in the analyses regardless of missing data, in line with recommendations for evaluating psychiatric clinical trials (Hamer and Simpson 2009; Whitehouse et al. 2019). Models incorporated fixed effects for treatment group (IA vs. CE [reference level]), time (post-intervention, follow-up vs. baseline [reference level]), and their interaction. Random effects for participants' intercepts were included to allow for deviations from the mean scores predicted by the model and to account for within-child correlation (Pinheiro et al. 2017). Because baseline age and MSEL Visual Reception (VR) T scores were significantly different between groups, we included both variables as covariates in all models. In addition, for any outcome measure that showed a significant baseline difference between groups, we tested a second version of the model that included the baseline value of that outcome as an additional covariate (beyond age and MSEL VR). We report results from both models in the main text of the Results. Covariates were grand mean centered. Statistical tests were two-sided, with $p < 0.05$ considered statistically significant. To evaluate the magnitude of observed intervention effects, Cohen's *d* was calculated and corrected using Hedges' *g* and the pooled standard deviation to provide an unadjusted effect size (Hedges 1981). Author RR confirms that she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses.

3 | Results

Figure 1 shows the participant flow through the RCT. Table 1 shows the demographic and baseline measures for the CE and IA groups. Table 2 shows the descriptive statistics of primary

and secondary outcomes and unadjusted Hedge's *g* by intervention group at each assessment time point. Table 3 shows the group-by-time interactions for the respective primary and secondary outcomes adjusted for age and Mullen VR and unadjusted between-group Hedge's *g*.

3.1 | Baseline Characteristics and Missing Data Analysis

There were no significant differences between the CE and IA groups in the proportion of infants meeting different combinations of eligibility criteria (Table S1) or in the baseline treatment received (see Table S2). Significant baseline differences were identified between groups in age (Table 1), with the IA group being significantly younger ($p = 0.01$) and lower on the MSEL VR scaled score at baseline ($p = 0.01$). Baseline imbalances were identified across outcome measures; therefore, age, MSEL VR scores, and the respective outcome metric were included as covariates in all reported models.

Missing data were minimal across primary and secondary outcomes (Table S9). At baseline, all 38 participants had complete data. Missing data occurred at post-intervention for one participant from each group; at follow-up, one additional participant from the CE group. Missing data ranged from 1 to 3 participants; no imputation methods were applied.

3.2 | Primary Outcomes

Figure 2 shows estimated marginal means, adjusted for baseline differences, for primary outcomes by group and assessment time point. Caregiver fidelity did not significantly differ by group at baseline (Table S10; CE = 60.13%, IA = 61.89%, $p = 0.80$). Compared to the CE group, caregivers in the IA group exhibited significantly greater increases in fidelity from baseline to post-intervention ($p = 0.001$) and from baseline to follow-up ($p = 0.03$).

For child primary outcomes (Table 3; Table S10), at baseline, there was no significant group difference in the proportion of time spent in CJE ($p = 0.91$), although the IA group exhibited fewer IJA bids than the CE group ($p = 0.004$). Increases in CJE and IJA were significantly greater for the IA group relative to the CE group from baseline to post-intervention (IJA: $p = 0.001$; CJE: $p < 0.001$). At follow-up, this effect persisted for IJA ($p = 0.001$), but not for CJE ($p = 0.17$). IJA improvements remained significant even after further adjusting for baseline group differences in IJA, with est. = 0.73, 95% CI [0.27, 1.19], $p = 0.002$ at post-intervention and est. = 0.76, 95% CI [0.29, 1.23], $p = 0.001$ at follow-up.

3.3 | Secondary Child Outcome Measures

At baseline, adjusted models revealed no significant differences between groups on the MSEL EL ($p = 0.32$) or MSEL RL ($p = 0.84$) T scores. However, the IA group had lower Visual Reception scores than the CE group ($p = 0.03$) (Table S11). The IA group exhibited a significantly greater increase in the MSEL

TABLE 2 | Descriptive statistics (means [M] and standard deviations [sd]) of primary and secondary outcomes and unadjusted Hedge's g by intervention group.

	Infant achievements						Caregiver education												
	Baseline		Post		Follow-up		Post vs. Base		Baseline		Post		Follow-up		Post vs. Base		F-up vs. Base		
	M (SD)		M (SD)		M (SD)		g		M (SD)		M (SD)		g		M (SD)		g		
Primary Outcome Measures																			
Caregiver fidelity (%)	61.89 (11.45)		73.60 (9.22)		70.51 (10.55)		1.10		60.13 (12.06)		60.66 (10.35)		0.76		60.47 (13.88)		0.05		0.03
CSBS DP IJA (frequency)	4.06 (3.54)		10.88 (9.25)		9.59 (5.87)		0.96		6.70 (5.64)		7.68 (5.21)		1.12		7.06 (4.81)		0.18		0.07
JERI CJE (%)	2.48 (4.30)		9.56 (12.46)		3.89 (6.16)		0.75		1.29 (1.61)		1.72 (2.38)		0.26		3.73 (5.86)		0.21		0.57
Secondary outcome measures																			
CSBS CQ social	8.88 (3.87)		9.38 (2.31)		9.06 (2.56)		0.15		9.44 (3.11)		9.67 (2.77)		0.05		9.33 (2.72)		0.07		-0.04
CSBS CQ speech	7.76 (2.99)		10.75 (2.96)		10.06 (2.19)		0.98		10.39 (3.43)		10.06 (3.75)		0.85		9.89 (3.10)		-0.09		-0.15
CSBS CQ symbolic	8.76 (2.66)		9.76 (2.86)		9.06 (2.19)		0.27		9.67 (3.07)		9.50 (3.19)		0.12		8.72 (2.40)		-0.05		-0.34
MSEL EL T score	36.44 (6.05)		39.53 (8.73)		40.71 (8.97)		0.40		39.05 (8.37)		38.95 (8.46)		0.55		40.78 (13.15)		-0.01		0.16
MSEL RL T score	38.61 (7.01)		40.65 (9.31)		40.76 (10.95)		0.24		37.15 (8.61)		39.74 (11.00)		0.23		40.28 (13.77)		0.26		0.27
MSEL VR T score	52.78 (6.54)		60.29 (8.53)		54.94 (7.20)		0.97		58.15 (6.14)		57.89 (9.69)		0.31		53.44 (8.20)		-0.03		-0.64
CDI Words understood	11.76 (14.72)		38.24 (25.55)		77.47 (50.75)		1.24		33.94 (51.47)		90.28 (89.04)		1.72		87.87 (68.11)		0.76		0.88
CDI Words produced	0.82 (1.74)		7.35 (8.36)		12.41 (13.85)		1.06		1.33 (1.28)		6.94 (8.00)		1.15		14.27 (15.97)		0.96		1.17

Abbreviations: CDI, Communicative Developmental Inventory; CJE, coordinated joint engagement; CSBS CQ, communication and symbolic behavior scales caregiver questionnaire; CSBS DP, Communication and Symbolic Behavior Scales Developmental Profile; EL, Expressive Language; F-up, follow up; g, Hedge's g, the mean difference within a group, based on the standard deviation of the differences, adjusted with a correction factor; IJA, frequency of spontaneous initiation of joint attention; JERI, joint engagement rating inventory; MSEL, Mullen Scales of Early Learning; RL, receptive language; VR, Visual Reception.

TABLE 3 | Group by time interactions by primary and secondary outcomes and unadjusted between-group Hedge's *g*, with 95% confidence intervals (CI).

	IA vs. CE × post				IA vs. CE × follow-up			
	Est.	95% CI	<i>p</i>	<i>g</i> [95% CI]	Est.	95% CI	<i>p</i>	<i>g</i> [95% CI]
Primary outcome measures								
Caregiver fidelity	0.55	[0.21, 0.89]	0.001	1.29 [0.56, 2.01]	0.36	[0.03, 0.7]	0.03	0.79 [0.09, 1.49]
JERI CJE	1.11	[0.48, 1.76]	<0.001	0.88 [0.18, 1.57]	-0.59	[-1.22, 0.02]	0.17	0.03 [-0.65, 0.70]
CSBS DP IJA	0.76	[0.31, 1.21]	0.001	0.42 [-0.25, 1.09]	0.80	[0.35, 1.26]	0.001	0.46 [-0.22, 1.14]
Secondary outcome measures								
CSBS CQ social	0.23	[-1.73, 2.18]	0.82	-0.11 [-0.80, 0.57]	0.06	[-1.88, 1.99]	0.95	-0.1 [-0.77, 0.57]
CSBS CQ speech	3.33	[0.77, 5.88]	0.01	0.2 [-0.49, 0.88]	2.97	[0.44, 5.51]	0.02	0.06 [-0.61, 0.73]
CSBS CQ symbolic	1.10	[-0.67, 2.87]	0.22	0.06 [-0.61, 0.73]	1.04	[-0.73, 2.81]	0.25	0.14 [-0.53, 0.82]
MSEL EL SS	3.01	[-4.09, 10.11]	0.40	0.07 [-0.60, 0.73]	2.58	[-4.58, 9.73]	0.48	-0.01 [-0.68, 0.67]
MSEL RL SS	-0.55	[-8.98, 7.89]	0.90	0.09 [-0.58, 0.75]	-0.91	[-9.41, 7.59]	0.83	0.04 [-0.63, 0.71]
MSEL VR SS	7.76	[1.79, 13.74]	0.01	0.26 [-0.41, 0.92]	7.07	[1.05, 13.10]	0.02	0.19 [-0.48, 0.86]
CDI words understood	0.21	[-0.37, 0.79]	0.48	-0.77 [-1.46, -0.07]	0.41	[-0.21, 1.03]	0.19	-0.17 [-0.88, 0.54]
CDI words produced	0.88	[-0.09, 1.85]	0.08	0.05 [-0.62, 0.72]	0.55	[-0.44, 1.55]	0.28	-0.12 [-0.83, 0.58]

Note: Estimates (Est.), 95% confidence intervals (CIs), and *p* values for each group × time interaction (IA vs. CE at post and follow-up) are adjusted for child age and baseline nonverbal cognition (MSEL VR SS) to account for baseline group differences. Hedge's *g* values (with 95% CIs) are unadjusted between-group effect sizes, calculated as the difference of means based on the pooled within-group standard deviation and corrected given the small sample size. Abbreviations: CDI, Communicative Developmental Inventory; CJE, coordinated joint engagement; CSBS CQ, Communication and Symbolic Behavior Scales Caregiver Questionnaire; CSBS DP, Communication and Symbolic Behavior Scales Developmental Profile; EL, Expressive Language; *g*, Hedge's *g*, the mean difference within a group, based on the standard deviation of the differences, adjusted with a correction factor; IJA, frequency of spontaneous initiation of joint attention; JERI, joint engagement rating inventory; MSEL, Mullen Scales of Early Learning; RL, Receptive Language; SS, standard score; VR, Visual Reception.

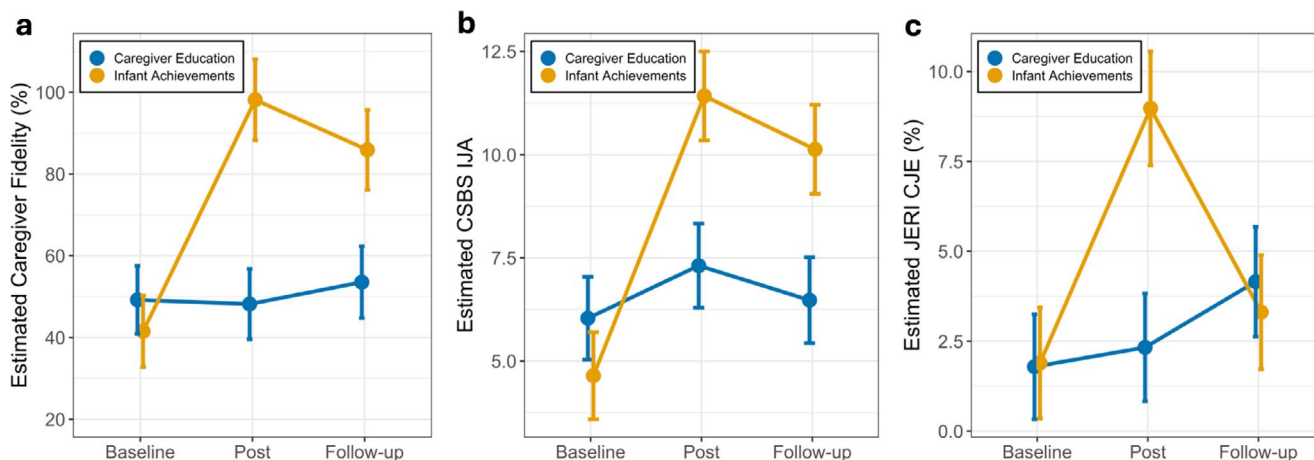


FIGURE 2 | Estimated marginal means for primary outcomes by group. Error bars denote ± one standard error from the mean. Estimated group means were adjusted for baseline age and mullen scales of early learning visual reception to account for baseline group differences.

VR standard score compared to the CE group from baseline to post-intervention ($p = 0.01$) and from baseline to follow-up ($p = 0.02$). Moreover, these VR improvements remained significant even after further adjusting for baseline group

differences in VR, with est. = 7.71, 95% CI [1.75, 13.67], $p = 0.01$ at post-intervention, and est. = 6.99, 95% CI [0.99, 13.00], $p = 0.02$ at follow-up. No significant group-by-time interaction effects were found for the MSEL EL or RL scales (Table 3). For

caregiver-reported CSBS CQ outcomes (Table S12), there were no significant baseline differences between groups on the Social ($p=0.61$) or Symbolic ($p=0.29$) composites; however, the IA group had significantly lower Speech scores than the CE group ($p=0.03$). Compared to the CE group, the IA group exhibited a significantly greater increase in the CSBS CQ Speech composite from baseline to post-intervention ($p=0.01$) and from baseline to follow-up ($p=0.02$) (Table 3). Moreover, these Speech improvements remained significant even after further adjusting for baseline CSBS CQ Speech composite, with $est.=3.54$, 95% CI [1.02, 6.05], $p=0.007$ at post-intervention and $est.=3.20$, 95% CI [0.71, 5.69], $p=0.01$ at follow-up. No other significant interaction effects were observed on the CSBS CQ Symbolic or Social composites (all $ps \geq 0.22$). On the CDI (Table S13), at baseline the IA group had significantly fewer Words Understood than the CE group ($p=0.01$), but no difference in Words Produced ($p=0.23$). Despite the lack of significant interaction effects between groups over time (IA vs. CE \times Post $p=0.08$ for Words Produced and $p=0.48$ for Words Understood; IA vs. CE \times Follow-up $p=0.28$ for Words Produced and $p=0.19$ for Words Understood), there was an overall increase in both CDI scales observed for both groups.

4 | Discussion

This is the first report, to our knowledge, of an RCT implemented in the first year of life with SCD infants. Consistent with hypotheses, caregivers in the IA group showed a significantly greater gain in fidelity from baseline to post-intervention, sustained through follow-up, in a generalization context, compared to the active control CE group. In addition, a significant intervention effect was observed for infants favoring the IA group on examiner-administered/coded measures of IJA and CJE. Finally, significant effects were observed on two secondary variables: clinician-administered nonverbal cognitive (Visual Reception [VR]) measure and caregiver-report measure of speech and word production (CSBS Caregiver Questionnaire [CSBS CQ]). The discrepancy in the results of the CSBS CQ and CDI is likely due to the CSBS inclusion of items focused on pre-linguistic skills foundational for word production. Such early intervention effects have important implications for short- and long-term developmental cohering and advances, and supporting brain adaptation processes (Johnson et al. 2021), thereby possibly optimizing signal processing and attenuating potential suboptimal cascading effects.

Intervention approaches for infants at elevated likelihood (EL) for, or with, social communication disabilities, including autism, must be designed to accelerate learning in the developmental context of lower infant engagement (Wan et al. 2012), atypical (Kaur et al. 2015) and attenuated play with objects (Koterba et al. 2014), and need for more support to engage in object play (Flanagan et al. 2024). Perturbation in infant play behavior impacts the bidirectional, transactional content and process of infant-caregiver interaction (Sameroff and Mackenzie 2003). For example, 6- and 10-month-olds with EL for autism were more passive in interactions with caregivers than same-age infants at low likelihood for autism, and caregivers of EL for autism infants showed higher levels of directive and lower sensitive responding than caregivers of low autism likelihood infants (Wan

et al. 2012). In day-to-day interactions, the reciprocal cascading effects on infant-environment-infant events can constrain learning in the short term. Delays in development, or limited object and person engagement, will have longer-term cascading effects (Johnson 2017), likely affecting other developmental trajectories and organization of infant-caregiver interaction (Campos et al. 2000).

Coaching caregivers to engage in child-contingent interactions supports infant learning (Masek et al. 2021). IA coaches provided reflective practice with constructive and supportive video-enhanced feedback to caregivers, both for sensitive responding and for providing developmentally stimulating input through NDBI strategies twice weekly for eight weeks; positive effects on caregiver fidelity were identified. Yet infant-responsive coaching delivered at low coaching density over an extended period may contribute to limited or no effects on caregiver fidelity (Green et al. 2015; Whitehouse et al. 2019, respectively). Attenuation in IA caregiver fidelity at eight weeks post-intervention (follow-up) aligns with reports by Green et al. (2017) and Whitehouse et al. (2021) at child follow-up ages two and three years. Over time, caregivers may change strategy use to adjust to their child's changing behavioral features and abilities (Bornstein et al. 2008; Landa et al. 2011).

For infants with SCD, the IA intervention yielded statistically significant effects for generalized social communication gains. Several candidate IA intervention ingredients for catalyzing early social communication gains include embedding caregiver coaching in contingent, high redundancy reciprocal person- and object-engagement routines using developmentally proximal, high-affordance objects to entice infant attention and engagement (Deak et al. 2014). This package of ingredients may entrain infant engagement, which is associated with increased gesture and language development (Salo et al. 2018; Tomasello and Farrar 1986). Increased joint engagement generates opportunities for caregivers to join in their infant's play, and to imitate and expand their infant's activities (Tamis-LeMonda et al. 2014) and may have contributed to the significant intervention effect on nonverbal cognition. Further, the IA effect on increased infant CJE offered the reciprocal interactions that, paired with responsive caregiver input during late infancy, may have been associated with gains in speech sound production sustained through the follow-up period (Ferjan Ramírez et al. 2019).

Post-intervention follow-up research in the near- and longer-term sheds light on potential intervention influences on the development of infants with, or at EL for, social communication developmental differences. Our findings show short-term sustained effects on social communication and speech but not on CJE, similar to Green et al.'s (2017) intervention follow-up finding, possibly indicating incomplete skill consolidation. However, infant intervention may have indirect influences on later social communication functioning. For example, Green et al.'s (2017) analyses of cumulative change revealed significant effects for researcher-coded child attentiveness/communication initiation at one and two years post-intervention, and Whitehouse et al. (2021) reported decreased autism-related behaviors and lower odds of developing autism in the intervention group at follow-up. For more robust long-term developmental gains, strategies implemented by caregivers must dynamically

change to align with children's evolving abilities (Bornstein et al. 2008; Landry et al. 2008).

4.1 | Limitations

While promising, our results are preliminary. Two primary limitations include small sample size and brief intervention and follow-up periods. While the sample size was not large, statistical significance and small to large effects were noted in group by time analyses for caregiver fidelity and three primary infant variables (researcher-administered and coded), and one secondary caregiver-reported variable. Replication with a larger sample is necessary. Short intervention and follow-up periods have the benefit of reducing extraneous effects on caregiver or infant change, thereby maximizing causal inference. Future research should assess acceptability, feasibility, and effectiveness in more economically and racially diverse samples to inform generalizability of findings.

5 | Conclusions

IA intervention empowers caregivers to implement child-responsive NDBI strategies with greater fidelity and promotes short-term advancements in pre-linguistic social communication development in infants (8–12 months) with social communication delays. Results highlight the importance of caregiver coaching and beginning child-responsive intervention during infancy when signs of delay appear, not waiting for delayed talking or autism consolidation in the second year of life. Support for communication development is critical to foster both autonomy and positive outcomes and is considered neurodivergent-affirming (Leadbitter et al. 2021). When developmental concerns arise, referrals for assessment and, if indicated, intervention should be made. Beginning intervention during the pre-linguistic phase of development could optimize processing and activate developmental cascades supporting longer-term development (Johnson et al. 2021). A key, and malleable, developmental target is joint engagement (initiating and responding to another person's actions, especially with a shared focus of attention, such as an object). Such ability in infancy is associated with joint attention and language skills near the first and second birthdays (Stallworthy et al. 2023). These abilities have cascading effects on social communication (pragmatics) into mid-childhood (Dillon et al. 2021).

Public health initiatives should focus on early signs of social communication delays (e.g., delays in babbling, triadic gaze, vocal reciprocity), including incipient autism. Also, universal developmental screening of infants is needed. Large-scale trials are needed to replicate results and to elucidate factors propelling early developmental shifts, short- and longer-term cascading effects of infant intervention, and how intervention ingredients should change with increasing child abilities over time.

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Disclosure

This parallel RCT protocol was approved by the Johns Hopkins Institutional Review Board and registered with clinicaltrials.gov (NCT03404505; <http://www.clinicaltrials.gov>).

Consent

Written informed consent was obtained from caregivers before participation.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.