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Outcomes of children receiving Group-Early Start Denver Model in an inclusive versus autism-specific setting: A pilot randomized controlled trial

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Abstract

A major topic of debate is whether children with autism spectrum disorder should be educated in inclusive or specialized settings. We examined the feasibility and preliminary effectiveness of delivering the Group-Early Start Denver Model to children with autism spectrum disorder in inclusive versus specialized classrooms. We randomly assigned 44 preschoolers with autism spectrum disorder to receive the Group-Early Start Denver Model across one school calendar year in classrooms that included only children with autism spectrum disorder or mostly children who were typically developing. Blind-rated indicators of teaching quality showed similar results across settings, which were above the local benchmark. Children showed improvements across blinded proximal measures of spontaneous vocalization, social interaction, and imitation and across distal measures of verbal cognition, adaptive behavior, and autism symptoms irrespective of intervention setting. Mothers of participants experienced a reduction in stress irrespective of child intervention setting. Across both settings, age at intervention start was negatively associated with gains in verbal cognition. Delivery of Group-Early Start Denver Model in an inclusive setting appeared to be feasible, with no significant differences in teaching quality and child improvements when the program was implemented in inclusive versus specialized classrooms.

Keywords

autism, community participatory research, early intervention, Early Start Denver Model, pilot randomized controlled trial, social inclusion

The question of whether children with disabilities, such as autism spectrum disorder (ASD), should be educated in inclusive or special settings has been the subject of long-standing debate (Bottema-Beutel et al., 2017; Odom and McEvoy, 1990; Pellicano et al., 2018; Schopler and Bristol, 1980; Wing, 2007). As a growing number of toddlers are diagnosed with ASD (Mazurek et al., 2014), this issue is becoming increasingly relevant to the implementation of early intervention (EI) programs (Data Accountability Center, 2007). Relevant dimensions of the debate include human rights considerations related to the inclusion versus segregation of individuals with disability, as well as the impact of inclusive versus special settings on the feasible and effective delivery of ASD EI programs.

The United Nations (2006) Convention on the Rights of Persons with Disabilities has articulated a human right for access to EI for young children with disabilities, stipulating that this should be provided in the least restrictive environment suitable to meet children's needs and include consistent opportunities for interaction with typically developing peers. Critical goals of inclusion include (1) the provision of opportunities for children with disability to learn from and participate in regular educational settings, (2) the prevention of discrimination and/or negative social perception for children with disability (which may be associated with specialized settings and absence of exposure in everyday

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settings), and (3) the opportunity for individuals without disability to learn about differences among people and become more accepting of diversity from an early age (Bricker, 1995; Martins et al., 2014).

Unlike specialized educational settings, inclusive classrooms offer children with ASD the opportunity to put to practice their developing skills during ongoing interactions with typically developing peers who—compared to peers with ASD—are more likely to be responsive to social initiations and provide rich and appropriate social-communicative input. In principle, interaction with competent "role model" peers could result in benefits across critical domains such as language, imitation, and joint engagement (Garfinkle and Schwartz, 2002; Harrower and Dunlap, 2001; Little, 2017).

Conversely, arguments in support of specialized settings include (1) the notion that the unique characteristics of children with ASD are better accommodated within "autism-friendly" learning environments and teaching approaches designed to address their particular educational needs and learning style; (2) the possibility that individuals with ASD might encounter peer rejection within inclusive settings, thereby exacerbating their social difficulties; and (3) the idea that inclusive settings are not designed to address the individualized needs of pupils with ASD, given the heterogeneity of strengths and needs within this population (Lowenthal, 1999; Majoko, 2016; Mesibov and Shea, 1996; Reed, 2015). Another frequently voiced concern is that the demands associated with the educational needs of children with ASD might lead teachers in inclusive settings to focus less on their typically developing students within the classroom (Hornby, 2014; Rafferty et al., 2001).

Only a few controlled studies—none of which include randomized assignment—have specifically compared outcomes for children across inclusive and specialized settings. Some studies documented similar outcomes across settings (Boyd et al., 2014; Harris et al., 1990); others reported a potential advantage for children in inclusive settings (Nahmias et al., 2014; Strain, 1984); and others still suggested better outcomes for children educated in specialized settings (Panerai et al., 2009; Reed et al., 2012). In addition, a small body of literature suggests that mothers of children receiving intervention in specialized settings experience significantly lower stress and better well-being compared to mothers of children receiving intervention in inclusive settings (Bitsika and Sharpley, 2004; Bromley et al., 2004). Overall, the mixed findings and the variability in methodological robustness and approaches adopted among existing studies preclude definitive conclusions on the relative benefits of inclusive versus specialized educational settings, pointing to the need for further evaluation. To the best of our knowledge, no study has yet provided a "head-to-head" comparison of EI outcomes in inclusive versus specialized settings using a randomized design.

Against this background, we conducted a pilot randomized controlled trial (RCT) of receiving a manualized EI program in inclusive versus specialized classrooms within a community childcare service. The specific EI model used in the trial was the group-based adaptation of the Early Start Denver Model (ESDM; Rogers and Dawson, 2010), a manualized evidence-based EI involving a set of teaching procedures and a curriculum designed to address the needs of preschoolers with ASD. Principles and strategies in ESDM are informed by developmental research, applied behavior analysis, and expertise from relevant allied health professions and early childhood education (Rogers and Dawson, 2010). Major treatment targets include skills that enable social learning and engagement in naturalistic social interaction and cooperative activities (e.g. spontaneous imitation, joint engagement, verbal and nonverbal communication; Rogers et al., 2017). The group-based adaptation of the ESDM (Group-ESDM or G-ESDM; Vivanti et al., 2017) uses the principles and strategies of ESDM within a group format, with one adult delivering instruction to small groups of 3–4 children. While research has documented favorable outcomes for children receiving the ESDM in the context of one-on-one delivery by trained interventionists in children's homes (Dawson et al., 2010) and preliminary evidence support implementation of the G-ESDM within specialized classrooms (Vivanti et al., 2014), no study has yet evaluated whether child outcomes differ when G-ESDM is implemented in an inclusive versus specialized setting.

Consistent with the scope of a pilot RCT, we randomly assigned 44 preschoolers with ASD to receive G-ESDM (Vivanti et al., 2017) in either an inclusive or autism-specific setting to evaluate the effect of intervention context on children's outcomes. We included various outcome measures at four levels—setting, teacher, parent, and child—to examine the feasibility and preliminary effectiveness of delivering G-ESDM in inclusive settings in order to inform the appropriateness of continuing to a future full-scale trial.

Specifically, we addressed the following questions:

1. Can the G-ESDM be successfully delivered by early childhood educators in an inclusive community preschool setting?
2. Will outcomes differ for preschoolers receiving the G-ESDM in inclusive versus specialized settings? To establish this, we included proximal measures of spontaneous vocalization, social interaction, and imitation and distal measures of verbal and nonverbal cognitive ability, adaptive behavior, autism symptoms, and parental stress.

In addition, based on previous research suggesting better outcomes for younger children receiving G-ESDM in a specialized setting (Vivanti et al., 2016a), we examined whether age at treatment onset was associated with children's outcomes in each setting.

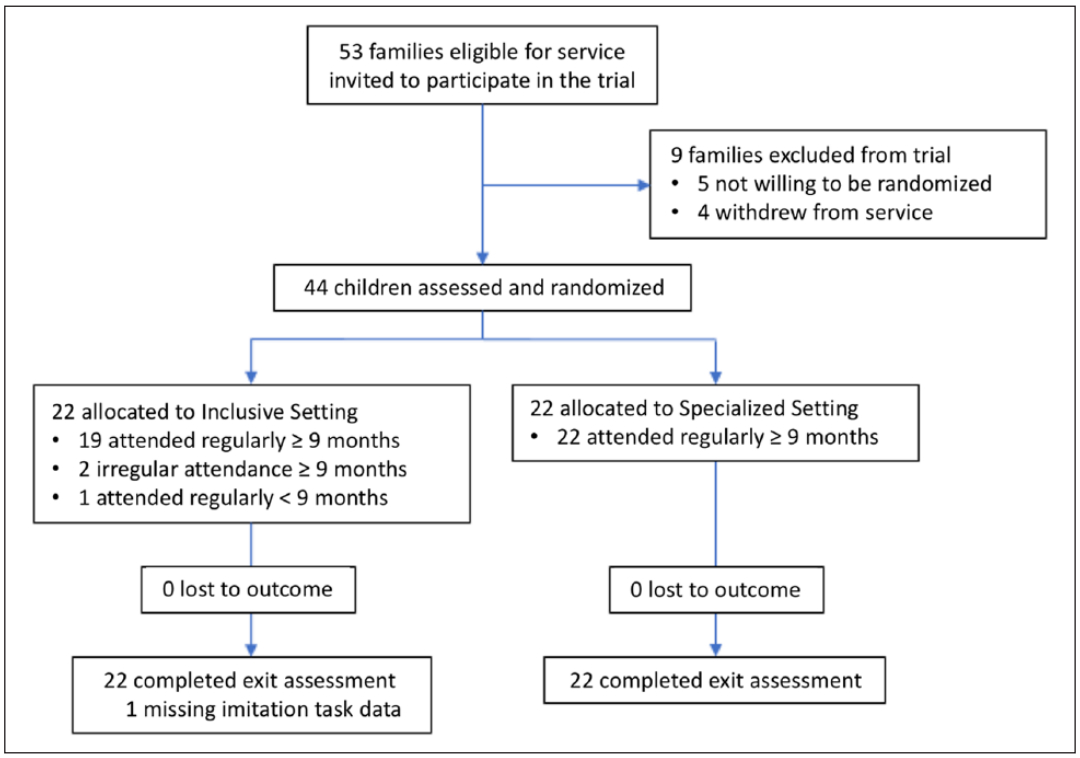

Figure 1. Study design and participant flow through the trial.

Methods

Design, participants, and procedure

The study protocol was approved by the La Trobe University Human Ethics Committee (UHEC 14-082). Participants were children with ASD aged between 15 and 32 months at the start of the school year who were offered (1) enrollment in EI in the community childcare center and (2) whose parents gave informed consent for random assignment into either an inclusive (hereafter, inclusive setting) or an autism-specific (hereafter, specialized setting) classroom.

Figure 1 summarizes the trial design. Assignment to the inclusive versus specialized settings was via block randomization procedure with stratification by child age (older than vs equal to or younger than 24 months). Following baseline assessments, children were randomized before the start of the school year and did not spend any time in the classroom prior to entering the study. All children exited at the end of the school calendar year, with exit assessments for the children enrolled in this trial conducted by research clinicians trained in the administration of the outcome measures, and kept blind to group assignment and study aims.

Across three school calendar years, we invited 53 families to participate in this trial, resulting in a final sample of 44 preschoolers with ASD who were randomized into the inclusive or specialized settings and had an exit assessment conducted at the end of the year. Children were eligible for this study, based on

- Having ASD symptoms consistent with *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5) criteria confirmed via clinical judgment on the basis of administration of the Autism Diagnostic Observation Schedule (ADOS-2; Lord et al., 2012) by a research-reliable assessor.
- Parental agreement that the child would attend at least 15 h per week—minimum 5 h per day, for 3 days per week—across one school calendar year.

Families of all eligible children enrolling in the service were invited to participate in this study, with no exclusion criteria based on children's behavioral characteristics (e.g. challenging behaviors) or developmental/cognitive level. Five invited families declined consent. Among the 48 preschoolers with ASD randomized into the inclusive or specialized settings, 4 withdrew from the service shortly afterward—1 from the specialized setting and 3 from the inclusive setting—with little intervention received and no exit assessment conducted. Hence, we retained 44 participants who received G-ESDM and had exit assessment data for analysis; 22 assigned to the inclusive setting and 22 to the specialized setting.

Baseline participant characterization is shown in Table 1, with no significant between-group differences on chronological age, cognitive and adaptive functioning, symptom

Table 1. Participant characteristics at baseline assessment.

	Inclusive setting ($N = 22$)	Specialized setting ($N = 22$)	Evaluation of group matching
Gender: M, F	15, 7	12, 10	$\chi^2(1) = 0.06$, $p = 0.81$
Chronological age (months): *M* (*SD*)	24.73 (4.72)	26.36 (4.64)	$t(42) = -1.16$, $p = 0.25$
MSEL VDQ: *M* (*SD*)	59.63 (22.82)	56.10 (35.58)	$t(42) = 0.36$, $p = 0.72$
MSEL NVDQ: *M* (*SD*)	77.94 (16.50)	71.59 (26.10)	$t(42) = 0.96$, $p = 0.34$
ADOS Social Affect Algorithm: *M* (*SD*)	13.23 (5.72)	13.91 (5.14)	$t(42) = -0.41$, $p = 0.68$
ADOS Repetitive Behaviors Algorithm: *M* (*SD*)	4.86 (1.38)	4.95 (1.93)	$t(42) = -0.19$, $p = 0.84$
VABS Adaptive Behavior Composite: *M* (*SD*)	78.73 (10.86)	76.86 (12.05)	$t(42) = 0.53$, $p = 0.59$
Parental Stress Index: *M* (*SD*)	102.27 (21.44)	105.19 (25.50)	$t(42) = -0.40$, $p = 0.68$
Maternal education	7% secondary 80% tertiary 13% postgraduate	21% secondary 64% tertiary 14% postgraduate	

ADOS: Autism Diagnostic Observation Schedule; MSEL: Mullen Scales of Early Learning; VDQ: verbal developmental quotient; NVDQ: nonverbal developmental quotient; VABS: Vineland Adaptive Behavior Scale; SD: standard deviation.

severity, maternal education, and maternal well-being. The treatment phase lasted for 10–11 months (February/March–December) and exit assessments were completed for all 44 participants, with minimal missing data (see Figure 1).

Following randomization and the commencement of the intervention year, we observed good retention of families, with only two children leaving the center early—both following 6 months of participation; in one case due to family decision to relocate, and in the other, due to considerable travel time presenting a barrier to ongoing attendance. Two other children retained across the school calendar year in the inclusion group had frequent periods of absence from the service. Following a conservative "intention to treat" analysis plan, exit assessments were completed for all of these children, with no attempt to adjust for intervention "dose."

Intervention context

The trial was conducted within the La Trobe University Community Children's Centre—a community service which includes an EI program for children with ASD across autism-specific classrooms and a regular day care program for children of families in the local community—and Gowrie Victoria, a second community day care service. Families of children with ASD were referred to the EI program via various sources, including community-based health-care professionals, autism information services, and self-referral.

The autism-specific EI program comprised the G-ESDM (Vivanti et al., 2017), a manualized adaptation of the ESDM for classrooms, with delivery by trained early childhood educators and allied health staff. In the G-ESDM, children's individual learning objectives are targeted through daily routines and group activities with a staff:child ratio of 1:4. Manualized procedures include daily routines that bring children with or without ASD together to play in cooperative activities, as well as peer-mediated strategies, with adults providing guidance so that children elicit and reinforce appropriate behaviors for their peers, and persist in their efforts to do so (Vivanti et al., 2017).

Intervention for the children randomized into the specialized setting was according to standard practice of the center, following the manualized G-ESDM approach. Up to 10 children with ASD attended the autism-specific classroom on any given day—this included participants involved in the trial (i.e. assigned to the specialized setting) in addition to other children with ASD who were not involved in the study. The children randomized to the inclusive setting for this trial received the same intervention based on the G-ESDM manual, but within one of four inclusive classrooms at either the La Trobe University's Community Children's Centre or Gowrie Victoria community childcare center. Each inclusive classroom had between one and three children with ASD attending on any given day, and an average of 12 typically developing peers. Like the specialized classroom, the staff:child ratio in the inclusive classrooms was 1:4.

Within the specialized setting, the G-ESDM was delivered by early childhood educators, one of whom was formally certified as an ESDM therapist, while other staff had participated in ESDM training workshops and received in-classroom coaching on the G-ESDM. Allied health specialists—including psychology, speech therapy, and occupational therapy professionals, all of whom were ESDM Certified Therapists or undergoing certification—also supported children in the specialized setting. Within the inclusive setting, intervention was delivered by an ESDM-certified therapist and other trained early childhood educators, with specialist support from the same allied health team. These early childhood educators had also participated in ESDM training workshops and received in-classroom coaching on the G-ESDM. ESDM skills training workshops were provided for other

non-certified staff at the beginning of each year, followed by continuing in-room coaching across the school year.

Implementation of the trial was planned according to a community-partnered participatory research approach (Jones and Wells, 2007); that is, a community-academic collaboration approach where stakeholders from La Trobe University and the community childcare centers were equal partners in the development and generation of research aims, design, implementation, and outputs. This process was initiated by the teaching staff at La Trobe University's Community Children's Centre, who asked to discuss current knowledge on inclusive practices for preschoolers with ASD receiving EI in group settings with researchers at La Trobe University's Olga Tennison Autism Research Centre to guide their decision-making. During a series of meetings involving the leadership and the staff members of both institutions, consensus was reached on the need to generate further evidence on the relevance of inclusive versus specialized settings for ASD EI delivery. Options regarding the research goals, methods, and outputs were discussed and selected based on consensus among all parties involved. Components of the projects that were directly influenced by school personnel included the focus on classroom, teacher, and family outcomes in addition to child outcomes, as well as the planning and implementation of information sessions for families.

Measures

Implementation measures. Adherence to delivery of EI was evaluated using the ESDM fidelity scale (available in the ESDM manual; Rogers and Dawson, 2010) whereby 13 key therapist behaviors are rated and the total score is expressed as a proportionate level of overall fidelity (see Supplementary Appendix A). The fidelity tool was used during initial training and subsequent coaching, and formal staff/classroom observations for fidelity rating by an ESDM-certified allied health professional were scheduled at least twice per school year.

Quality of the early childhood education environment was evaluated each year for each classroom using the Sustained Shared Thinking and Emotional Well-Being (SSTEW) scale (Howard et al., 2018; Siraj et al., 2015); a standardized classroom observation measure of the quality of pedagogical practices in early childhood education settings. Each of five dimensions is rated on a 7-point scale (anchored such that 1 = inadequate, 3 = minimal/adequate, 5 = good, 7 = excellent) and then averaged for a total SSTEW score. SSTEW ratings for this study were completed once per classroom per year by researchers independent of the study team, certified in use of the measure, and blind to the study aims (see Supplementary Appendix A).

Blinded proximal outcome measures. Measures of spontaneous vocalization, social interaction, and imitation were taken as indices of proximal child outcome, all derived blind to each child's assigned setting. These measures, which reflect skills that are specifically targeted within the ESDM (Rogers et al., 2017), are described in detail in Supplementary Appendix B and summarized below.

Spontaneous vocalization was measured using Language ENvironment Analysis (LENA; Gilkerson and Richards, 2008; Xu et al., 2009). We took 45-min LENA recordings with each child at the start and end of the intervention year, during unstructured 1:1 interactions with an adult, for a measure of the frequency of spontaneous child vocalization during situations that provided opportunities for language use but without explicit instruction for the child to speak. Data were extracted by a blinded research assistant and analyzed through the LENA automated speech analysis software.

Spontaneous social interaction was measured through the Modified Classroom Observation Schedule to Measure Intentional Communication (M-COSMIC; Clifford et al., 2010). For each child, video samples were captured toward the start and end of the school year, comprising 5 min of free play and 5 min of semi-structured snack time footage. Following Clifford et al. (2010), these were coded off-line by blinded research assistants to generate a total number of social-communicative acts by the target child across the 10-min sample. Inter-rater agreement based on a proportion of tapes (30%) that were double-coded was excellent (intraclass correlation coefficient (ICC) = 0.93).

Spontaneous imitation was measured following an experimental paradigm detailed by Vivanti et al. (2016b; Experiment 3), in which children were shown a series of eight short videos during which a demonstrator performs actions on one of eight available objects. Identical objects were available to the child who had the opportunity to imitate what was seen but was given no explicit instruction to do so. For each trial, 2 points were given for *imitation* of the demonstrator's action, 1 point for *any action* performed on the same object used by the demonstrator, and 0 points for *any other response*, including picking up objects not used by the demonstrator, with a total imitation score retained for analysis. Scoring of video-recorded child performance was performed off-line by a blinded research assistant. Intraclass correlation based on a proportion of tapes (20%) that were double-coded was 0.90.

Additional information on each measure is available in Supplementary Appendix B.

Distal outcome measures. One standardized direct assessment of the child administered blind to group assignment, and three non-blinded parent-report measures were also completed at intake and exit, to quantify distal intervention targets. The Mullen Scales of Early Learning (MSEL; Mullen, 1995) were used to quantify child developmental ability across verbal and nonverbal cognition. A verbal developmental quotient (VDQ) was computed for each

child based on age-equivalence scores in the receptive and expressive language domains as a function of chronological age, while a nonverbal developmental quotient (NVDQ) was generated from age-equivalence scores in the visual reception and fine motor domains.

Parents completed the Vineland Adaptive Behavior Scales—2nd Edition (VABS-II; Sparrow et al., 2005) with the Adaptive Behavior Composite (ABC) standard score providing a measure of adaptive behavior. Parents also completed questionnaire measures of child autism symptoms: the Social Communication Questionnaire (SCQ; Rutter et al., 2003) and the Repetitive Behavior Scale–Revised (RBS-R; Bodfish et al., 2000), with total scores retained for analysis.

Parent outcome measure. Mothers of participants completed the Parenting Stress Index (PSI; Abidin, 2012) at the start and end of school year, for a self-report measure of stress associated with the parenting role.

Analysis plan

To address the feasibility and effect on classroom teaching quality of providing EI for preschoolers with ASD in an inclusive setting, we examined the degree of fidelity to the ESDM achieved by staff implementing the intervention within each setting and compared blind-rated SSTEW scores across each setting and against the current local benchmark (established independently of the current research, through the assessment of 54 Australian early childhood education classrooms; Howard et al., 2018). To evaluate the relative effectiveness of receiving EI in inclusive versus autism-specific specialized classrooms, we conducted a series of mixed 2 (Setting) × 2 (Time) analysis of variances (ANOVAs) on the proximal and distal outcome measures. Finally, we examined the association between chronological age at treatment start and changes across outcomes measures in the two settings through partial correlation and regression analyses.

Results

Feasibility of implementation

Formal observations against the ESDM fidelity scale indicated average treatment adherence of core staff members who delivered intervention within the inclusive setting to be 72% in School Year 1, 76% in School Year 2, and 82% in School Year 3. Staff turn-over occurred across the study period but was particularly pronounced across Year 2 and into Year 3. Consequently, substantial investment was made by the ESDM-certified allied health team to provide training and ongoing coaching to new staff during Year 3. In the specialized setting, the average fidelity level of core staff members delivering intervention was 80% in School Year 1, 81% in School Year 2, and 84% in School Year 3 (with less pronounced turn-over of staff within this setting). Among the team of ESDM-certified allied health professionals who supported the program across both settings, all had achieved the nominal 80% fidelity threshold through the process of certification, and maintained this level thereafter, approaching an average fidelity level of 85% by Year 3 (with strong stability of these staff across the study period).

As shown in Figure 2, results from the blind-rated SSTEW indicated that teaching quality in the classrooms where trial participants were placed was classified as "good" overall across both the inclusive and specialized settings. Subscales scores varied from adequate to excellent with no substantive differences between the inclusive and specialized settings on any indicators, and the overall rates were well above the independently ascertained SSTEW benchmark reported across observations of 54 Australian early childcare centers (i.e. $M = 3.89$, $SD = 1.06$; Howard et al., 2018).

Child outcomes

Table 2 shows descriptive statistics and results of the ANOVAs for the three blinded proximal outcome measures—frequency of spontaneous vocalizations (captured via LENA recordings), social interaction (measured via the M-COSMIC), and imitation performance (from the experimental task detailed in Vivanti et al., 2016b). Spontaneous vocalizations, social interaction, and imitation scores showed significant improvement over time but no main effect of Setting or Setting × Time interaction. That is, the children in each setting increased their frequency of spontaneous vocalizations, social interaction, and imitation across the intervention year, with no between-group differences apparent at baseline or any evidence of superior gains among children in one setting over the other.

Table 2 also shows data for the four distal outcome measures—VDQ and NVDQ from the blinded MSEL assessment, ABC from the VABS-II parent interview, and autism symptoms from the two parent-report questionnaires (SCQ symptom severity and RBS-R repetitive symptoms). No significant main effects or interaction terms presented for either NVDQ or RBS-R. By contrast, for VDQ, ABC, and SCQ, there were significant main effects of time but no significant main effect of Setting or Setting × Group interaction. Again, this suggests improvements in verbal cognition and adaptive behavior, and reduction in social symptom presentation across the intervention year for children in both settings, with no between-group differences at baseline or any evidence of differential gains as a function of intervention setting.

Parent outcome. As shown in Table 2, the ANOVA on self-reported parenting stress (PSI) also showed a significant main effect of time, but no main effect of Setting or Setting × Group interaction. This suggests reduction in

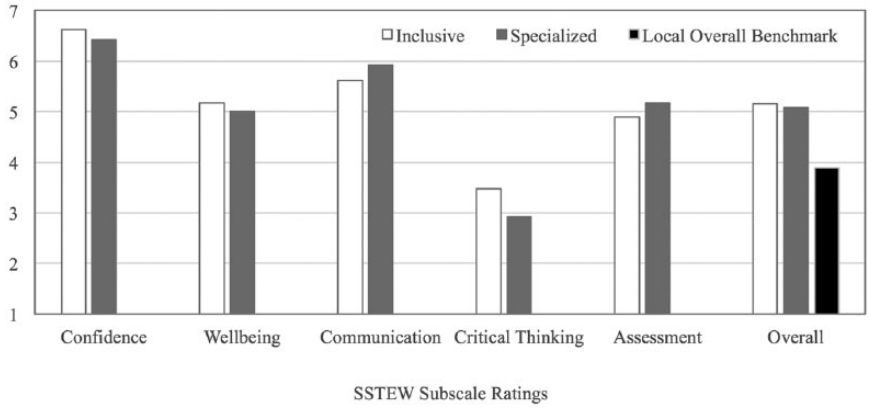

Figure 2. Average ratings on Sustained Shared Thinking and Emotional Well-Being (SSTEW) scale for inclusive and specialized classrooms, and in comparison with Australian benchmark (Howard et al., 2018).

Table 2. Descriptive and inferential statistics for proximal and distal child outcomes and parent outcome.

	Inclusive setting		Specialized setting		Main effect: time			Main effect: setting			Interaction		
	Baseline	Exit	Baseline	Exit	*F*	*p*	ES	*F*	*p*	ES	*F*	*p*	ES
Proximal child outcomes													
Spontaneous vocalization	138.77 (97.12)	205.50 (102.0)	127.31 (88.4)	220.36 (94.26)	24.83	<0.001	0.37	0.67	0.41	0.01	0.67	0.41	0.01
Social engagement	16.59 (11.11)	19.71 (10.53)	10.55 (7.77)	20.27 (11.47)	10.59	0.002	0.20	1.25	0.26	0.03	2.80	0.10	0.06
Imitation	14.84 (13.85)	27.73 (27.19)	14.20 (12.67)	24.71 (25.83)	6.64	0.01	0.15	0.12	0.72	0.00	0.06	0.79	0.00
Distal child outcomes													
MSEL VDQ	59.63 (22.82)	66.38 (28.91)	56.10 (35.58)	67.97 (38.20)	10.73	0.002	0.20	0.00	0.92	0.00	0.70	0.40	0.01
MSEL NVDQ	77.94 (16.50)	70.92 (24.05)	71.59 (26.10)	73.49 (29.36)	0.89	0.35	0.02	0.07	0.74	0.00	2.71	0.11	0.06
VABS ABC	78.73 (10.86)	84.00 (14.74)	76.86 (12.05)	82.09 (17.53)	9.99	0.003	0.19	0.23	0.63	0.00	0.00	0.98	0.00
SCQ	18.29 (6.10)	14.05 (7.15)	17.10 (5.89)	12.62 (7.76)	22.41	<0.001	0.36	0.48	0.48	0.01	0.01	0.89	0.00
RBS-R	25.90 (13.12)	23.63 (16.50)	16.38 (8.74)	19.71 (18.01)	0.04	0.83	0.01	3.48	0.07	0.07	1.16	0.28	0.02
Parent outcome													
PSI	102.27 (21.44)	95.86 (18.69)	105.19 (25.50)	98.58 (22.88)	4.16	0.04	0.09	0.40	0.52	0.01	0.28	0.59	0.00

ABC: Adaptive Behavior Composite; ES: partial eta squared effect size; MSEL: Mullen Scales of Early Learning; RBS-R: Repetitive Behavior Scale–Revised; PSI: Parenting Stress Index; SCQ: Social Communication Questionnaire; VDQ: verbal developmental quotient; NVDQ: nonverbal developmental quotient; VABS: Vineland Adaptive Behavior Scale.
Imitation task missing at exit for one child in Inclusive Setting.

parenting stress among mothers irrespective of the setting in which their children received intervention, with no evidence of baseline differences or differential influence of intervention setting.

Associations between age and outcomes. Based on previous research suggesting better outcomes for children who received the ESDM at a younger age, we examined partial correlations between chronological age at treatment start and outcome measures, controlling for baseline scores on each given measure. We found that, in each group, chronological age was negatively associated with VDQ at treatment exit (inclusive setting partial $r=-0.52$, $p=0.01$; segregated setting partial $r=-0.56$, $p<0.005$). A follow-up linear regression on exit VDQ, with baseline VDQ entered at Step 1, intervention setting entered at Step 2, and chronological age entered at Step 3 indicated that age continued to be a significant predictor of outcome VDQ, independent of these other factors ($p=0.001$; see Table 3). No significant associations were found between age and the other outcome measures.

Discussion

While the issue of whether children with ASD should be educated in inclusive or special settings is highly debated, the evidence base in this area is modest. To our knowledge, this study is the first to adopt an experimental design to

Table 3. Hierarchical regression analysis predicting outcome verbal developmental quotient.

Predictor variables	Verbal developmental quotient								
	Step 1			Step 2			Step 3		
	B	*SE B*	β	*B*	*SE B*	β	*B*	*SE B*	β
Baseline VDQ	0.93	0.09	0.82***	0.93	0.09	0.82***	0.99	0.09	0.87***
Setting				4.64	5.81	0.07	8.21	5.22	0.12
Age							−2.00	0.56	−0.28**
R^2	0.07			0.05			0.02		
F Change	89.13***			44.50***			42.40***		

VDQ: verbal developmental quotient; SE: standard error.
$p = 0.05$; ***$p < 0.001$; **$p = 0.001$.

investigate the relative benefit of providing EI for children with ASD placed within an inclusive versus specialized (autism-specific) setting. Data from this pilot RCT suggest that implementation of the G-ESDM for children with ASD placed within inclusive early childhood education settings is feasible, with no significant differences in child and parent outcomes compared to delivery of the same EI model within specialized classrooms.

Participant uptake and retention within the trial suggest that the study and intervention were acceptable to families. In addition, teacher fidelity data suggest that, with adequate support, early childhood educators were able to learn and implement the intervention protocol to a high degree of fidelity, although the nominal threshold of fidelity >80% was only achieved by staff in the inclusive setting within the third year of the study, and with substantial investment from the ESDM-certified allied health team to train incoming staff and provide regular ongoing coaching thereafter. Results of the independent SSTEW evaluation indicate that our implementation of the RCT and delivery of G-ESDM was consistent with the delivery of high-quality pedagogical practices for early childhood, with similar ratings observed across the inclusive and specialized classrooms. While a common argument against inclusion is that staff would have to focus disproportionate attention on the child with ASD to the detriment of teaching quality to the rest of the class (Hornby, 2014; Rafferty et al., 2001), SSTEW indicators of teaching quality across the inclusive classrooms in this study were rated well above an independently derived local benchmark computed from ratings of 54 Australian early childhood settings (Howard et al., 2018). Hence, implementation of our trial and delivery of G-ESDM in the inclusive setting appeared feasible and did not appear to compromise the quality of teaching provided to all children (with and without autism).

None of our analyses on the pilot RCT outcome data suggested superiority of one setting over the other. Children randomly assigned to both settings made gains on blind-rated measures of spontaneous vocalization, social interaction, spontaneous imitation, verbal cognition as measured through the MSEL, as well as parent-reported autism symptom presentation (SCQ) and adaptive functioning (VABS). Similarly, and in contrast to previous research (Bitsika and Sharpley, 2004; Bromley et al., 2004), we found that mothers of participants in our study experienced reduction in their stress level during the school year irrespective of their child's allocated setting. However, no changes were reported over time on children's repetitive behavior symptoms (parent-report RBS-R), or in terms of their nonverbal cognition (although in the latter case, children did make raw-score gains), suggesting the need for more work to successfully address these two intervention targets in community settings.

Interestingly, changes in cognitive functioning observed in this study were in the small to medium range, while those reported in the original trial testing the efficacy of ESDM (Dawson et al., 2010) were of medium to large effect size (and similar to other intensive individualized interventions; Makrygianni et al., 2018). Importantly, however, outcomes reported by Dawson et al. (2010) were following 1:1 (rather than group) delivery of ESDM. Conversely, magnitude of the change observed here in adaptive and social functioning (as measured using the VABS and SCQ) compared favorably to results documented in research on 1:1 ESDM (i.e. Dawson et al., 2010) and other intensive EI approaches (Makrygianni et al., 2018). This pattern points to the need for further research focused on the comparative benefits of group-based versus individualized ASD interventions across areas of functioning. Finally, consistent with previous literature on individual ESDM (Rogers et al., 2012), G-ESDM (Vivanti et al., 2016a), and other approaches (e.g. Smith et al., 2015), our data suggest that children who start intervention at a younger age might have better outcomes in the language domain.

Our study adds to the growing literature attesting the feasibility of conducting experimental trials within community educational settings (Chang et al., 2016; Iadarola et al., 2018; Kaale et al., 2014). Relevant obstacles in this area include practical challenges with modifying regular

school routines without interfering with regulatory constraints and violating quality performance standards by which schools are held accountable, as well as conflicting stakeholder goals (e.g. the school mission of addressing educational needs of children versus the research priority to assign participants to educational programs at random; Bosworth, 2015; Cook, 2002). Consistent with emerging evidence in the field (Locke et al., 2017; Shire et al., 2017; Vivanti et al., 2018), the current trial suggests that these challenges can be successfully addressed using a community-partnered participatory research approach.

Limitations and conclusion

Although consistent with the scope of a pilot RCT, the small size of our participant sample, coupled with the heterogeneity of children's outcomes, limits our ability to detect potentially meaningful but small changes as statistically significant. However, small effect sizes observed for our Setting × Time interaction terms suggest that lack of differences in outcomes across settings did not reflect lack of statistical power. Importantly, however, the study was not adequately powered to conclusively establish equivalence of gains across settings.

It should also be noted that intervention delivery in the inclusive setting fell below the nominal 80% threshold against the ESDM clinical fidelity tool during the first 2 years of program operations, resulting in variable treatment quality across the study period, and indicating that adherence to the G-ESDM procedures—while ultimately feasible—was challenging for staff in the inclusive setting. Future research attention should be dedicated toward understanding the resource requirements necessary to support teachers to reach fidelity in EI delivery and, further, to establish the extent to which this could be feasibly maintained after cessation of ongoing evaluation and monitoring.

It is also plausible that the intervention contexts in this study, which included staff trained in the G-ESDM across two setting types, may differ substantially from typical forms of instruction occurring in specialized versus inclusive settings. In addition, the low staff-child ratio in the classroom and the relatively high socioeconomic status (SES) of the families involved limit generalizability to ordinary contexts in which inclusive and specialized programs are implemented with fewer resources. Hence, inferences drawn from this study regarding special versus inclusive education should be considered with caution. It should also be stressed that intervention changes experienced by children receiving G-ESDM might be different from those associated with the delivery of individual ESDM; therefore, this study should not be used to draw inference on the effects of delivering 1:1 ESDM in inclusive settings.

An additional limitation to be addressed by future research includes the lack of systematic measurement of the frequency and complexity of social opportunities available to children with ASD in inclusive versus specialized settings. Finally, while the primary focus of this study was on children with ASD, additional research on inclusion should consider how the behavior of typical children and educators may shape, and be shaped by, regular interaction experiences with children with ASD in the classroom, and by the experience of implementation of the G-ESDM.

To our knowledge, this is the first study to examine delivery of an evidence-supported EI for ASD in an inclusive versus specialized setting, using an experimental design with random assignment of children to settings. Delivery of the G-ESDM within an inclusive setting does not seem to preclude children with ASD and their families from experiencing similar benefits to those observed within an autism-specific specialized setting. Given that contemporary views on disability emphasize the importance of social inclusion (United Nations, 2006), and given also the potential cost-benefit to individuals, communities, and policy makers if interventions can be effectively embedded within inclusive settings (Odom et al., 2001), replication of the current findings within a full-scale equivalence trial is now indicated. Given the known phenotypic heterogeneity in ASD (Waterhouse, 2013), such an endeavor should also ensure sufficient power for a robust test of potential moderator effects, thus providing information regarding *for whom* access to intervention within socially inclusive settings might be most appropriate, and whether there remain certain subgroups of children with ASD for whom intervention within autism-specific specialized settings remains the most effective option.

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