Parent-Implemented Social Intervention for Toddlers With Autism: An RCT

WHAT'S KNOWN ON THIS SUBJECT: Randomized controlled trials (RCTs) of intensive clinician-implemented interventions have demonstrated significant improvements in outcomes of toddlers and preschool children with autism spectrum disorder. RCTs of parent-implemented interventions have demonstrated improvements in parent skills, but generally they have not demonstrated effects on children's outcomes.

WHAT THIS STUDY ADDS: This RCT found significantly greater improvements with individual home coaching on child outcome measures of social communication, adaptive behavior, and developmental level. These findings support the efficacy of a parent-implemented intervention using little professional time, which increases potential community viability.

abstract

OBJECTIVES: To compare the effects of two 9-month parent-implemented interventions within the Early Social Interaction (ESI) Project. Both individual-ESI, offered 2 or 3 times per week at home or in the community, and group-ESI, offered once per week in a clinic, taught parents how to embed strategies to support social communication throughout everyday activities.

METHODS: Participants in the randomized controlled trial included 82 children diagnosed with autism spectrum disorder at 16 to 20 months. Children were matched on pretreatment nonverbal developmental level and pairs were randomly assigned to treatment condition. Child outcomes included measures of social communication, autism symptoms, adaptive behavior, and developmental level. Child outcomes are reported from baseline to the end of the 9-month interventions.

RESULTS: Children in individual-ESI showed differential change on a standardized examiner-administered observational measure of social communication, as they improved at a faster rate than children in group-ESI. Individual-ESI also showed differential efficacy on a parent report measure of communication, daily living, and social skills, as they showed improvement or stability, whereas group-ESI led to worsening or no significant change on these skills. Finally, individual-ESI showed differential change on examiner-administered measures of receptive language skills, as children in individual-ESI improved significantly, whereas group-ESI showed no change.

CONCLUSIONS: These findings support the efficacy of individual-ESI compared with group-ESI on child outcomes, suggesting the importance of individualized parent coaching in natural environments. The efficacy of a parent-implemented intervention using little professional time has potential for community viability, which is particularly important in light of the lack of main effects on child outcomes of most other parent-implemented interventions. *Pediatrics* 2014;134:1084–1093

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KEY WORDS

autism, early intervention, toddlers, parent-implemented, outcomes

ABBREVIATIONS

ADOS—Autism Diagnostic Observation Schedule
ASD—autism spectrum disorder
CSBS—Communication and Symbolic Behavior Scales
EI—early intervention
ESI—Early Social Interaction
FSU—Florida State University
IDEA—Individuals With Disabilities Education Act
MSEL—Mullen Scales of Early Learning
RCT—randomized controlled trial
RRB—Restricted, Repetitive Behavior
SA—Social Affect
SCERTS—Social Communication, Emotional Regulation, and Transactional Supports
UM—University of Michigan
VABS—Vineland Adaptive Behavior Scales

Dr Wetherby conceptualized and designed the study, oversaw implementation at Florida State University, and drafted the manuscript; Ms Guthrie supervised data collection of child measures and conducted statistical analyses; Dr Woods helped conceptualize and implement the intervention model; Dr Schatschneider contributed to the design and oversaw statistical analyses; Ms Holland coordinated training of interventionists across both sites; Dr Morgan supervised data collection of intervention measures; Dr Lord helped conceptualize the study and oversaw implementation at the University of Michigan; and all authors approved the final manuscript as submitted.

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Effective early intervention (EI) for children with autism spectrum disorder (ASD) has the potential to improve outcomes, which can reduce education costs.[1–3] EI is a national priority, as evidenced by the Individuals With Disabilities Education Act (IDEA) Part C[4] and the American Academy of Pediatrics[5] recommendation for universal autism screening at age 18 to 24 months. Although a stable diagnosis is possible at 18 to 24 months,[6–8] most children are not diagnosed with ASD until age 4, or later for lower-income, minority, and rural families,[9–11] meaning the window of opportunity for EI is missed.

The National Research Council[1] recommendation that children receive 25 hours per week of active engagement in systematically planned, developmentally appropriate educational activities is supported by recent systematic reviews.[12,13] The recommended intensity of service and urgency of access[4] reflects that early social attention deficits lead to cascading effects on learning and developmental outcomes.[14–16]

Randomized controlled trials (RCTs) with preschoolers with ASD demonstrated significant improvements on joint engagement[17,18] and outcomes more distal to treatment targets, including IQ,[19,20] and language,[21,22] but only 1 study improved autism symptoms.[23] RCTs with toddlers offer promise. In a clinician-delivered 2-year RCT of the Early Start Denver Model,[20] significant effects were reported on child outcomes of developmental level and adaptive behavior but not on autism symptoms. In another 6-month RCT of an interpersonal synchrony supplement to classroom-based comprehensive intervention,[24,25] short- and long-term effects were reported on social communication, developmental level, and adaptive functioning. Autism symptoms improved during treatment, but improvements were not sustained.

In contrast, large-scale RCTs of parent-implemented interventions have not reported main effects on child outcome measures but have found medium to large effects on increasing parent responsivity, synchronization, or interaction skills.[26–28] The 2 RCTs of young toddlers did not find significant effects on child outcomes, but both had limited sessions (11–12).[26,28] Parent-implemented interventions offering ≥18 sessions were more promising, with significant effects on targeted parent changes.[22,23,27] The 1 treatment offered at home found differential effects on expressive language.[29] Factors that may contribute to lack of effects of parent-implemented interventions on child outcomes include limited number of sessions (11–24), length (3–12 months), and clinic-based interventions, which may not support generalization.

Existing research has implications for treatments of toddlers with ASD. First, longitudinal and cross-sectional studies suggest that parental involvement is key to long-term change.[30,31] Although intensive clinician-implemented treatments often include parents, the focus is on clinician–child curricula rather than parent implementation. Second, few interventions resulted in changes in core autism features unless specifically targeted. Third, current studies highlight potential limitations of existing parent education approaches, underscoring the need for innovative methods leading to stronger treatment effects. Finally, it is vital to improve earlier access to care. Intervention started before 24 months, when symptoms are generally less severe, may reduce the need for more intensive clinician-implemented intervention later. Limitations of existing approaches identify a critical need for evidence-based, community-viable interventions for toddlers with ASD that can be adopted and implemented by public systems.[32–35]

To address these needs, we developed the Early Social Interaction (ESI) Project[36] by incorporating evidence-based active ingredients. Professional time is reduced through parent implementation in natural environments, integrating features consistent with IDEA Part C but also addressing the intensity needed for children with ASD: patient-centered approach, learning in natural environments, collaborative coaching to support parent learning and generalization, developmental framework to prioritize child outcomes, systematic instruction using evidence-based strategies, and intensity needed for children with ASD, achieved by embedding strategies in everyday activities intended for parent implementation ≥25 hours per week. The aim of this RCT was to compare the effects of 2 different ESI conditions, which vary in how (individual or group), how often, and where (home or clinic) parents of toddlers with ASD are taught, on child outcome measures of social communication, autism symptoms, adaptive behavior, and developmental level.

METHODS

Study Procedures

Families of 82 toddlers with ASD were randomly assigned to one of two 9-month parent-implemented intervention conditions: individual or group. Child outcomes were measured at baseline and the end of the 9-month intervention.

Participants

One hundred thirty-five children were assessed for eligibility from 2 sites: Florida State University (FSU) and University of Michigan (UM). FSU recruited children from primary care screening by using the Communication and Symbolic Behavior Scales (CSBS).[8,16,37] UM children were referred because of parental or professional concern. Fifty-three were excluded: 20 did not meet inclusion criteria, 28 enrolled in other intervention research studies, and 5 refused to participate. Eighty-two children enrolled in this study. This study was approved by FSU and UM institutional review boards,

and all families gave written informed consent for participation.

Children included in this study received an ASD diagnosis between ages 16 and 20 months and lived within 50 miles of either research site. Experienced diagnosticians administered the Autism Diagnostic Observation Schedule (ADOS),[38–40] home observation, parent report measures, standardized measures, and developmental history. Clinical judgment was used to make a best estimate diagnosis, the gold standard[41,42] shown to predict later diagnosis.[6] See Table 1 for baseline characteristics.

TABLE 1 Participant Demographics and Baseline Characteristics

	Individual-ESI ($N = 42$)	Group-ESI ($N = 40$)	p	Hedges's g
Demographics				
Age	19.64 (1.93)	19.58 (1.42)	.86	0.04
Ethnicity			.58	—
White, %	73.8	72.5	—	—
Black, %	7.1	10.0	—	—
Other, %	14.3	15.0	—	—
Gender, % male	81.0	92.5	.13	—
Maternal age	31.98 (5.74)	31.71 (5.44)	.83	0.05
Maternal education	15.64 (2.07)	15.51 (2.26)	.80	0.06
Communication and Symbolic Behavior Scales				
Social Composite	37.02 (17.25)	39.49 (21.11)	.57	0.13
Speech Composite	8.61 (2.32)	6.50 (10.03)	.42	0.18
Symbolic Composite	24.00 (16.60)	21.54 (15.15)	.49	0.15
Autism Diagnostic Observation Schedule				
Social Affect	13.50 (4.28)	14.43 (3.86)	.47	0.17
Restricted, Repetitive Behavior	3.05 (1.50)	2.85 (1.55)	.66	0.10
Vineland Adaptive Behavior Scales				
Communication	78.83 (13.06)	79.79 (13.51)	.98	0.01
Daily Living	86.60 (10.98)	87.42 (11.97)	.97	0.01
Socialization	84.55 (8.77)	87.21 (9.62)	.52	0.15
Motor	94.55 (8.85)	95.34 (11.66)	.72	0.08
Adaptive Behavior Composite	83.98 (8.93)	85.03 (11.37)	.65	0.07
Mullen Scales of Early Learning				
Visual Reception	42.07 (13.01)	40.42 (10.44)	.45	0.17
Fine Motor	46.20 (11.59)	42.48 (12.65)	.15	0.33
Receptive Language	29.27 (12.34)	31.35 (12.61)	.39	0.19
Expressive Language	29.61 (11.22)	28.68 (10.95)	.66	0.10
Early Learning Composite	75.56 (16.68)	74.05 (16.86)	.69	0.17

P and Hedges's *g* values refer to comparison of individual-ESI and group-ESI conditions. —, not applicable.

Intervention Procedures

Children were randomly assigned to individual-ESI or group-ESI that varied in how and where parents were taught. In both conditions, training focused on teaching parents the importance of intensive intervention and how to support active engagement in natural environments. The manualized Social Communication, Emotional Regulation, and Transactional Supports (SCERTS) curriculum was used for both conditions.[43,44] Parents were encouraged to embed evidence-based strategies for child targets in everyday activities for ≥25 hours per week. See Supplemental Information about the ESI model and SCERTS curriculum.

Individual-ESI Condition

Interventionists met individually with parents for 3 sessions per week (2 home, 1 clinic) for 6 months and 2 sessions per week (1 home, 1 community, eg, playground, grocery store, restaurant) for 3 months for maintenance and generalization. Intervention sessions included reviewing and updates, practicing supports and strategies in 3 to 5 different activities, problem solving, and planning. A 4-step collaborative coaching model was used: (1) identify what works, with direct teaching if needed, (2) guided practice with parent in an active role and provide feedback, (3) caregiver-led practice and reflection with feedback, and (4) interventionist back-out for caregiver independence. Interventionists were trained to ≥80% fidelity on 20 items. Fidelity was monitored for 20% of sessions, with an average of 81% fidelity (95% confidence interval, 80% to 82%).

Group-ESI Condition

Interventionists met with groups of 4 or 5 families of children with ASD, communication delays, or typical development in a clinic for 1 session per week. The SCERTS curriculum was organized into 9 monthly topics. An educational meeting was held the first week of the month, where content was discussed without children. The remaining sessions were playgroups that provided opportunities to talk with interventionists and other parents, with practice using strategies. Interventionists were trained to ≥80% fidelity on 10 items. Fidelity was monitored for 20% of sessions with an average of 88% (95% confidence interval, 86%–90%).

Child Measures

Diagnosticians for all measures were blind to intervention condition. Child outcome measures of social communication, autism symptoms, adaptive behavior, and developmental level were collected at baseline and after 9 months of intervention.

Social Communication Skills

The CSBS Behavior Sample is a standardized, norm-referenced examiner-administered assessment using systematic naturalistic sampling procedures to encourage spontaneous social communication.[37,45,46] Twenty items are summed to form Social, Speech, and Symbolic composites.

Autism Symptoms

The ADOS,[38–40] the gold standard examiner-administered diagnostic measure of ASD,

yields Social Affect (SA) and Restricted, Repetitive Behavior (RRB) domain totals by using the ADOS revised algorithms[47] to measure autism symptom severity.

Adaptive Behavior

The Vineland Adaptive Behavior Scales, Second Edition (VABS-II[48]) parent report interview yields standard scores for Communication, Daily Living, Socialization, and Motor.

Developmental Level

The Mullen Scales of Early Learning (MSEL),[49] administered by an examiner, measures developmental level with *T* scores for Visual Reception, Fine Motor, Receptive Language, and Expressive Language.

Intervention Hours

ESI Intervention Hours

Number of sessions per week attended was recorded for 9 months, with a total possible average of 3.33 hours/week of individual or 1 hour/week of group. Parents in individual-ESI attended 80% of scheduled sessions, averaging 2.46 (SD = 0.93) hours/week. Parents in group-ESI attended 82% of scheduled sessions, averaging 0.80 (SD = 0.42) hours/week.

Other Intervention Hours

Parents reported hours of psychosocial and educational intervention in addition to ESI at baseline and updated monthly. The weekly average calculated for individual-ESI was 1.26 (SD = 1.09) hours/week of other intervention, and group-ESI was 1.37 (SD = 1.31). No differences were observed between conditions ($P = .66$) or sites ($P = .11$).

Family Evaluation Survey

After the 9-month intervention, parents completed a 20-item survey designed for this study to measure parent perception of family-centered practice (12 items), intervention satisfaction (4 items), and sense of self-efficacy supporting their child's development (4 items) by using a 4-point rating scale. Reliability was acceptable for each subscale (family-centered, $\alpha = 92$; satisfaction, $\alpha = 0.85$; self-efficacy, $\alpha = 0.79$). Parents in both conditions rated family-centered practice (M = 3.56, SD = 0.55), satisfaction (M = 3.60, SD = 0.50), and self-efficacy (M = 3.45, SD = 0.73) high. Differences were not observed between conditions.

Randomization

Children were randomly assigned by a computer-generated list to either individual-ESI or group-ESI according to a matched random assignment process, which is preferred to stratifying.[50] Children were matched on baseline nonverbal developmental level. The first member of each matched pair was randomly assigned to individual or group, and then the other member received the other condition. A trickle process was used as children were enrolled over time, with the matched pair filled when the second member matching that developmental level was determined eligible to allow immediate enrollment.[50,51]

Data Analysis

Repeated-measures analyses of variance with fixed between- and within-subjects factors were used to determine main effects of time (repeated measures) and interactions between time and treatment condition. Models were run through SPSS MIXED (IBM SPSS Statistics, IBM Corporation) to use maximum likelihood estimation in handling of missing data. Contrasts were performed on outcome measures with significant interaction effects. Consistent with an intent-to-treat approach, all participants were included in analyses regardless of dropout status, with maximum likelihood used to handle missing data from attrition. When available, follow-up data from children who dropped from treatment were include in analyses.

RESULTS

Preliminary Analyses

Outcome variables were examined for nonnormality, with particular attention paid to MSEL and VABS standard scores, which may show floor effects in children with developmental delays. Indices of skewness and kurtosis indicated normality for the majority of outcome variables (ie, skew and kurtosis values $<|2|$). Nonnormality was observed for some language measures (ie, MSEL Receptive and Expressive Language and CSBS Speech Composite), so these variables were log transformed. Homogeneity of variance was violated for some outcome variables. However, the models used are robust to these violations, particularly when groups are nearly equal in size.[52] Standard scores were used when available, rather than raw scores or age equivalents, given the superior psychometric properties of standard scores and the ordinal nature of age equivalent scores.[53] When both age equivalents and standardized scores were available (ie, MSEL and VABS), findings were identical in models run with each type of score.

The randomized matching procedure created baseline equivalency between conditions, as *P* values for all group comparisons on baseline measures were $>.10$ (range, .15–.98; see Table 1). Condition groups did not differ on demographic variables or hours of other intervention. Differences by site were not observed on demographic variables, CSBS, ADOS, or VABS ($P > .10$, range, .10–.95). However, as expected given differences in recruitment strategies, FSU children had significantly higher scores on MSEL Visual Reception ($P = .05$) and Fine Motor ($P = .01$), but not Receptive or Expressive Language. Site × time × condition effects were calculated and reported to examine

potential differential efficacy of treatment by site.

Attrition, defined as failure to return for follow-up assessment (regardless of treatment completion), was 16% (13/82) overall, 19% (8/42) in individual-ESI, and 13% (5/40) in group-ESI. Attrition was comparable between conditions ($P = .42$) and sites ($P = .91$). Data from 2 children in individual-ESI and 1 child in group-ESI who dropped treatment during the study were included in analyses. Thus, 33 of the 42 children who were enrolled in individual-ESI and 34 of the 40 who were enrolled in group-ESI completed intervention. Figure 1 shows the participant flowchart. Table 2 reports statistics for child outcomes after the first intervention condition and results of the linear mixed model analyses. Figure 2 illustrates significant effects from baseline to the end of intervention.

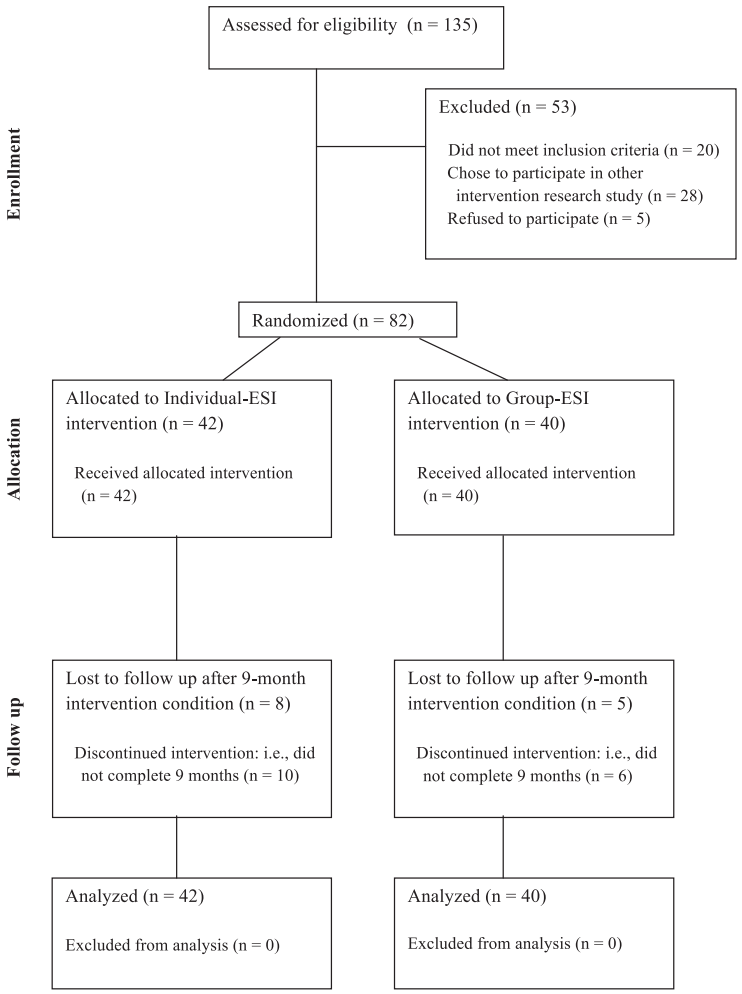

FIGURE 1
Participant Flowchart.

Social Communication Skills: CSBS

Analyses revealed a significant time × condition interaction effect for the Social Composite with a small effect size. Contrasts indicated that both conditions showed significant improvement, but children in individual-ESI showed significantly greater improvement. Significant main effects of time without significant interaction effects were found for Speech and Symbolic Composites, indicating that both conditions showed similar rates of improvement. However, the current study cannot determine whether improvements in speech and symbolic skills resulted from treatment effects or maturation.

Autism Symptoms: ADOS

Analyses revealed significant main effects of time without significant interaction effects for SA and RRB domain scores. Children in both conditions showed improvement in SA and worsening on RRB.

Adaptive Behavior: VABS

A significant interaction effect was found on Communication with a medium effect size. Contrasts revealed that children in individual-ESI demonstrated significant improvement, whereas group-ESI showed no change. A significant interaction effect was also found on Daily Living with a medium effect size. Contrasts revealed significant improvement in individual-ESI and no change in group-ESI. A significant interaction effect was also found on Socialization with a medium effect size. Contrasts revealed stability in individual-ESI and a significant decrease in group-ESI. Finally, a significant main effect of time without a significant interaction effect was observed for Motor Skills, as both groups showed decreases in standard scores after intervention compared with baseline. Analyses using raw scores revealed significant increases, indicating that decreases in standard scores were not caused by loss of skills during intervention but by failure to progress, comparable to VABS norms.

Developmental Skills: MSEL

Nonverbal Skills

Analyses revealed no significant main effect of time or interaction effect for Visual Reception, as children in both groups did not gain *T* scores but did maintain their scores and keep up with normative progress (9-month gain in 9 months) compared with MSEL norms. A significant main time effect without

TABLE 2 Child Outcome Measures and Linear Mixed Model Results

	Child Outcome Measures								Linear Mixed Model Results					
	Individual-ESI				Group-ESI				Time (Across Condition)			Time × Condition		
	M	SE	Δ	95% CI	M	SE	Δ	95% CI	*p*	Hedges's *g*	CLES	*p*	Hedges's *g*	CLES
Communication and Symbolic Behavior Scales														
Social Composite	59.4	3.8	22.3	15.5 to 29.1	51.9	3.9	12.4	5.5 to 19.3	<.001	0.76	0.70	.04	0.48	0.63
Speech Composite[a]	1.4	0.1	0.7	0.5 to 0.9	1.3	0.1	0.8	0.6 to 1.0	<.001	1.27	0.82	.81	0.05	0.51
Speech Composite[b]	42.1	3.8	33.7	24.9 to 42.6	34.0	4.1	27.5	18.4 to 36.6	—	—	—	—	—	—
Symbolic Composite	52.6	3.6	28.9	21.5 to 36.3	48.6	3.8	27.0	19.4 to 34.6	<.001	1.28	0.82	.72	0.13	0.54
Autism Diagnostic Observation Schedule														
Social Affect	10.9	0.7	−2.6	−3.8 to −1.4	12.3	0.7	−2.1	−3.4 to −0.9	<.001	−0.51	0.36	.61	0.15	0.54
Restricted, Repetitive Behavior	3.4	0.3	0.4	−0.2 to 1.0	3.6	0.3	0.7	0.1 to 1.4	.01	0.38	0.61	.43	0.17	0.55
Vineland Adaptive Behavior Scales														
Communication	90.2	2.2	11.8	7.7 to 15.9	82.9	2.3	3.1	−1.0 to 7.3	<.001	0.50	0.64	.004	0.69	0.69
Daily Living	91.0	1.7	4.2	0.2 to 8.1	85.0	1.8	−2.5	−6.5 to 1.5	.56	0.07	0.52	.02	0.58	0.66
Socialization	84.1	1.5	−0.9	−4.1 to 2.5	81.2	1.5	−5.6	−9.0 to −2.3	.008	−0.31	0.41	.04	0.66	0.68
Motor	88.8	1.6	−5.5	−8.8 to −2.2	87.6	1.6	−8.4	−11.8 to −5.0	<.001	−0.69	0.31	.22	0.34	0.59
Adaptive Behavior Composite	86.2	1.6	2.2	−1.0 to 5.5	81.7	1.6	−3.3	−6.7 to 0.0	.65	−0.14	0.46	.02	0.72	0.69
Mullen Scales of Early Learning														
Visual Reception	42.1	2.2	−0.1	−4.2 to 4.0	39.2	2.2	−1.2	−5.4 to 2.9	.65	−0.04	0.49	.70	0.03	0.51
Fine Motor	37.2	2.0	−9.0	−13.1 to −5.0	37.7	2.1	−4.7	−8.8 to −0.7	<.001	−0.57	0.34	.14	0.41	0.61
Receptive Language[a]	1.6	0.0	0.1	0.1 to 0.2	1.5	0.0	0.0	0.0 to 0.1	<.001	0.41	0.61	.008	0.58	0.66
Receptive Language[b]	39.5	2.2	10.1	6.2 to 14.1	34.1	2.3	2.8	−1.2 to 6.8	—	—	—	—	—	—
Expressive Language[a]	1.6	0.0	0.1	0.1 to 0.2	1.5	0.0	0.1	0.0 to 0.1	<.001	0.54	0.65	.61	0.18	0.55
Expressive Language[b]	39.0	2.2	9.0	4.7 to 13.3	36.2	2.2	7.5	3.3 to 11.8	—	—	—	—	—	—
Early Learning Composite	81.7	3.3	5.9	0.2 to 11.6	76.2	3.4	2.1	−3.7 to −7.9	.06	0.20	0.56	.36	0.13	0.54

F values for linear mixed model results can be found in the Supplemental Table 3. Estimated marginal means are presented. CI, confidence interval; CLES, Common Language Effect Size; Δ, mean change from baseline to end of intervention; CLES, which is derived from the *g* effect, represents the likelihood that a randomly selected child from individual-ESI will show greater improvement than a randomly selected child from group-ESI. —, not applicable.

[a] Estimated marginal means, SEs, and linear mixed model results using log transformed variables.

[b] Estimated marginal means and SEs presented using nontransformed variables.

a significant interaction effect was also found for Fine Motor. However, children in both groups demonstrated lower *T* scores after intervention compared with baseline. Analyses using age equivalents revealed that children showed an increase in age equivalents during intervention. Thus, the observed decrease in Fine Motor *T* scores was caused by failure to make normative progress rather than loss of skills during intervention.

Verbal Skills

A significant interaction effect was found for Receptive Language with a medium effect size. Contrasts revealed that children in individual-ESI demonstrated significant improvement, whereas group-ESI showed no change during intervention. A significant main effect of time without a significant interaction effect was found for Expressive Language, as children in both conditions demonstrated improvement.

Site and Other Intervention Effects

Given differences between sites on baseline MSEL Visual Reception and Fine Motor, site was examined as a potential threat to validity of treatment effects. However, site was not found to interact with any significant time × condition effects, indicating that the differential effect of individual-ESI did not differ by site for any measures. Children's participation in other interventions outside ESI was also examined in relation to significant findings and not found to interact with any significant time × condition effects, indicating that other intervention hours did not explain differential efficacy of individual-ESI.

DISCUSSION

This study is the first large RCT to compare two 9-month parent-implemented interventions for toddlers with ASD resulting in significant effects on child outcomes. Group-ESI is similar to other group parent interventions held once per

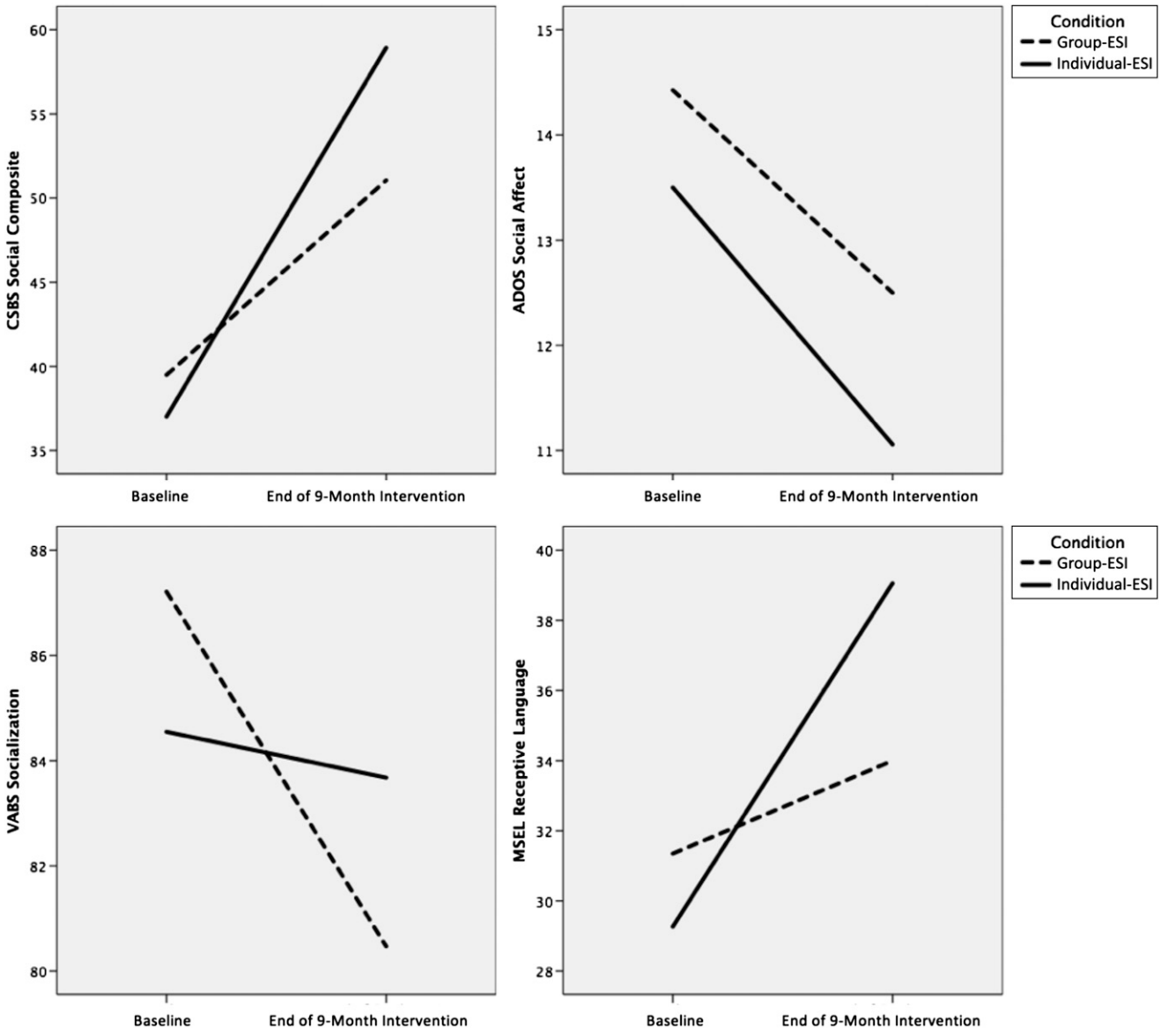

FIGURE 2
Mean Scores for Individual-ESI and Group-ESI from Baseline to End of 9-Month Intervention Condition.

week in a clinic[26–28] and contrasts with individual-ESI, which was offered in individual sessions 2 or 3 times per week, with 2 at home. Taken together, these findings support the differential efficacy of individual-ESI on some child outcomes compared with group-ESI. Individual-ESI led to significantly greater improvement on social components of communication and receptive language compared with group-ESI. Individual-ESI also resulted in stability or slight improvements on Daily Living and Socialization, in contrast to the worsening seen in the group-ESI condition. These findings are particularly important given limited main effects of other parent education and parent-implemented interventions on child outcomes for toddlers with ASD. Comparing 2 ESI conditions is a conservative approach to test efficacy, and yet individual-ESI was superior on 6 child outcomes. The young age of these toddlers at baseline may contribute to these novel treatment effects.

Strengths of this study are the use of random assignment with a large 2-site sample using gold standard measures of child outcomes, blind diagnosticians, and standardized observational measures, which are less susceptible to expectation of change than parent report. Comparison of 2 active teaching conditions provides information on differential effects; however, this study cannot rule out alternative explanations such as maturation for improvements found in both conditions. Child improvements in core social deficits and expressive language were observed for parent groups held once a week for 9 months, findings that are in contrast to other briefer

interventions that may not have been sufficiently intensive to affect these child outcomes. Teaching parents in individual-ESI at home for an additional 2 sessions per week led to significant effects on early social skills and receptive language and lessened the worsening of adaptive behaviors. Improvements in core social deficits have been demonstrated in only a few other treatment studies.[23,24] Although both groups worsened on motor standard scores, it is important to note that motor skills were high at baseline, with the average score within normal limits.

It is possible that the significant effects observed on adaptive behavior, which is a parent report measure, are confounded by parent expectations in that parents participating in individual-ESI were more likely to rate their child's adaptive behavior highly than parents in group-ESI. However, this limitation is tempered by the significant findings on related constructs assessed by blinded examiner-administered measures (eg, significant effect on VABS Socialization and CSBS Social Composite; VABS Communication and MSEL Receptive Language).

A limitation of this study is that follow-up measures are not available after the 9-month intervention to examine maintenance of effects. Another limitation is that children in both conditions received an active treatment; therefore, maturation cannot be easily separated from intervention effects. However, comparing these outcomes with studies that report longitudinal trajectories for toddlers with ASD and other treatment studies suggests that the expected developmental trajectory is a worsening of standard scores, as seen on motor composites for both MSEL and VABS.[30,54–58] Our findings contribute by demonstrating the efficacy of a 9-month low-intensity treatment, which led to increases in social and language skills and some reduction of the expected worsening in developmental trajectory, which may prevent the secondary impact of autism symptoms on intellectual ability.

Important future research directions include performing mediation analysis of the effect of parent change in transactional supports on child outcomes, along with examining characteristics of children who show substantial response to treatment, now that we have demonstrated effects on child outcomes. Additional research is needed to replicate these findings, to examine the effect of the ESI model with younger children and with different combinations or dosage of the 2 conditions, and to document the time needed by Part C service providers to learn the ESI model and effectiveness of community implementation.

CONCLUSIONS

Current health care and education systems are challenged to provide intervention of adequate intensity that is shown to be effective for toddlers with ASD. Services delivered by professionals within IDEA Part C average 2 to 3 hours/week.[59] ESI incorporates evidence-based active ingredients implemented by parents in natural environments while maintaining professional time comparable to that of current Part C systems, increasing the potential for community viability. The efficacy of individual-ESI compared with group-ESI on many child outcomes is particularly important in light of the lack of main effects on child outcomes of most other parent-implemented interventions with toddlers with ASD. Although there may be a narrow window of time for effectiveness of this approach, the potential to identify children with ASD by 18 to 24 months is within our reach.[6,8,60] Availability of community-viable treatments for toddlers with ASD makes the recommendations of the Council on Children with Disabilities[3] for collaboration of primary care and Part C systems possible and offers promise for addressing existing health disparities in access to EI.

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Parent-Implemented Social Intervention for Toddlers With Autism: An RCT

Amy M. Wetherby, Whitney Guthrie, Juliann Woods, Christopher Schatschneider, Renee D. Holland, Lindee Morgan and Catherine Lord

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Supplemental Information on the Early Social Interaction Project

The Early Social Interaction (ESI) Project is a comprehensive early intervention approach developed for toddlers with autism spectrum disorder (ASD) and their families incorporating evidence-based active ingredients consistent with requirements of the Individuals With Disabilities Education Act (IDEA) Part C early intervention program. This supplemental information provides details on the ESI model and the Social Communication, Emotional Regulation, and Transactional Supports (SCERTS) curriculum-based assessment and intervention model. Video illustrations of ESI, SCERTS, and many other commonly used interventions for children with ASD can be found in the Treatment section of the ASD Video Glossary available online.

The ESI model incorporates the following features:

Family-centered approach. A family-centered approach addresses the family's needs, concerns, and priorities throughout the assessment and intervention process. Respecting family members' perceptions, priorities, and preferences, developing active participatory and relational partnerships, and building capacity and unity are key components of an effective family-centered program. Families are more involved in the achievement of goals when they have been stakeholders in their development.

Learning in natural environments. Natural environments are defined in IDEA Part C as the everyday activities, routines, and settings typical for any family, including their home, child care, and community locations such as the park or grocery store. Everyday activities such as mealtime, play, caregiving, and family chores provide authentic opportunities to embed teaching of objectives that are functional to the activity and therefore naturally support acquisition and generalization of the skills. Individual coaching of families to embed evidence-based intervention strategies throughout the day requires interventionist and parent consideration of the sequence, ease of strategy use, and frequency of opportunity within various activities. Group parent education meetings and playgroups including families of young typical children also offer a natural environment for family members of children with ASD to get information and support.

Collaborative coaching to support parent learning and generalization. Individual intervention sessions are organized to build parent capacity to engage in their children's learning and include updating session plan, practicing supports and strategies in 3 to 5 different activities, problem solving, and planning for ongoing intervention between sessions. A 4-step collaborative coaching model based on adult learning research is used: (1) identify what works, with direct teaching if needed; (2) guided practice with parent in an active role, provide feedback; (3) caregiver-led practice and reflection with feedback; and (4) interventionist backout for caregiver independence. The interventionist coaches the caregiver in each new activity at the first level and moves to level 4 as quickly as possible to promote caregiver competence, confidence, and independence. Coaching in a variety of everyday activities promotes generalization of caregiver learning so the caregiver can support the child's learning throughout the day as planned or as opportunities arise.

Developmental framework to prioritize child outcomes. ESI uses SCERTS, a manualized curriculum-based assessment and intervention framework, to identify goals and objectives and monitor progress (Prizant, Wetherby, Rubin, Laurent, & Rydell, 2006). The acronym *SCERTS* refers to Social Communication (SC), Emotional Regulation (ER), and Transactional Support (TS), which are the primary developmental dimensions targeted to support the development of children with ASD and their families. The SCERTS curriculum-based assessment includes parent report and observation forms administered in the child's home with the family to identify high-priority goals and objectives. Assessments are updated quarterly. The SC and ER domains delineate specific, measurable goals and objectives for the child and are organized by communication stage, beginning with children who are in the Social Partner Stage, before the development of any words. The TS domains delineate specific, measurable goals and objectives for the parent or other communicative partners

and include teaching strategies and learning supports that are selected to help the child meet his or her individualized goals and objectives. Social communication targets for toddlers with ASD include expanding the use of gestures, sounds, and words, initiating spontaneous verbal and nonverbal communication, understanding the meaning of words, initiating and responding to joint attention, increasing functional object use and pretend play, and extending reciprocity in interaction. Emotional regulation targets for toddlers with ASD include being available for learning and expressing emotion, expanding self-regulatory strategies to calm self when dysregulated, using communication to help regulate emotion when frustrated or help is needed, and using regulatory strategies to stay engaged in activities and handle new and changing situations. SC and ER targets are integrated to prevent the development of problem behavior, consistent with positive behavior support.

Systematic instruction using evidence-based strategies. Children with ASD can learn from everyday activities and experiences when learning opportunities are structured and systematic techniques are used to foster active engagement. ESI incorporates systematic instruction using evidence-based behavioral strategies that are developmentally sensible for toddlers. Ongoing monitoring with corresponding adjustments in programming is based on observational data collected within activities. Parents learn to use intervention strategies matched to the priority objectives within daily activities to increase opportunities for teaching and learning whenever the activity occurs.

Intensity needed for children with ASD. The intensity needed for children with ASD is achieved through the integration of the core features of ESI. Parents partner with professionals to plan an individualized, developmentally sensible intervention program using SCERTS to address the impact of the child's autism symptoms on learning. Professionals coach parents on how to competently and systematically use intervention strategies throughout the day in typical activities where the skills are meaningful for the child. This process of embedding strategies in everyday activities is designed to support parent implementation of 25 hours/week of active child engagement. Although the intensity of intervention necessary to provide optimal outcomes is not yet determined for infants and toddlers at risk for ASD, research suggests that more time spent in active, positive engagement results in better outcomes for preschoolers. A minimum of 25 hours per week of active engagement in intervention has been recommended as soon as children are suspected of having ASD. This approach provides a way to maximize intensity of intervention and reduce professional time.

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SUPPLEMENTAL TABLE 3 Child Outcome Measures and Linear Mixed Model Results With *F* Values

	Child Outcome Measures								Linear Mixed Model Results							
	Individual-ESI				Group-ESI				Time (Across Condition)				Time × Condition			
	M	SE	Δ	95% CI	M	SE	Δ	95% CI	*F*	*p*	Hedges's *g*	CLES	*F*	*p*	Hedges's *g*	CLES
Communication and Symbolic Behavior Scales																
Social Composite	59.4	3.8	22.3	15.5 to 29.1	51.9	3.9	12.4	5.5 to 19.3	50.61	<.001	0.76	0.70	4.14	.04	0.48	0.63
Speech Composite[a]	1.4	0.1	0.7	0.5 to 0.9	1.3	0.1	0.8	0.6 to 1.0	98.06	<.001	1.27	0.82	0.06	.81	0.05	0.51
Speech Composite[b]	42.1	3.8	33.7	24.9 to 42.6	34.0	4.1	27.5	18.4 to 36.6	—	—	—	—	—	—	—	—
Symbolic Composite	52.6	3.6	28.9	21.5 to 36.3	48.6	3.8	27.0	19.4 to 34.6	75.02	<.001	1.28	0.82	0.13	.72	0.13	0.54
Autism Diagnostic Observation Schedule																
Social Affect	10.9	0.7	−2.6	−3.8 to −1.4	12.3	0.7	−2.1	−3.4 to −0.9	30.38	<.001	−0.51	0.36	0.27	.61	0.15	0.54
RRB	3.4	0.3	0.4	−0.2 to 1.0	3.6	0.3	0.7	0.1 to 1.4	6.87	.01	0.38	0.61	0.63	.43	0.17	0.55
Vineland Adaptive Behavior Scales																
Communication	90.2	2.2	11.8	7.7 to 15.9	82.9	2.3	3.1	−1.0 to 7.3	26.01	<.001	0.50	0.64	8.76	.004	0.69	0.69
Daily Living	91.0	1.7	4.2	0.2 to 8.1	85.0	1.8	−2.5	−6.5 to 1.5	0.34	.56	0.07	0.52	5.62	.02	0.58	0.66
Socialization	84.1	1.5	−0.9	−4.1 to 2.5	81.2	1.5	−5.6	−9.0 to −2.3	7.31	.008	−0.31	0.41	4.18	.04	0.66	0.68
Motor	88.8	1.6	−5.5	−8.8 to −2.2	87.6	1.6	−8.4	−11.8 to −5.0	34.21	<.001	−0.69	0.31	1.51	.22	0.34	0.59
Adaptive Behavior Composite	86.2	1.6	2.2	−1.0 to 5.5	81.7	1.6	−3.3	−6.7 to 0.0	0.21	.65	−0.14	0.46	5.66	.02	0.72	0.69
Mullen Scales of Early Learning																
Visual Reception	42.1	2.2	−0.1	−4.2 to 4.0	39.2	2.2	−1.2	−5.4 to 2.9	0.21	.65	−0.04	0.49	0.15	.70	0.03	0.51
Fine Motor	37.2	2.0	−9.0	−13.1 to −5.0	37.7	2.1	−4.7	−8.8 to −0.7	22.60	<.001	−0.57	0.34	2.18	.14	0.41	0.61
Receptive Language[a]	1.6	0.0	0.1	0.1 to 0.2	1.5	0.0	0.0	0.0 to 0.1	16.10	<.001	0.41	0.61	7.46	.008	0.58	0.66
Receptive Language[b]	39.5	2.2	10.1	6.2 to 14.1	34.1	2.3	2.8	−1.2 to 6.8	—	—	—	—	—	—	—	—
Expressive Language[a]	1.6	0.0	0.1	0.1 to 0.2	1.5	0.0	0.1	0.0 to 0.1	26.52	<.001	0.54	0.65	0.27	.61	0.18	0.55
Expressive Language[b]	39.0	2.2	9.0	4.7 to 13.3	36.2	2.2	7.5	3.3 to 11.8	—	—	—	—	—	—	—	—
Early Learning Composite	81.7	3.3	5.9	0.2 to 11.6	76.2	3.4	2.1	−3.7 to −7.9	3.80	.06	0.20	0.56	0.85	.36	0.13	0.54

Estimated marginal means are presented. CI, confidence interval; CLES, Common Language Effect Size; Δ, mean change from baseline to end of intervention. CLES, which is derived from the *g* effect, represents the likelihood that a randomly selected child from the individual-ESI group will show greater improvement than a randomly selected child from the group-ESI group.

[a] Estimated marginal means, SEs, and linear mixed model results using log transformed variables.

[b] Estimated marginal means and SEs presented using nontransformed variables.