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Vivanti, Giacomo
Paynter, Jessica
Duncan, Ed
et al.

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Effectiveness and Feasibility of the Early Start Denver Model Implemented in a Group-Based Community Childcare Setting

**Giacomo Vivanti · Jessica Paynter ·
Ed Duncan · Hannah Fothergill · Cheryl Dissanayake ·
Sally J. Rogers · the Victorian ASELCC Team**

Abstract   A recent study documented the efficacy of the Early Start Denver Model (ESDM) delivered in a 1:1 fashion. In the current study we investigated the effectiveness and feasibility of the ESDM in the context of a long-day care community service, with a child-staff ratio of 1:3. Outcomes of 27 preschoolers with ASD undergoing 15–25 h per week of ESDM over 12 months were compared to those of 30 peers with ASD undergoing a different intervention program delivered in a similar community long-day care service. Children in both groups made gains in cognitive, adaptive and social skills. Participants in the ESDM group showed significantly higher gains in developmental rate and receptive language.

G. Vivanti (✉) · C. Dissanayake
Olga Tennison Autism Research Centre, School of Psychological Science, La Trobe University, Bundoora Campus, Melbourne, VIC 3086, Australia
e-mail: g.vivanti@latrobe.edu.au

G. Vivanti · E. Duncan · the Victorian ASELCC Team
Victorian Autism Specific Early Learning and Care Centre, La Trobe University, Melbourne, VIC, Australia

J. Paynter · H. Fothergill
Research and Psychology Department, AEIOU Foundation, Brisbane, Australia

S. J. Rogers
The MIND Institute, University of California, Davis Medical Center, Sacramento, CA, USA

Introduction

A critical priority in the field of autism is the translation of evidence-based intervention programs into sustainable community practice (Anagnostou et al. 2011; Volkmar et al. 2011). This process, however, presents numerous challenges. For example, intervention programs developed and tested within University-based research contexts often involve high staff-to-child ratios, high levels of intensity, highly trained clinicians, and rigorous adherence to clearly defined treatment strategies. Standard community services often lack the resources, both in terms of costs and expertise, to implement similar programs. Research in this area indicates that interventions shown to be efficacious in rigorous trials are not always implemented in the way they were originally intended when transported into community practice (Dingfelder and Mandell 2011; Stahmer 2007), and evidence for the effectiveness of community-delivered intervention in ASD is mixed (Chasson et al. 2007; Magiati et al. 2007).

Another challenge inherent in the translational process is that of outcome evaluation. Grant-funded research on treatment efficacy is typically based on randomized controlled trials (RCTs), a rigorous procedure that involves random allocation of participants into a treatment and a control group to minimize the potential influence of confounding factors. Randomization into different groups, however, is usually unattainable outside of University-based settings, and incompatible with most regulations and policies of community services where the primary aim is to

address the individual needs of the child and family and meet their priorities and choices. Other methodological procedures relevant in University-based efficacy research, such as 'blind' evaluation of treatment outcomes, have little relevance in the culture and practice of community services. As a consequence, very few RCTs exist in the context of community-based services (Kaale et al. 2012; Strain and Bovey 2011).

Given the steady increase in the number of efficacy studies conducted in University settings, there is an increasing need for translational research to evaluate whether the positive results documented in these trials extend to the community settings in which the intervention programs should ultimately be delivered. The present study, therefore, focuses on the community implementation of the Early Start Denver Model (ESDM), a manualized comprehensive early intervention program developed specifically for toddlers and preschoolers with ASD (Rogers and Dawson 2010). The ESDM principles are informed by both developmental science (with an emphasis on the relevance of early social engagement for neurocognitive development) and behavioural science (with an emphasis on the rigorous application of behavioural principles and systematic data collection). Learning objectives are based on individual profiles of strengths and weaknesses, with a particular focus on developmental domains that are foundational to social learning and social-cognitive development, including verbal and nonverbal communication, imitation, emotion sharing, joint attention, play, social orienting, and attention. Teaching episodes are embedded within the framework of naturalistic and intrinsically rewarding joint activities built on the child's spontaneous interests and motivation.

Evidence for the efficacy of the ESDM is documented in an RCT (Dawson et al. 2010) indicating significant gains in cognitive, language, and adaptive abilities in a group of preschoolers with ASD receiving 15 h per week of individual home-based treatment over 2 years, as well as 4 h per month of individual parent coaching. Moreover, two recent studies offer preliminary evidence of favourable outcomes following delivery of the ESDM in a group-setting (Eapen et al. 2013; Vivanti et al. 2013). To date, however, no controlled study has investigated the effectiveness of the ESDM in the context of community-based provision.

The intervention program delivered at the Victorian Autism Specific Early Learning and Care Centre (Victorian ASELCC) in Melbourne, Australia, provided a unique opportunity to study the outcomes of the ESDM implemented in a group-based community childcare setting. Located at La Trobe University's Community Children's Centre the program offers long-day care for 10 h per day (8:15 a.m.–6:15 p.m.). While originally funded by the federal government to provide not otherwise specified 'affordable early learning programs in a long-day care setting' the Victorian ASELCC elected to offer the ESDM intervention to children with ASD enrolled in the childcare program. This choice was motivated by two main rationales. The first was to address the increasing need for early intervention that followed the successful application of ASD early detection and diagnosis programs in the Melbourne area (Barbaro and Dissanayake 2010; Barbaro et al. 2011). As the ESDM has a specific focus on early development, it was preferred over other programs that do not have a developmental framework. Secondly, the ESDM manual (Rogers and Dawson 2010) includes a chapter focused on group-setting implementation, providing specific guidelines for delivery of the program in the context of the childcare setting.

Compared to the delivery format described in the Dawson et al. (2010) RCT study, three significant adaptations were introduced in order to provide ESDM therapy within the Australian childcare regulatory framework, the operational guidelines, and the budget provided for the operation of the Victorian ASELCC: (1) delivery was provided in the childcare centre in rooms with a maximum of 10 children and a staff-child ratio of 1:3; (2) group-based parent information sessions were provided instead of individual coaching; (3) chronological age of children enrolled in the program was 18–60 months, rather than 18–30 months.

Study Aims

The primary aim was to analyse the effectiveness of the ESDM program delivered in a community childcare group setting. Effectiveness was measured through analysis of the outcomes of pre-schoolers with ASD who received 15–25 h per week of ESDM in a community long-day care service over a 12-month period compared to preschool children who received a non-manualised, community-based educational program in a similar setting and with a similar level of intensity. We also investigated whether there were pre-treatment factors associated with treatment outcomes. We followed the guidelines on ASD effectiveness studies outlined by Lord et al. (2005), which recommend the use of relatively few inclusion/exclusion criteria and broad outcome measures. We hypothesised that participants in the ESDM group would show superior gains in cognitive, adaptive and social functioning compared to those in the comparison group.

The secondary aim in the current study was to document the feasibility of the ESDM in the context of a long-day community childcare setting. Feasibility was operationalized based on the guidelines outlined in Bowen et al. (2009), which include the following indicators: acceptability (how the individuals involved in the program react to the intervention), demand (the likelihood of the program to be chosen

by the potential end-users), implementation (the degree of execution of the program against manualized procedures/guidelines), practicality (the extent to which delivery of the program is attainable within the situational constraints), adaptation and integration (the level of system change needed to deliver the program into the existing infrastructure). A combination of different measures, including analyses of service utilization, surveys and external evaluation reports findings were used to document each of these aspects.

Methods

Ethics Approval

The study protocol was approved by the La Trobe University Human Ethics Committee (UHEC 10-084) and by the University of Queensland Human Ethics Committee (Project number 2011001241).

Participants

Eligibility criteria for enrolment in the Victorian ASELCC program (established by the Department of Family, Community Services, Housing, and Indigenous Affairs) involved a diagnosis of ASD from a community-based diagnostician and chronological age from 0 to 6 years. Similarly, eligibility criteria for enrolment in the comparison community educational program required a diagnosis of ASD from a medical professional (paediatrician or child psychiatrist) and chronological age from 2.5 to 6 years. Both programs provide service only to children with ASD.

Children enrolled in the two programs were included in the current study on the basis of the following inclusion criteria:

- Enrolled in either the Victorian ASELCC program or the comparison generic educational program for a minimum of 15 h per week over a 12-month period;
- Chronological age between 18 and 60 months at baseline;
- A diagnosis of ASD at intake, confirmed by trained clinicians at each centre through the Autism Diagnostic Observation Schedule (ADOS; Lord et al. 2000).

Neither of the two programs had exclusion/inclusion criteria based on children's behavioural characteristics (e.g. aggression, challenging behaviours). In the Victorian ASELCC site, 27 consecutive children meeting inclusion criteria were enrolled in the present study (ESDM group). Two families who had initially accepted to have their children enrolled in the program and were eligible for the study elected to withdraw before treatment started due to logistical challenges with attending the centre regularly. In the comparison group, the first 30 consecutive children meeting inclusion criteria were included. No participant withdrew from the program. Participant characteristics are detailed in Table 1, where it can be seen that there were no significant differences in the two groups on pre-treatment chronological age, cognitive and language level, adaptive functioning, and autism severity, and effect sizes were small. SES and mother education data were available for the ESDM group but not for the comparison group.

Measures

Effectiveness

The following measures were administered to all participants at baseline and approximately 12 months after the start of treatment.

Developmental level was measured through the Mullen Scales of Early Learning (MSEL; Mullen 1995), a standardized measure of early development, yielding standardized T Scores and age equivalent (AE) scores on the following subscales: Visual Reception, Fine Motor, Receptive Language, and Expressive Language. Following Anderson et al. (2013) and Rogers et al. (2012), since the standard T scores on the MSEL have a floor of 20, and many participants had scores at this floor level, developmental quotient scores (DQ: AE scores/chronological age × 100) were created from the subscale age equivalent scores for use as outcome measures of intervention. An overall developmental quotient was also created by combining the four subscale scores.

ASD symptom severity was measured using the ADOS-G, a standardized diagnostic observational instrument that quantifies autism symptoms in social reciprocity, communication, play and repetitive behaviours (Lord et al. 2000). On the basis of language development level, two participants in each group were administered the ADOS Module 2 (phrase speech) and all the remaining participants were administered the ADOS module 1. The ADOS calibrated severity score algorithms (Gotham et al. 2007), which allow for comparison of autism severity across participants tested with different ADOS modules, were utilized.

Adaptive behaviour was assessed using the parent questionnaire form of the Vineland Adaptive Behavior Scales II (VABS-2; Sparrow et al. 2005). Domains assessed include Communication, Socialization, Motor Skills, and Daily Living Skills, as well as an overall composite score of these domains.

Feasibility

Indicators of *Acceptability* (i.e. how the individuals involved in the program react to the intervention) included

Table 1 Participant characteristics at baseline (pre-treatment)

	ESDM (N = 27)	Control (N = 30)	t test p value	Effect size (Cohen's d)
Gender (M, F)	23, 4	27, 3	–	
Chronological age (months): M (SD)	40.30 (9.55)	41.97 (6.71)	.45	.20
MSEL, visual reception DQ: M (SD)	59.36 (16.65)	55.29 (18.15)	.38	.23
MSEL, fine motor DQ: M (SD)	61.75 (15.93)	58.85 (15.73)	.49	.18
MSEL, receptive language DQ: M (SD)	42.00 (20.54)	39.29 (20.27)	.61	.13
MSEL, expressive language DQ: M (SD)	50.72 (21.61)	42.62 (22.25)	.16	.36
MSEL, Total DQ M (SD)	53.46 (16.29)	49.01 (17.40)	.32	.26
ADOS, social affect: M (SD)	12.93 (4.13)	12.48 (4.38)	.69	.10
ADOS, repetitive behaviours: M (SD)	4.37 (2.06)	3.79 (2.09)	.30	.27
ADOS, calibrated severity score: M (SD)	6.78 (2.34)	6.31 (2.10)	.43	.21
VABS, communication SS: M (SD)	64.67 (14.22)	63.13 (12.43)	.66	.11
VABS, daily leaving skills SS: M (SD)	74.63 (13.28)	70.17 (10.30)	.16	.37
VABS, socialisation SS: M (SD)	70.70 (18.61)	71.57 (11.11)	.83	.05
VABS, motor SS: M (SD)	75.41 (13.46)	81.87 (12.80)	.07	.49
VABS, Adaptive Behavior Composite: M (SD)	68.74 (12.63)	68.50 (9.21)	.93	.02
Time to follow-up	11.90 (1.29)	11.80 (2.13)	.79	.05
Annual family income	44 % low, 42 % middle, 14 % high	N/A		
Mother education	38 % secondary. 37 % tertiary, 25 % postgraduate	N/A		

Low income < 60,000 AUS per year; middle income = 60,000–100,000; high income > 115,000

retention rate and the results of a survey to parents and staff at post-treatment (after 12 months in the program).

As an indicator of *Demand* (i.e., the likelihood of the program to be used), we looked at the applications to use the ESDM program among the potential end-users (i.e. pre-schoolers with ASD in the Melbourne area) over the first 24 months of the program.

Indicators of *implementation* of the ESDM included the degree of execution of the program against the procedures outlined in Rogers and Dawson (2010, Chapter 10). This parameter was documented through fidelity monitoring procedures (see treatment adherence section).

The *practicality* of the program (i.e. the extent to which the program is delivered within the situational constraints) was operationalised in terms of the degree to which it was possible to maintain the principles and strategies of the ESDM within the regulatory constraints of the Early Years National Quality Framework, which regulates the delivery of community childcare programs and services in Australia. Independent evaluations by the Australian Children's Education and Care Quality Authority were used to assess this parameter.

Adaptation and integration were operationalised and documented in terms of the level of system change needed to integrate the ESDM into the existing infrastructure/program of the Community Childcare Centre. This was assessed through both an independent evaluation conducted by the Australian Government (Department of Family, Community Services, Housing, and Indigenous Affairs) and internal documentation of structural and operational changes over the course of the first 12 months of the program.

Design

This study employed a quasi-experimental design. Primary outcome measures included the MSEL overall DQ, the VABS composite score, and the ADOS severity score. Secondary outcome measures included the MSEL, VABS and ADOS subscale scores.

Procedure

In the ESDM group, baseline (pre-treatment) assessments were completed at the childcare centre prior to the start of treatment, and outcome (post-treatment) assessments approximately 12 months later by different clinicians. Testing was conducted by five different clinicians with expertise in the administration of the ADOS and the MSEL. Although not blind to group status, clinicians were blind to whether the assessment was a pre- or a post-treatment evaluation. Moreover assessors and research staff were completely independent of treatment delivery. While inter-rater reliability was not evaluated, the assessors had demonstrated research reliability in the administration of the ADOS.

In the comparison group, child assessments were completed at the organisation's therapy support office, at a

Table 2 Program characteristics and summary

Area	ESDM group	Comparison group
Environment	Preschool/childcare group setting (autism-specific setting)	Preschool/childcare group setting (autism-specific setting)
Educational framework	Developmental, play-based	Developmental, play-based
Intervention Program (Guidelines for good practice—Prior et al. 2011)	Combined intervention-ESDM	Combined Educational and Therapy Program drawing from evidence-based Autism-specific strategies (e.g., NAC 2009)
Manualised intervention	Yes	No
Assessments used	ESDM curriculum checklist	Classroom observations, standardised assessments (VABS, PLS, MSEL, SCQ, ADOS)
Assessment frequency	Every 3 months	Standardised yearly, classroom checklists daily
Number of individual goals per child	16 per assessment cycle	2–3 goals every 6 months
Data collection on goals	Yes	Yes
	Daily	Daily
Educators	Teachers, diploma in early childhood, certificate III in early childhood education	Teachers, diploma in early childhood, certificate III in early childhood education
Allied Health	Speech pathologist, psychologist, occupational therapist	Speech pathologist, occupational therapist, limited psychology input[a]
Team approach	Transdisciplinary	Transdisciplinary
Approach to challenging behaviours	positive behaviour support	positive behaviour support
Use of visual supports	Low	High
	Alternative decision making process for individual children	Visual supports throughout day and routines and communication (e.g., schedules, PECS)
Child to adult ratio	Max 1:2; min 1:4	Max 1:2; min 1:4
Team training provided	Yes	Yes
	ESDM	Range of strategies across disciplines
Modifications to the environment	Nil	Strategies drawn from TEACCH e.g., visual supports, structured teaching
	Modeled on a typical pre-school environment	

[a] One psychologist over nine sites including the two in this research

different location to the one in which intervention was delivered. Assessments were completed by two members of the research team at the organisation, who had extensive experience in assessing children with ASD and were independent of treatment delivery. However, they were not blind to group status. Like in the ESDM group, assessors in the comparison group had demonstrated research reliability in the ADOS, however inter-rater reliability was not evaluated. Baseline assessments were completed prior to entry to the program and outcome assessments were completed after approximately 12 months in the program. As illustrated in Table 1, there was no statistical difference in the follow-up time between the two groups.

Intervention

The main characteristics of the two treatments are summarised in Table 2.

ESDM

Principles and strategies of the ESDM implemented in a group environment are similar to the ones used in the 1:1 delivery, with learning objectives defined on the basis of each child's regular ESDM curriculum assessments (completed in partnership with primary carers), and educational strategies based on developmental and behavioural principles delivered within a relationship-based framework. The staff in the ESDM group worked as an interdisciplinary team to implement the program comprising early educational teachers and childcare staff as well as a speech pathologist, psychologist, and an occupational therapist. Children were separated into two playrooms, with 10 children maximum allocated in each playroom based on chronological age (children aged 18- to 36-month in one playroom and those older than 36 months in the other one).

In the ESDM group implementation, individual learning objectives are targeted within small circle group activities

and 'play activity centres'. To illustrate, book activities, or song-based routines involving groups of 3–4 children are organized to target expressive and receptive language, gestural and vocal imitation, turn-taking, joint attention, cognitive goals (e.g., matching, counting), social (e.g., giving and sharing materials) and play skills. Moreover, 'activity centres' involving a variety of naturalistic, age-appropriate play activities are set with the aim of building learning opportunities based on children's interests and motivation; these are designed to encourage participation in cooperative activities based on common interests, as well as engagement in purposeful play and intentional communication. In addition to these activities, classroom routines provide continuous opportunities for therapist-child teaching interaction based on the ESDM principles.

A series of six 2-h parent information sessions on the ESDM strategies were conducted using materials from the ESDM introductory training module. While parents were encouraged to implement the ESDM strategies at home, unlike the therapists, they were not required to demonstrate fidelity of implementation. No measurements were collected of parent intervention within the home.

Comparison Group

Two sites were used for data collection in the comparison group. Each centre was running the same educational program, providing intervention for approximately 30 children at each, and was arranged into three classrooms of approximately 10 children led by an early years or special education teacher. Staff at each centre included a multi-disciplinary team of speech pathologists, occupational therapists, early years teachers, and childcare professionals. Classrooms were grouped by ability level (rather than chronological age) with staff: child ratio ranging from 1:2 to 1:4 depending on children's learning needs.

The program in the comparison group has been previously described in Paynter et al. (2012) and Paynter and Falvey-Henderson (2011), and can be characterised as a "generic" intervention program for ASD, that is, a program that does not subscribe to a single method, philosophy, or theoretical approach, but instead aims to be comprehensive and offer a range of teaching strategies derived from best practice guidelines.

Each child had an individual plan based on her/his strengths and needs determined through multidisciplinary assessment and set in partnership with families. The choice of teaching and therapy strategies used with each child was based on knowledge of evidence-based practices (e.g., drawing from the National Autism Centre guidelines 2009) and Australian reviews of good practice (Prior et al. 2011) along with clinical judgement and expertise, taking into account parent values and priorities (Prior et al. 2011). The

intervention used at the centres includes strategies drawn from the TEACCH program (Treatment and Education of Autistic and Communication Handicapped Children; Schopler 1994) such as the use of visual supports/visual schedules, and strategies drawn from applied behaviour analysis (e.g., structured large and small group teaching activities) to ensure routine and predictability, reducing stress, and promoting independent learning. Augmentative communication systems (e.g., Picture Exchange Communication System PECS; Frost and Bondy 1994) are also used where indicated by assessment. The predominant approach involves the creation of an "autism-friendly" environment (via visual supports, structured activities, and the use of consistent routines) to facilitate leaning in the four key domains: Social and Emotional, Language and Communication, Physical, and Cognitive skills. Additionally, teaching occurs throughout the day in natural contexts such as free play, snack time, outside play, self-help activities, as well as circle and mat times using naturalistic strategies (e.g., pivotal response training, naturalistic teaching strategies; see National Autism Centre 2009). Speech and occupational therapy consultation is conducted within the context of the classroom. The family education component consisted of regular parent training by allied health and teaching staff and covered a range of topics such as play skills, managing challenging behavior, transitions and communication strategies. As two separate sites were used for data collection, participants' characteristics differences between sites were analysed, and none were found.

In both the ESDM and the comparison group all families complied with the requirement that the Victorian ASELCC and the comparison service would be their main intervention providers. It was also requested that any additional practitioner providing extra-hours of therapy outside the centre would be involved, together with the families, in regular meetings with the centre's staff to ensure consistency across intervention settings.

Treatment Adherence

To ensure that the ESDM was implemented in the way it was originally intended, a multistep fidelity process was put in place. All staff first familiarised themselves with the treatment fidelity guidelines detailed in Rogers and Dawson (2010), and attended the ESDM introductory and advanced training modules prior to the program launch. This was organized on site and involved certified trainers who were directly involved in the foundation and development of the ESDM. Afterward, the staff submitted a series of videos that were reviewed by independent certified ESDM trainers. The evaluation of treatment adherence was based on the ESDM fidelity tool, a Likert-based 5

point rating system that focuses on 13 therapist behaviours (Rogers and Dawson 2010). The core staff members reached fidelity and were certified as ESDM therapists within the first semester of the program. The average score achieved on the 5 point ranking system was 4.34. Following certification, adherence to intervention procedures was ensured through ongoing support and monitoring of implementation from independent ESDM trainers. A second evaluation of all certified staff conducted approximately 6 month later resulted in an average score of 4.59.

Cost and Funding

Implementation of the ESDM for each full time placement at the centre costs approximately AU $48,000 per year. Families contributed to this cost with a weekly fee of AU $381 ($\sim$AU $18,000 per year) for a full time placement within the childcare facility. The comparison group program cost was approximately AU $46,000 for a full time placement at the centre. After organisational fund raising in addition to state and federal funding, approximately AU $18,000 of annual fees are paid by families for a full time placement at the comparison site. Although the two centres were operating under different business models, the overall costs per child was similar, and the fees paid by parents at both services were comparable to the average fee for a community long-day care service. Equity of access for both services was facilitated by current national regulations on childcare rebates that provided up to 50 % rebates on this weekly cost, up to a maximum amount per child per year based on criteria established by the Federal Government.
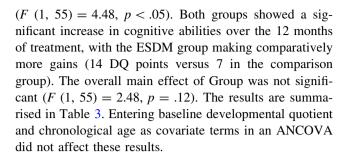
Results

Effectiveness

We employed 2 × 2 repeated measures analyses of variance (ANOVAs) with Time as the within subjects factor and Group as the between subjects factor to test the study hypotheses. We first analysed outcomes relative to the primary outcome measures. VABS scores at post-treatment were not available for 3 participants in the ESDM group, and ADOS at post-treatment was not available for 1 participant in the comparison group, resulting in slightly different Ns in these analyses.

Primary Outcome Measures

MSEL Overall DQ

Results of the ANOVA indicated a Time effect (F (1, 55) = 46.84, $p < .001$), and Group × Time interaction

(F (1, 55) = 4.48, $p < .05$). Both groups showed a significant increase in cognitive abilities over the 12 months of treatment, with the ESDM group making comparatively more gains (14 DQ points versus 7 in the comparison group). The overall main effect of Group was not significant (F (1, 55) = 2.48, $p = .12$). The results are summarised in Table 3. Entering baseline developmental quotient and chronological age as covariate terms in an ANCOVA did not affect these results.

VABS ABC

As illustrated in Table 3, the 2 × 2 ANOVA indicated a main effect of Time (F (1, 52) = 5.96, $p = .01$), but no main effect of Group (F (1, 52) = .01, $p = .89$), or Group × Time interaction (F (1, 52) = .95, $p = .33$). While participants in both groups made significant gains in adaptive functioning, there was no evidence for superiority of gains in one treatment over the other.

ADOS Severity Score

The 2 × 2 ANOVA indicated no main effect of Time (F (1, 52) = .01, $p = .92$), Group (F (1, 52) = 1.63, $p = .20$) or Group × Time interaction (F (1, 52) = .21, $p = .64$) on the ADOS severity score.

Secondary Outcome Measures

We next looked at group differences at the subscale level.

MSEL Subscales[1]

There was a main effect of Time and no main effect of Group for each of the MSEL subscales as evident in Table 4, indicating improvements in each treatment group across all developmental areas. However, a significant Group × Time interaction (F (1, 55) = 5.42, $p < .05$) was found for Receptive Language, with the ESDM group making comparatively more gains on receptive language than the comparison group. This result was confirmed when baseline developmental quotient and chronological age were entered as covariate terms in an ANCOVA.

VABS Subscales

As reported in Table 5, there was a main effect of Time on the VABS Communication subscale with both groups

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[1] This result and the other MSEL resulted reported here remained unchanged if Age Equivalence Scores are used instead of DQ scores. Mullen results using Age Equivalence Scores are reported in "Appendix".

Table 3 Participant cognitive, adaptive and social functioning at pre- and post-treatment

	12-month outcome								Group comparison					
	ESDM				Control				Time			Group × Time interaction		
	Baseline		Time 2		Baseline		Time 2							
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P	ES	F	P	ES
MSEL DQ	53.46	16.29	67.21	20.17	49.01	17.40	56.26	22.53	46.84	<.001	.46	4.48	<.05	.07
VABS ABC	70.21	12.55	72.13	13.48	68.50	9.21	72.97	15.45	5.96	.01	.10	.95	.33	.01
ADOS SS	6.78	2.34	6.89	2.34	6.31	2.10	6.14	1.62	.01	.92	.00	.21	.63	.00

Primary outcome measures

F F value; P p value; ES partial eta squared effect size

Table 4 Secondary outcome measures—MSEL subscales pre- and post-treatment scores

	12-month outcome								Group comparison					
	ESDM				Control				Time			Group × Time interaction		
	Baseline		Time 2		Baseline		Time 2							
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P	ES	F	P	ES
MSEL VR DQ	59.36	16.65	73.82	25.21	55.29	18.15	63.24	22.00	27.61	<.001	.33	2.33	.13	.04
MSEL FM DQ	61.75	15.93	68.83	17.88	58.85	15.73	61.70	23.47	6.17	.01	.10	1.12	.29	.02
MSEL RL DQ	42.00	20.54	62.00	24.65	39.29	20.27	49.55	24.06	55.33	<.001	.48	5.42	<.05	.09
MSEL EL DQ	50.73	21.61	64.18	21.03	42.62	22.25	50.56	25.95	29.64	<.001	.35	1.96	.16	.03

F F value; P p value; ES partial eta squared effect size

Table 5 Secondary outcome measures VABS subscales pre- and post-treatment scores

	12-month outcome								Group comparison					
	ESDM				Control				Time			Group × Time interaction		
	Baseline		Time 2		Baseline		Time 2							
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P	ES	F	P	ES
VABS Comm	66.00	14.20	73.38	16.47	63.13	12.43	73.17	19.83	21.83	<.001	.29	.50	.47	.01
VABS DSL	76.04	13.17	75.17	13.28	70.17	10.30	74.20	17.79	.92	.34	.01	2.22	.14	.04
VABS Social	71.96	19.34	71.42	12.06	71.57	11.11	75.00	13.25	52.00	.31	.02	1.97	.16	.03
VABS Motor	77.25	13.24	77.46	15.17	81.87	12.80	80.17	15.39	.18	.67	.00	.29	.58	.00

F F value; P p value; ES partial eta squared effect size

increasing their scores across the 12-month period (F (1, 52) = 21.83, $p < .001$). There were no main effects of Time, Group or Group × Time interaction on each of the other subscales indicating that participants across groups maintained their VABS standard scores in all areas with the exception of the communication domain where they improved significantly over 1 year of treatment.

ADOS Subscales

As reported in Table 6, there was a significant Time effect on the Social Affect scale of the ADOS with a decrease in severity of social affect symptoms following treatment (F (1, 54) = 5.40, $p < .05$), and no main effect of Group or Time × Group interaction. There were no main effects of Time, Group or Time × Group interaction with regard to the Repetitive Behaviours scale of the ADOS.

Predictors of Outcomes

Additional analyses were conducted to investigate factors associated with outcomes. The following putative predictor variables were selected on the basis of theoretical relevance to the outcomes and previous research findings (Magiati

Table 6 Secondary outcome measures—ADOS subscales pre- and post-treatment scores

	12-month outcome								Group comparison					
	ESDM				Control				Time			Group × Time interaction		
	Baseline		Time 2		Baseline		Time 2							
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P	ES	F	P	ES
ADOS social affect	12.93	4.13	11.96	4.67	12.48	4.38	11.00	4.81	5.40	<.05	.09	.24	.62	.00
ADOS RBBs	4.37	2.06	4.07	2.33	3.79	2.09	3.55	1.47	.85	.36	.01	.00	.92	.00

F F value; *P* p value; *ES* partial eta squared effect size

Table 7 Correlations between putative predictors and gains in the primary outcome measures

| | ESDM | | | Control | | |
	MSEL Δ	VABS Δ	ADOS Δ	MSEL Δ	VABS Δ	ADOS Δ
Baseline ADOS	−.20	.12	−.53**	−.01	−.28	−.69**
Baseline MSEL	.09	.14	.28	.11	.21	.16
Baseline receptive language	.01	.15	.15	.10	.08	.13
Baseline expressive language	−.18	.21	.00	.05	.12	.12
Baseline VABS	.15	−.25	.64**	.34[†]	.30	.18
Chronological age	−.12	.13	−.32	−.36*	−.09	.02

Δ indicates mean change from baseline to post-treatment; [†] $p < .07$; * $p < .05$; ** $p < .01$

Table 8 Summary of hierarchical regression analysis for variables predicting gains in MSEL DQ

| Predictor variables | Gains in MSEL DQ | | | | | | | | |
	B	SE B	β	B	SE B	β	B	SE B	β
Group	−6.49	3.06	−.27*	−5.94	3.02	−.25[†]	−1.71	.72	−.25*
Age				−.32	.18	−.22	−.24	.19	−.16
Baseline VABS							.19	.14	.17
R^2	.07			.05			.02		
F Change	4.48*			3.09			1.66		

[†] $p = .05$; * $p < .05$

et al. 2012): Baseline symptom severity (ADOS severity score), baseline developmental level (MSEL overall DQ), baseline language level (MSEL receptive and expressive language DQs), baseline adaptive functioning (VABS baseline ABC score) and chronological age. The correlations between these predictors and outcome measures (as reflected in change scores between pre- and post-treatment on the MSEL overall DQ, VABS ABC and ADOS severity) were examined first (see Table 7). Follow-up linear regressions with those predictors that showed a significant correlation with the outcome measures were then conducted, with group entered at the first step and the independent variables entered according to the strength of the bivariate correlation.

The regression on gains in MSEL DQs, which included group, chronological age and baseline VABS as predictors, showed that the only predictor variable that accounted for a significant amount of the variance was group (see Table 8). The regression on ADOS gains included group, baseline ADOS and baseline VABS as predictors, and showed that baseline ADOS was the only significant predictor in the model (see Table 9).

Feasibility

Acceptability

Results from a parent survey indicated that, on a five point Likert-based scale, more than 90 % of parents agreed or strongly agreed on the program being suitable and satisfying. Specific questions on the survey included "The program offers an appropriate early learning and intervention model for my child", "The program offers a high level of care for my child" and "The staff displays a high level of professionalism in implementing the program". Likewise, a survey based on a similar format documented that more than 80 % of staff rated the program as high on acceptability. Specific items in the survey included "The

Table 9 Summary of hierarchical regression analysis for variables predicting gains in ADOS severity scores

Predictor variables	Gains in ADOS Severity Scores								
	B	$SE\ B$	β	B	$SE\ B$	B	B	$SE\ B$	β
Group	−.28	.60	−.06	−.57	.49	−.12	−.51	.49	−.11
Baseline ADOS				−.61	.11	−.60**	−.52	.14	−.51**
Baseline VABS							.03	.92	.14
R^2	.07			.05			.02		
F Change	4.48*			3.09			1.66		

* $p < .05$; ** $p < .001$

program addresses the developmental and educational needs of young children with ASD" and "The training I received on the ESDM facilitated my capacity to perform my duties". The retention rate of families enrolled in the program was >90 %, and retention rate was >90 % amongst the staff, with the core staff members who were successfully trained to fidelity in the ESDM when the program was launched (most of whom were junior professionals with little previous expertise in ASD) retaining their positions throughout the duration of the program.

Demand

Since the start of the program in 2010, 255 families applied for a place in the autism specific program, indicating that demand for the program far exceeded the program capacity.

Implementation

All the required components were executed within the program on a consistent basis by the ESDM trained and certified staff, as indicated by an independent evaluation of the program by the developers of the ESDM through site visits and review of videos (see treatment adherence section).

Practicality

A number of audits were conducted by the Australian Children's Education and Care Quality Authority, which indicated that the requirements of the ESDM were consistent with those of the regulatory body (Early Years National Quality Framework regulation). The latest evaluation report summary statement indicates "The service is rated as Meeting National Quality Standard overall. The service also achieved a rating of Exceeding National Quality Standard for some standards and quality areas. The service demonstrated consistent strengths in collaborative partnerships with families and communities, and leadership and service management" (Australian Children's

Education and Care Quality Authority National Quality Standard Assessment and Rating Report 2014).

Adaptation and Integration

While it was anticipated that the integration of the ESDM in a community childcare setting would be challenging, the functioning of the childcare facility was not negatively affected by the implementation of the model. An independent evaluation of the program commissioned by the Federal Government (Department of Family, Community Services, Housing, and Indigenous Affairs 2012), indicated that "the model of integrating an autism specific program within a long-day childcare setting provides positive outcomes". Nevertheless, a number of obstacles had to be overcome in order to ensure successful integration of the program.

The obstacles included changes in the expectations of staff activities (e.g., conducting the ESDM assessments and writing goals every 3 months) as well as changes in the environment (i.e., moving light switches out of children's reach). Tracking individual children's programs and monitoring gains on a daily basis proved to be a significant challenge, and this prompted the development of a customised electronic data collection system. Specific challenges identified by the independent government evaluation include the following "The ESDM is a resource intensive model to implement" and "this model provides a very high level of service to a very small number of families. These children are receiving what could be considered to be a 'gold standard' level of assistance" and the centre is "experiencing considerable pressure from those parents who miss out to make more places available"

Discussion

Over the past decades, evidence has accumulated supporting the effectiveness of various behavioural/psychosocial treatments for a number of conditions (Kern et al. 2009; Riosa et al. 2011; Weisz and Kazdin 2010).

However, few effectiveness studies have been conducted in the field of ASD (Drahota et al. 2012; Lord et al. 2005; Magiati et al. 2007; Mandell et al. 2013). In this community effectiveness study we examined the outcomes for preschoolers with ASD undergoing the ESDM and a generic autism educational intervention program delivered in the context of community day care services. We found that children in both groups made significant gains in cognitive skills, adaptive functioning, and social communication, suggesting that relatively intensive community implementation of behaviourally based early intervention programs is beneficial for preschoolers with ASD. We also found that children receiving ESDM in a group setting showed significantly greater increases in developmental rates, and significantly greater gains in receptive language development as compared to the comparison group. We did not find changes in global symptom severity, as measured by the ADOS, in either of the groups.

The pattern of results found in this community-based study is similar to the outcomes of the 1:1 ESDM implementation documented in the Dawson et al. (2010) RCT study. Notably, in both studies, participants receiving ESDM after 12 months showed gains in the MSEL that were superior to those observed in the comparison group, gains in VABS that were comparable to those of the comparison group (although in the Dawson paper group differences emerged at 24 months), and no significant changes in ADOS global severity scores. Moreover, when considering the MSEL subscales, in both studies, participants undergoing ESDM intervention showed the most sizeable gains in the area of receptive language, and the least gains in the area of fine motor skills. Given the critical relevance of early cognitive and language skills for long-term outcomes in ASD (Howlin et al. 2009, 2013), the ESDM program appears to be a promising approach for pre-schoolers with ASD not only in the context of 1:1 delivery (as documented by Dawson et al. 2010) but also in community-based group settings. Results of our controlled study are also consistent with those reported in Eapen et al. (2013) and Vivanti et al. (2013), providing further support for the usefulness of this approach in the context of group-based community settings. Further research is needed to replicate and extend the results presented here and to analyse the cost-effectiveness of this program in the short and long term.

As in previous intervention studies (Howlin 2011), there was remarkable individual variability in gains across groups and domains. However, initial developmental level, language and chronological age were not significantly associated with outcomes, a surprising finding considering previous literature (Howlin and Savage 2013; Rogers and Vismara 2008) but one previously reported for the 2010 ESDM RCT study (Dawson, unpublished address 2012). Rather, we found that children with more severe autistic symptoms showed fewer gains across groups. As the ADOS severity score is a composite score reflecting a number of underlying processes, more research is needed to understand the specific factors associated with individual differences in outcomes. A fine-grained analysis on predictors of outcomes in the same sample was recently published (Vivanti et al. 2013) showing that individual differences in play, joint attention and imitation were strongly related to treatment outcomes. However, as data on these measures were not available for the comparison group, it remains unclear whether this set of predictors is specific to the ESDM.

The analysis of feasibility indicators suggests that the ESDM has the potential to be implemented under real-world conditions, including the use of teachers and childcare staff recruited through standard channels as therapists, the inclusion of young children referred through community agencies, and therapy provided within the regulatory constraints of community long-day care provision. The overall cost of providing full time care and intervention across the two therapy groups was similar. While this cost was relatively high, these programs have the benefit of sustainability compared to the significantly higher cost of equivalent 1:1 therapy. Additional benefits include the fact that families were accessing childcare services (paying a standard childcare fee) rather than needing to be at home for the delivery of therapy, and therefore were able to engage in employment and other community activities. Based on these considerations, community implementation of this program appears to be a promising model for other community-based programs to effectively address the learning needs of young children of ASD. However, while the service was accessed by many families from low socio-economic status (see Table 1), the program was not accessible for those families who could not afford day-care fees. Nevertheless it is important to note that daycare fees in Australia are subsidized for families, particularly for those in the low-income bracket. However, more research is needed to facilitate universal accessibility of evidence-based early intervention programs for all children in the spectrum.

A limitation in the current study was that the intervention program delivered at the comparison group site was not manualized and did not involve a formal fidelity process, so that treatment adherence was not testable; thus information on similarities and differences with the ESDM was limited. In the absence of manualized guidelines, it was not clear to what extent the comparison program was representative of a standard community program or whether the sizeable gains obtained by children in the comparison program were due to specific strategies and procedures. It should also be noted that in the current study community implementation of the ESDM was analysed and documented in the context of the Australian regulatory

framework. Given the significant variations in legislations across different countries, more research is needed to investigate the feasibility of this model across different contexts. Moreover, the relatively small sample size might have reduced our ability to detect significant treatment moderators. Future research should focus on comparing delivery of the ESDM to other manualized treatments using large sample sizes that are better powered to detect putative moderators, and that allow for a more fine-grained investigation of how different treatment strategies might affect different developmental domains in different children.

Finally, while parent information sessions were provided in the ESDM group, no formal requirement was placed on implementing treatment strategies at home; thus it was not possible to factor the role of parents into the results documented in the study. Given the relevance of parent involvement in ASD intervention (Dunn 2013), future research is needed to investigate the role of parents in the context of community-based treatment provision. Another relevant limitation is that data on family SES and maternal education were available only for the ESDM group, and therefore we were unable to control for these potential confounding factors. This issue, together with the major caveats inherent in the use of quasi-experimental designs, points to the need for future larger scale studies investigating treatment outcomes in the context of community-based services studies, controlling for all the potentially confounding contextual factors (Vivanti et al. 2014). Moreover, research designs involving cluster randomized trials with childcare centres as the unit of analysis could provide a more rigorous methodology to test effectiveness of community implemented programs in future research. As these types of studies present with many logistical challenges, the establishment of solid partnerships between research institutions (e.g., academia) and community providers is necessary to facilitate progress in this critical area (Dingfelder and Mandell 2011).

In conclusion, this study was the first community effectiveness controlled study of ESDM. Even with the adaptations of delivering ESDM in small groups and at a much larger teacher:student ratio than the 1:1 described in the previous literature on ESDM, this controlled study replicated several findings from the 2010 Dawson et al. efficacy study, in particular the significantly greater DQ gains in the ESDM group than the comparison group, and the faster rate of receptive language development in the ESDM sample. Given the convergence of these findings with the original study, and the efforts to implement ESDM in a manner consistent with the manual and fidelity measures, this first controlled effectiveness study indicates that the ESDM may have positive effects on development of young children in the context of community-based group settings. The findings also suggest that community childcare settings can successfully implement manualized autism-specific early interventions.

Appendix

See Table 10.

Table 10 Cognitive outcomes using MSEL age equivalence scores

	12-month outcome								Group comparison					
	ESDM				Control				Time			Group × Time interaction		
	Baseline		Time 2		Baseline		Time 2							
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	P	ES	F	P	ES
MSEL overall AE	20.97	7.33	34.12	11.16	20.50	7.85	29.85	11.64	179.41	<.001	.76	5.11	<.05	.08
MSEL VR AE	23.19	5.86	35.26	10.63	23.03	7.30	33.53	11.12	121.07	<.001	.68	2.83	.09	.05
MSEL FM AE	23.96	5.86	35.26	10.63	24.57	7.22	32.97	12.73	83.05	.001	.60	1.79	.18	.03
MSEL RL AE	16.56	9.32	31.26	11.94	16.40	8.99	26.20	12.18	141.16	<.001	.72	5.65	<.05	.09
MSEL EL AE	20.19	9.82	32.48	10.44	18.00	10.15	26.70	13.46	122.35	<.001	.69	3.59	.06	.06

F F value; *P* p value; *ES* partial eta squared effect size

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