

Effects of Parent-Implemented Early Start Denver Model Intervention on Chinese Toddlers with Autism Spectrum Disorder: A Non-Randomized Controlled Trial

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To evaluate the effects of a 26-week, high-intensity, parent-implemented Early Start Denver Model (P-ESDM) intervention on developmental outcomes, severity of autism spectrum disorder (ASD), and parental stress of ASD toddlers in China. Subjects in P-ESDM group ($n = 23$) were recruited from 1.5- to 2.5-year-old toddlers who were screened positive in Xuhui and Minhang Districts and were diagnosed with ASD. A community (comparison) group of age-matched toddlers with ASD ($n = 20$) was recruited from other areas. Subjects of the P-ESDM group attended 1.5-hr parent coaching per week for 26 weeks, and those in the community group received interventions available from communities. Assessments were conducted at baseline (T1) and 26 weeks later (T2). After adjusting for baseline differences between the two groups, P-ESDM group demonstrated greater improvement than the community group in general development, especially in Language domain. Neither group demonstrated significant change in ASD severity, but the P-ESDM group showed greater improvement in social affect, parent-reported social communication and symbolic play than community group did. Finally, parents in P-ESDM group experienced decreased parenting stress while those in community group showed an opposite trend, though the differences did not reach significant association with the P-ESDM intervention. Chinese toddlers with ASD receiving 26 weeks of P-ESDM via regular coaching sessions showed significant greater improvement than those receiving community interventions in multiple aspects of development including social communications. These findings add support to the importance of providing early screening, diagnosis, and immediate referral for evidence-based interventions to improve outcome of young children with ASD. *Autism Res* 2017, 0: 000–000. © 2017 International Society for Autism Research, Wiley Periodicals, Inc.

Lay Summary: The development of early screening and diagnosis of autism spectrum disorder (ASD) in China has highlighted the importance of early intervention for young children with ASD. Our current study demonstrated that parent-implemented Early Start Denver Model (P-ESDM) via coaching from professionals improved developmental outcomes, especially in the language domain, and social communicational behaviors of Chinese toddlers with ASD. P-ESDM may help parents in China provide effective early intervention to their children with ASD via improving their skills when they are still at a waiting list for services or lack access to intervention, and has the potential to alleviate their parenting stress.

Keywords: early intervention; autism spectrum disorder; toddler; Parent-implemented Early Start Denver Model (P-ESDM); parenting stress

As a group of complex neurodevelopmental disorders, autism spectrum disorder (ASD) is characterized by deficits in social communication and interaction, and restricted and repetitive patterns of behaviors, interests, or activities, presenting in the early childhood and ranging widely in severity [American Psychiatric Association, 2013]. Although the pathogenesis of ASD is generally considered to arise from the interactions of genetic and environmental factors [Newschaffer et al., 2007], a

specific mechanism is unknown [Edmiston, Ashwood, & Van de Water, 2017; Huguët, Ey, & Bourgeron, 2013]. While ASD has been considered a severe and chronic disability for decades, dozens of studies have demonstrated that early intervention can improve both short- and long-term outcomes of children with ASD [Dawson et al., 2012; Dawson et al., 2010; Leaf et al., 2009; McEachin, Smith, & Lovaas, 1993; Rogers et al., 2014; Taubman et al., 2001; Wetherby et al., 2014].

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Among a wide variety of intervention approaches, the Naturalistic Developmental Behavioral Interventions (NDBIs) are now arousing more and more attention due to their consistency with the characteristics of infants' and toddlers' learning processes [Schreibman et al., 2015]. NDBIs integrate developmental and relationship-based approaches with strategies of applied behavior analysis, and emphasize establishing joint activity routines in natural environments, including play and daily life activities in which many learning opportunities can be embedded. An increasing number of studies have demonstrated the effects of NDBIs, including focused [Ingersoll, B 2010; Kaale, Fagerland, Martinsen, & Smith, 2014; Kaale, Smith, & Sponheim, 2012] and comprehensive interventions [Dawson et al, 2010], on children who have ASD. Early Start Denver Model (ESDM) [Dawson et al., 2010] is one of the representative approaches of comprehensive NDBIs.

The positive effect of ESDM has been documented by previous studies [Dawson et al, 2010; Vismara, Young, & Rogers, 2013; Rogers et al., 2014; Vivanti et al., 2014; Devescovi et al., 2016; Vivanti, Dissanayake, & Victorian, 2016; Waddington, van der Meer, & Sigafos, 2016; Touzet et al., 2017]. Reports from the first randomized controlled trial [Dawson et al., 2010, 2012] indicated that ESDM intervention delivered by therapists for 2 years improved cognitive, linguistic, and adaptive behavior and also reduced severity of symptoms of ASD toddlers compared with community interventions, and the gains were maintained 2 years later [Estes et al., 2015]. Furthermore, the improvements in social behavior after ESDM intervention were associated with normalized patterns of brain activity [Dawson et al., 2012] unlike the community treated children.

In recent decades, there has been a growing appreciation among practitioners of the importance of early intervention for ASD. An increasing number of studies supported the efficacy of parent-delivered early interventions for children with ASD and other developmental disorders [McConachie & Diggle, 2007; Green et al., 2010; Keen, Couzens, Muspratt, & Rodger, 2010; Wetherby et al., 2014]. Even low-intensity parent-implemented early intervention contributes to better generalization and maintenance of acquired skills. Wong et al. [2015] reviewed 1090 qualified English articles and recommended parent-implemented intervention (PII) as one of 27 focused intervention practices that met the criteria of evidence-based practice. Therefore, conducting and training parents/caregivers to be important implementers and collaborators of the intervention program of ASD individuals has become a topic of study in early intervention of ASD.

Rogers, Vismara, and Dawson [Rogers et al., 2012] developed parent-implemented ESDM, which fits well with the importance ESDM places on the quality of

social relationship between children with ASD and their caregivers. Although the P-ESDM had not demonstrated as large effects on toddlers' developmental outcomes and severity of diagnoses as does delivery of intensive ESDM [Vismara, Colombi, & Rogers, 2009; Rogers et al., 2012; Vismara et al., 2013], it has shown significant effects on parental stress levels compared with community intervention [Estes et al., 2014]. A current randomized controlled trial of low intensity P-ESDM demonstrates a positive relationship between parent mastery of P-ESDM techniques and amount of social communication development of their children (Rogers et al., in review).

Currently in China, interventions for ASD toddlers under 3 years have been under-developed, and there has been a lack of a systematic, evidence-based, practical method of early ASD intervention [Huang, Jia, & Wheeler, 2013; Song, Giannotti, & Reichow, 2013]. Meanwhile, parents and caregivers of toddlers with ASD have little access to interventions for their children or training for themselves about early intervention. Given the need in China, we introduced P-ESDM and tested its effects on developmental and social-communicational outcomes of Chinese toddlers with ASD and on parenting stress of their parents, using the same curriculum and techniques as those in the original P-ESDM studies. Given the inconsistent findings of P-ESDM and the suggestion by Rogers et al that intensity and duration may be important variables, we provided P-ESDM at a slightly higher intensity and a longer duration than in the previous P-ESDM studies.

Participants

Recruitment

The toddlers in the P-ESDM group were recruited from a group who screened positive using Checklist for Autism in Toddlers (CHAT-23) [Wong et al., 2004; Wu, Xu, Liu, Xia, & Cao, 2010] in community health centers of Xuhui and Minhang Districts, referred to Maternal and Child Health Care Hospitals and ultimately diagnosed in the Department of Child Health Care, Children's Hospital of Fudan University. Subjects in the community group were ASD toddlers from other regions who got the diagnosis in the same center. The inclusion and exclusion criteria of the two groups were in detail below.

P-ESDM group inclusion criteria:

1. Toddlers diagnosed with ASD according to a clinical judgement based on the criteria of ASD in Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [American Psychiatric Association, 2013] and further confirmed with Autism Diagnostic Observation Schedule, Second Edition (ADOS-2)

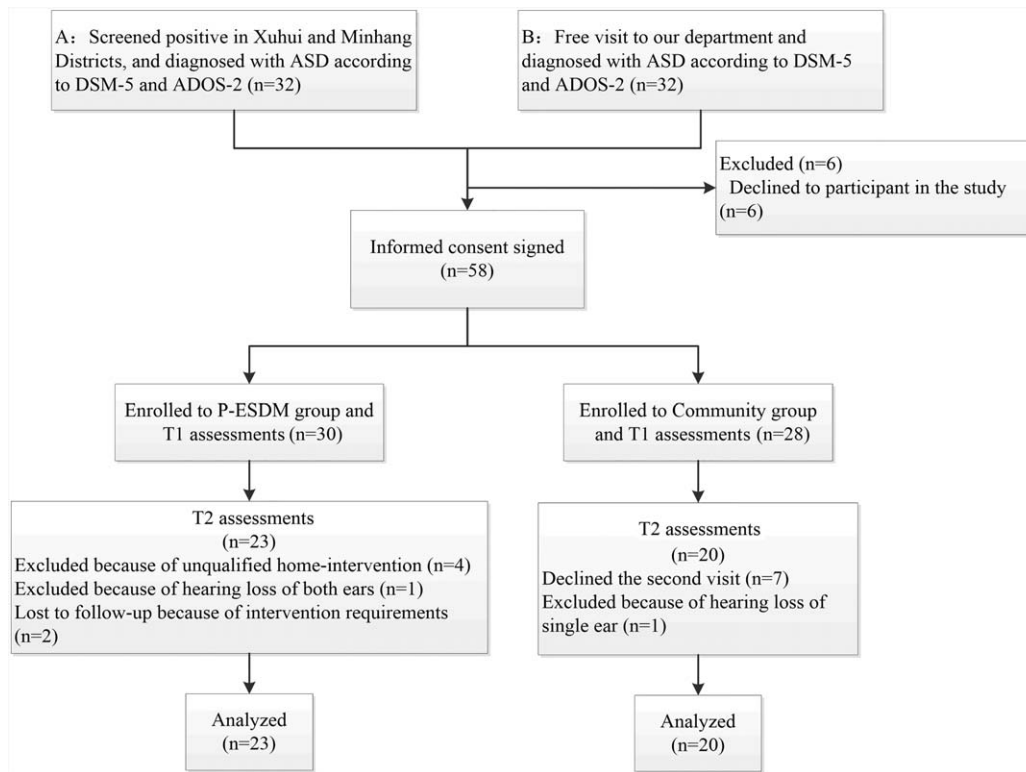


Figure 1. P-ESDM participant chart. ASD: autism spectrum disorder; DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; ADOS-2: Autism Diagnostic Observation Schedule, Second Edition; P-ESDM: Parent-implemented Early Start Denver Model; T1: Baseline; T2: Post-intervention.

[Gotham, Risi, Pickles, & Lord, 2007; Lord et al., 2000];

2. Ages 1.5-2.5 years;
3. Parents/caregivers understood the content of the study and agreed to participate in, to receive 26-week ESDM intervention after having a conversation with the researchers, and signed the informed consent during the enrollment.

Exclusion criteria:

1. Rett Syndrome, Fragile X Syndrome, Angelman Syndrome, Prader-Willi Syndrome, tuberous sclerosis, and other syndromes caused by known genetic defects or inherited metabolic diseases;
2. Toddlers with brain injuries;
3. Toddlers with physical or sensory disabilities;
4. Failure of parents to attend a 1-day parent training before beginning treatment;
5. More than three consecutive unexcused absences in the one-to-one treatment sessions over 26 weeks;
6. Parents did not complete the "Intervention Record Sheets" or provide home videos as assigned three times across the 26 weeks.

Community group (CG): This group included children and parents who disagreed to receive the P-ESDM intervention and those who would not be

living in Shanghai for the next 6 months, but agreed to receive the assessments and examinations required in the study. The other inclusion and exclusion criteria of participants in the community group were the same as that in the P-ESDM group.

Figure 1 shows the participant flowchart. Retention rates were 76.7% for the P-ESDM group (23/30) and 71.4% for the community group (20/28) at the post-intervention (T2) assessments.

Methods

The ethics committee of Children's Hospital of Fudan University approved the study. All the toddlers received the assessments, examinations, and interventions under informed consent signed by their parents or caregivers.

Measurements

Baseline (T1) Assessments.

1. Developmental and behavioral medical history, demographic factors and family situations, including birth weight (BW), gestational age (GA), delivery mode, maternal age, paternal age, family income, and parents' education degrees.

2. Griffiths Development Scales-Chinese version (GDS-C) [Li et al., 2016; Xia, Challis, & Faragher, 2016]: The GDS-C is a standardized developmental assessment tool used for children from birth to 8 years old in China. There are five domains (A-E: Locomotor, Personal-Social, Language, Eye-hand Coordination, and Performance) for toddlers under 2 years old, and one more domain (F: Practical Reasoning) for children aged from 2 to 8. It was localized and validated from Griffiths Mental Development scales Extended Revised [Luiz et al., 2004; Luiz et al., 2006]. The developmental ages (DA) are referred from the norms and developmental quotients (DQs) are calculated by DA/CA (chronological age)*100. DQs for domains have a mean of 100 (SD: 15).
3. Autism Diagnostic Observation Schedule, Second Edition (ADOS-2): ADOS-2 [Gotham et al., 2007; Lord et al., 2000] is used for observing autism symptoms in social affect (SA), play, restricted and repetitive behaviors (RRBs) in a series of standardized, semi-structured activities. The score of each item in the algorithm ranges from 0 to 2, with higher score indicating more severe deficits. The total score of SA and RRB can be transformed into a standardized severity score to compare directly across modules.
4. Communication and Symbolic Behavior Scales Developmental Profile-Infant Toddler Checklist, CSBS-DP-ITC [Wetherby & Prizant, 2002]: This is a parent-reported questionnaire widely used for screening communication disorders including ASD in infants and toddlers between 6 and 24 months old. The whole scale consists of 24 items divided into three subscales (social, speech, and symbolic composite) and an open question at the end. The changes in raw scores of each subscale and the whole scale partly reflect the change in social communication skills of children.
5. Parenting Stress Index-Short Form (PSI-SF): Developed by Abidin [1995], the PSI-SF is a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree) with three reverse-scoring items. It includes three subscales with 12 items each: parenting distress (PD), parent-child dysfunctional interaction (PCDI), and difficult child (DC). The PSI-SF score is considered to be an indicator of parenting stress associated with parents' anxiety, interactions with their children and child behaviors. Higher score relates to higher parenting stress.
6. Symptom checklist-90-revised (SCL-90-R): SCL-90-R [Derogatis, 1977] is a five-point Likert scale ranging from 1 (none) to 5 (severe) responding to each item. It helps evaluate a broad range of psychological problems and symptoms with items describing nine primary symptom dimensions. In the present study, parents of toddlers self-reported their possible mental difficulties by completing SCL-90-R.
7. Parent-completed measure: Intervention History Form. All parents were required to complete a weekly form in which they recorded all interventions other than P-ESDM received that week, beginning at T1 and continuing until T2, the end of the 26 weeks of active participation. We got the average intervention hours per week [Rogers et al., 2012] in the following manner. We calculated the number of weeks between their enrolling in and completing our study (W_T), the number of weeks (W) each treatment occurred from start to ending dates, the length of any breaks in treatment (W_b), the length of time of each treatment session (t), its frequency per week (F), and the ratio of adults and children (r) of each intervention. We then calculated the intensity of each intervention (INT), expressed as the average number of hours of 1:1 treatment per week using the following formula: $INT = t * F * (W - W_b) * r / W_T$, and summed all INTs to indicate the total amount of treatment received.

Post-Intervention (T2) Assessments. All measures except the SCL-90-R were re-administered to both groups of subjects at the completion of 26 weeks.

Raters. The professionals who administrated those assessments were trained and blind to group assignment of each subject.

Description of the experimental intervention

The concept of ESDM intervention, which emphasizes following children's interests and active learning in daily routines, is somewhat different from the current parenting style in most Chinese families. Therefore, in order to improve the awareness of parents/caregivers to ASD, and to provide parents a general knowledge of P-ESDM intervention, parents in the P-ESDM group began training by reading the Chinese version of the book "An Early Start for Your Child with Autism - Using Everyday Activities to Help Kids Connect, Communicate, and Learn" [Rogers et al., 2012], followed by a one-day grouped parent training course and 26 consecutive 1.5-hr parent coaching sessions with their child and a therapist. During the 8 hr 1-day parent-training course, professionals introduced the main principles of ESDM, and described some essential P-ESDM techniques including play, imitation, nonverbal and verbal communication.

The previous P-ESDM study has demonstrated that parent-delivered ESDM for 12 weeks increased parent interaction skills and child progress markedly, but not

to a significantly greater extent than community intervention. Therefore, we planned to extend the duration of intervention to 26 weeks (2 cycles including 2 ESDM assessments) to determine effects of a longer treatment period.

Of the 26 consecutive coaching sessions, Session 1 and Session 14 were devoted to administrating the ESDM curriculum assessment and developing child's learning objectives. The topics of Sessions 2 to 11 were: (a) increasing child's attention and motivation; (b) using sensory social routines; (c) promoting dyadic engagement and joint activity routines; (d) enhancing nonverbal communication; (e) building imitation skills; (f) facilitating joint attention; (g) promoting speech development; (h) using antecedent-behavior-consequence relationships ("ABC's of learning"); (i) employing prompting, shaping, and fading techniques; and (j) conducting functional assessment of behavior to develop new interventions [Rogers et al., 2012].

Before each coaching session, therapists would request parents to read the corresponding chapter of the parents' book (Chinese version). At the beginning of each session, the therapist introduced the main points, and demonstrated the interpersonal process showing how to employ child-centered play sessions in several different activities, focusing on the topic of each session. In the last part of each session, the therapist discussed the topic while viewing the parent's videos of at least three activities at home with the parent. During the later coaching sessions (Sessions 15 to 26), the parents did direct work with their children in the second half of the session while the therapists coached them to embed child learning objectives into activities and create more learning opportunities for the child, ending with a brief review and discussion of the parent's videos at home.

Parents and caregivers of toddlers in the community group carried out a variety of interventions available in their communities.

Quality Control

Before beginning the study, therapists in this study attended the introductory and advanced ESDM workshop held by Professor Sally J. Rogers' team, and supervision from them during the study. Therapists met together to provide peer supervision weekly for 1.5 hr to discuss the implementation of the intervention to various children and to review fidelity of ESDM implementation by watching, coding, and discussing two 15 min video recordings of sessions from therapists in the study. The fidelity of each therapist was recorded once a month using the Early Start Denver Model Fidelity Coding Sheet [Rogers & Dawson, 2010] to follow the trajectory of change. The average fidelity of all therapists was on the

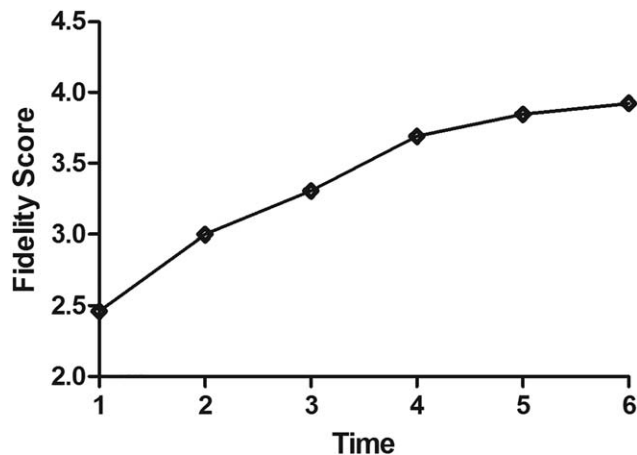


Figure 2. The trajectory of therapists' fidelity. the fidelity of ESDM intervention by therapists ranged from 1 to 5 with the higher score indicating higher quality of ESDM intervention.

rise and approached nearly 4 (1–5 with the higher score of fidelity indicating higher quality of ESDM therapy) when the intervention ended (Fig. 2). While we noted that the fidelity score at the beginning of the intervention was lower, because the trend of score was improving over the time, the low score at beginning may not have a significant impact on the overall efficacy at the end of intervention. At the time of the current publication, one of the authors (Qiong Xu) had been certified as an ESDM therapist by Dr. Rogers' team.

We asked parents to complete an "Intervention Record Sheet" weekly in which they recorded the activities, durations, and persons who interacted with the child every day. In addition, parents recorded at least three videos of different types of activities to review and discuss with their therapist.

Data Analysis

Descriptive statistics included frequency (%) and means and standard deviations (SD) for categorical and continuous variables, respectively. *t*-tests, non-parametric tests, and chi-square tests were used to compare the distributions of demographic data between the P-ESDM group and the community group, also to compare the changes over time of the two groups in developmental outcomes and ASD symptoms of children and parental stress.

To manage possible baseline differences between the two groups due to the non-randomized design, we used generalized linear model for further group comparisons to minimize the impact of other factors. We used the change scores between T2 and T1 ($\Delta=T2-T1$) as dependent variables, included categorical (education degree, annual family income, group) and continuous variables (intervention hours, baseline scores of domains in GDS-C) on which the two groups differed significantly

Table 1. Baseline Demographic Characteristics for P-ESDM and Community Control Groups

	P-ESDM group		Community group		χ^2/t	<i>P</i>
	<i>N</i>	%	<i>N</i>	%		
Gender	23		20		0.414 [†]	0.520
Male	21	91.3	17	85		
Female	2	8.7	3	15		
Paternal education					13.427 [†]	0.004
Primary/middle school	0	0	4	20		
High school	1	4.3	6	30		
College	15	65.2	9	45		
Graduate or higher	7	30.5	1	5		
Maternal education					8.950 [†]	0.047
Primary/middle school	0	0	4	20		
High school	4	17.4	5	25		
College degree	15	65.2	10	50		
Graduate or higher	4	17.4	1	5		
Delivery method					0.053 [†]	0.818
Vaginal	13	56.52	12	60.00		
Caesarean	10	43.48	8	40.00		
Family income (RMB/year)					8.468 [†]	0.076
More than ¥ 500K	3	13.1	1	5		
¥ 200–500K	9	39.1	2	35		
¥ 100–200K	10	43.5	12	35		
¥ 50–100K	1	4.3	3	15		
Less than ¥ 50K	0	0	2	10		
Baseline age (months)	26.65 ± 3.37		26.43 ± 4.52		0.188 [‡]	0.852
Paternal age (years)	32.09 ± 4.29		31.15 ± 6.34		0.575 [‡]	0.569
Maternal age (years)	29.39 ± 2.78		29.20 ± 4.54		0.169 [‡]	0.866
Gestational age (weeks)	39.35 ± 1.50		38.90 ± 1.07		1.113 [‡]	0.272
Birth weight (kg)	3.40 ± 0.29		3.44 ± 0.43		−0.414 [‡]	0.681
Paternal SCL-90-R score	149.53 ± 39.01		147.85 ± 43.97		0.126 [‡]	0.901
Maternal SCL-90-R score	133.27 ± 24.63		138.40 ± 46.54		−0.440 [‡]	0.663

P-ESDM: Parent-Implemented Early Start Denver Model.

†: chi-square test; ‡: *t* test. Data in rows from Baseline age to Birth weight are shown in mean ± standard deviation (SD).

(defined as a *P* value of 0.1 or greater) at baseline as factors and covariates respectively, with domains of GDS-C and subscales of ITC/PSI-SF as a repeated measure, and ran the regression models.

Results

Our primary hypothesis was that the P-ESDM would improve developmental outcomes and severity of ASD symptoms. Moreover, the secondary hypothesis was that the parent-implemented early intervention would also alleviate the parenting stress of parents of Chinese ASD toddlers.

Group Performances on Baseline and After-Intervention Data

The main demographic characteristics of children, parents and families in P-ESDM and community group (control) are presented in Table 1. Although well matched on most demographic variables, there were significant group differences on maternal (*P* = 0.047) and paternal (*P* = 0.004) educational degrees, and a

trend toward significance in annual family income between two groups (*P* = 0.076).

The group comparisons from T1 to T2 are shown in Table 2. At the baseline, the P-ESDM and community group differed significantly in children's DQs of Personal-Social, Language, Eye-hand Coordination and Performance domains. The two groups showed no significant difference in their baseline ADOS severity scores (*t* = −1.321, *P* = 0.195), but differed significantly in baseline Social Affect score (*t* = −2.057, *P* = 0.047).

At T2, the change scores of DQ in Language domain of the GDS-C showed the most significant difference, with an improvement of 23.63 points in the P-ESDM group compared with 2.25 points in the community group (*P* = 0.002). In Eye-Hand Coordination domain, the P-ESDM group also demonstrated an average DQ increase of 8.28 points compared with a decrease of 0.80 points in the community group (*P* = 0.026). The improvement in Locomotor and Personal-Social domains was also greater in P-ESDM group than that in the community group, a difference which approached significance (*P* = 0.084 and 0.093, respectively). In

Table 2. Child and Parent Variables: Intervention Group Differences with Time Point as a Repeated Measure

	P-ESDM group				Community group				P value (P-T1 vs C-T1)	P value (P-Δvs C-Δ)
	N	T1	T2	Δ	N	T1	T2	Δ		
Age (months)	23	26.65 ± 3.37	34.93 ± 3.00	8.28	20	26.43 ± 4.52	34.15 ± 4.67	7.72	0.852	0.156
GDS-C										
A:Locomotor (LM)	23	79.26 ± 8.00	80.26 ± 15.05	1.00	20	78.55 ± 13.26	71.70 ± 13.27	-6.85	0.830	0.084
B:Personal-Social (P-S)	23	66.74 ± 15.60	74.48 ± 10.60	7.74	20	51.45 ± 14.02	50.95 ± 10.79	-0.45	0.002	0.093
C:Language (Lan)	23	44.96 ± 18.98	68.59 ± 22.08	23.63	20	35.40 ± 15.65	37.65 ± 22.52	2.25	0.021 †	0.002 †
D:Eye-hand (E-H)	23	67.70 ± 15.26	75.98 ± 13.25	8.28	20	56.90 ± 13.68	56.10 ± 12.38	-0.80	0.020	0.026
E:Performance (PM)	23	75.52 ± 15.60	75.17 ± 10.33	-0.34	20	60.15 ± 14.63	58.85 ± 15.11	-1.30	0.002	0.843
ADOS-SA	20	15.95 ± 2.52	13.25 ± 2.63	-2.70	19	17.53 ± 2.25	16.26 ± 2.54	-1.20	0.047	0.030 †
ADOS-RRB	20	1.75 ± 1.50	1.95 ± 1.57	0.20	19	2.16 ± 1.12	2.16 ± 0.76	0.00	0.127†	0.304†
ADOS Severity Score	20	6.40 ± 1.23	6.30 ± 1.26	-0.10	19	6.89 ± 1.10	6.58 ± 1.12	-0.31	0.195	0.577†
CSBS-DP-ITC										
Social composite	17	9.21 ± 2.26	15.79 ± 3.79	6.57	16	9.93 ± 2.76	12.43 ± 3.58	2.50	0.452	0.005
Speech composite	17	5.00 ± 1.80	11.43 ± 3.13	6.43	16	5.40 ± 2.50	7.38 ± 4.32	2.06	0.627	0.000
Symbolic composite	17	7.21 ± 1.58	13.71 ± 3.15	6.50	16	7.67 ± 3.09	9.25 ± 3.53	1.81	0.621	0.000 †
Total	17	21.43 ± 3.94	40.93 ± 8.06	19.50	16	23.00 ± 7.24	29.06 ± 10.25	6.37	0.472	0.001 †
PSI-SF	20				20					
PD	20	33.50 ± 2.95	31.00 ± 5.33	-2.50	20	32.25 ± 7.94	33.40 ± 7.02	1.15	0.516	0.031
PCDI	20	32.55 ± 6.85	28.95 ± 4.56	-3.60	20	30.25 ± 5.54	31.70 ± 7.72	1.45	0.250	0.017
DC	20	34.30 ± 5.81	32.60 ± 6.48	-1.70	20	31.75 ± 6.48	34.30 ± 5.84	2.55	0.198	0.037
Total	20	100.35 ± 11.12	92.55 ± 10.63	-7.80	20	94.25 ± 17.81	99.40 ± 17.10	5.15	0.202	0.003 †
Intervention hours†	21		4.57 ± 1.98		18		3.25 ± 2.40		<i>P</i> = 0.061	

P values in bold indicated that there was a significant difference between the corresponding ages/scores/hours of the two groups (*P* < 0.05).

P-T1 vs C-T1: Comparison of baseline ages/scores/hours between the P-ESDM group and the Community group.

P-Δ vs C-Δ: Comparison of changed ages/scores (T2-T1) between the P-ESDM group and the Community group.

P-ESDM: Parent-Implemented Early Start Denver Model.

GDS-C: Griffiths Developmental Scales – Chinese; LM: Locomotor; P-S: Personal-Social; Lan: Language; E-H: Eye-Hand; PM: Performance.

ADOS: Autism Diagnostic Observation Schedule; SA: Social Affect; RRB: Restricted Repetitive Behavior.

CSBS-DP-ITC: Communication and Symbolic Behavior Scales Developmental Profile Infant-Toddler Checklist.

PSI-SF: Parenting Stress Index-Short Form; PD: parenting distress; PCDI: parent-child dysfunctional interaction; DC: difficult child.

†: Mann-Whitney Test. The others were *t*-tests.

contrast, neither the P-ESDM nor the community group demonstrated significant changes on ADOS severity scores (*P* = 0.577).

Similarly, the improvement on ITC scores in the P-ESDM group differed significantly from those in the community group. In each subscale and the total score of the ITP, toddlers in the P-ESDM group improved more significantly than those did in the Community group (all *P* values lower than 0.01).

In terms of changes in parental stress over time, the P-ESDM parents reported a decrease in stress ($\Delta < 0$) between T2 and T1, whereas the community parents reported increasing stress ($\Delta > 0$), resulting in a significant group difference between the P-ESDM and the Community group (*P* = 0.003 for the total score of PSI-SF).

Generalized Linear Model of Change in Child and Parent Outcomes

We performed generalized linear model (GLM) in order to account for the significant baseline differences in our groups at T1 as we examined the effects of the experimental treatment. For these analyses we used difference

scores between T2 and T1 ($\Delta = T2 - T1$) as dependent variables. Considering the correlations among the scores in each domain or subscale, we ran the GLM with domains or subscales as a repeated factor. The factors also included maternal education degree, annual family income and group. Paternal education degree was excluded because of its high correlation with maternal education degree ($r = 0.627$, *P* < 0.001). The intervention hour was included as a common covariate. In addition, the scores of Personal-social, Eye-hand coordination, and Performance domain in GDS-C, in which the groups significantly differed at T1, were included as covariates when analyzing group difference in developmental outcomes.

Using generalized linear models, the differences between the two groups with regard to the changed scores of GDS-C were analyzed (Table 3). Calculation of regression coefficients (*B*) showed that toddlers in the community group, regardless of other differences, had significantly less improvement in scores of GDS-C ($B = -14.624$, *P* < 0.001) compared to toddlers in the P-ESDM group, especially in the Language domain ($B = -14.477$, *P* < 0.001). Additionally, intervention hour was positively associated with significant improvement in

Table 3. Factors Associated with the Changes in Child and Parent Outcome Using Generalized Linear Model

Parameter	B	SE	Wald χ^2	Df	P value
ΔGDS-C score (T2-T1)					
P-ESDM group (reference)	-	-	-	-	-
Community group	-14.624	3.050	22.995	1	0.000
LM	1.860	3.116	0.357	1	0.550
P-S	-4.721	3.116	2.296	1	0.130
Lan	-14.477	3.116	21.587	1	0.000
E-H	-4.849	3.050	2.422	1	0.120
PM (reference)	-	-	-	-	-
Family income (RMB/yr)					
Less than ¥ 50K (reference)	-	-	-	-	-
¥ 50-100K	-7.111	6.037	1.387	1	0.239
¥ 100-200K	1.976	6.644	0.089	1	0.766
¥ 200-500K	1.922	6.395	0.090	1	0.764
More than ¥ 500K	-3.111	7.379	0.178	1	0.673
Maternal education					
Primary/middle school (reference)	-	-	-	-	-
High school	-0.115	4.849	0.001	1	0.981
College degree	-8.559	4.866	3.094	1	0.079
Graduate or higher	-5.575	6.686	0.695	1	0.404
Intervention Hour					
P-S-T1	1.333	0.462	8.314	1	0.004
Lan-T1	-0.306	0.121	6.361	1	0.012
E-H-T1	-0.067	0.089	0.571	1	0.450
E-H-T1	-0.020	0.102	0.038	1	0.845
PM-T1	-0.043	0.103	0.174	1	0.676
ΔADOS severity					
P-ESDM group (reference)	-	-	-	-	-
Community group	0.573	0.406	1.993	1	0.158
ADOS severity-T1	-0.585	0.147	15.935	1	0.000
ΔSA					
P-ESDM group (reference)	-	-	-	-	-
Community group	3.168	0.873	13.157	1	0.000
SA1	-0.719	0.154	21.678	1	0.000
ΔRRB					
P-ESDM group (reference)	-	-	-	-	-
Community group	0.227	0.440	0.267	1	0.606
RRB1	-0.640	0.149	18.517	1	0.000
ΔITC					
P-ESDM group (reference)	-	-	-	-	-
Community group	-5.560	0.753	54.512	1	0.000
Family income (RMB/yr)					
Less than ¥ 50K (reference)	-	-	-	-	-
¥ 50-100K	0.181	1.413	0.016	1	0.898
¥ 100-200K	3.958	1.746	5.141	1	0.023
¥ 200-500K	3.978	1.718	5.359	1	0.021
More than ¥ 500K	2.434	1.974	1.520	1	0.218
Maternal education					
Primary/middle school (reference)	-	-	-	-	-
High school	-0.275	1.412	2.161	1	0.142
College degree	-4.293	1.386	9.601	1	0.002
Graduate or higher	0.515	1.713	0.091	1	0.764
Intervention hour					
ITC-Total-T1	0.386	0.114	11.455	1	0.001
ITC-Total-T1	-0.175	0.053	11.080	1	0.001
ΔPSI-SF					
P-ESDM group (reference)	-	-	-	-	-
Community group	1.585	1.222	1.680	1	0.195
Maternal education					
Primary/middle school (reference)	-	-	-	-	-
High school	7.987	2.168	13.572	1	0.000
College degree	7.376	2.089	12.472	1	0.000
Graduate or higher	7.628	2.849	7.168	1	0.007
PSI-SF-T1	-0.134	0.034	15.640	1	0.000

P values in bold indicated that there was a significant difference between the corresponding ages/scores/hours of the two groups ($P < 0.05$).

Maternal education is listed with the first category (Primary/middle school) as the reference; Annual family income are listed with the first category (Less than ¥ 50K) as the reference.

GDS-C: Griffiths Development Scales-Chinese; LM: Locomotor; P-S: Personal and Social; Lan: Language; E-H: Eye-Hand Coordination; PM: Performance.

P-S-T1: baseline score of Personal and Social domain; Lan-T1: baseline score of language domain; E-H-T1: baseline score of Eye-Hand Coordination domain; PM-T1: baseline score of Performance domain.

ADOS: Autism Diagnostic Observation Schedule; SA1: baseline Social Affect score; Δ SA: the change score for Social Affect (T2-T1); RRB1: baseline score for Restricted Repetitive Behavior; Δ RRB: the change score for Restricted Repetitive Behavior (T2-T1).

ITC: Infant-Toddler Checklist; ITC-Total-T1: baseline score of ITC; Δ ITC: the change in total score of ITC (T2-T1).

PSI-SF: Parent stress index-short form; PSI-SF-T1: baseline total score of PSI-SF; Δ PSI-SF: the change in total score of PSI-SF (T2-T1).

Due to space limitation, we only reported effects of positive variables and the P-ESDM intervention in GLM except the GDS-C model.

developmental outcomes of ASD toddlers ($B = 1.333$, $P = 0.004$).

In terms of core symptoms of ASD, the GLM revealed that P-ESDM intervention would not lead to significant decrease of ADOS severity score compared to other interventions in community. However, after adjusting for the effect of baseline Social Affect score, P-ESDM intervention contributed significantly to the decrease in ADOS Social Affect score ($B = 3.168$, $P < 0.001$), but did not contribute to the change in RRBs.

On the ITC, P-ESDM intervention compared to the community group, as well as the baseline total score, contributed to improvement on the social, speech, and symbolic play. In addition, intervention that is more intensive would be related to more improvement in the ITC scores ($B = 0.386$, $P = 0.001$). In terms of family factors, both higher family income and higher maternal education degree were associated to more improvement.

In terms of the parent stress scores, although toddlers in the two groups showed an opposite trend in change of parenting stress on the three subscales of PSI-SF, only baseline score and maternal education degree contributed significantly to overall change of parenting stress. P-ESDM treatment did not contribute significantly to change on this measure.

Discussion

The present study is the first non-randomized controlled trial of Parent-implemented Early Start Denver Model in China. We recruited 30 18–30-month ASD toddlers and parents referred from community health care centers as subjects receiving P-ESDM intervention, and 28 age and developmentally matched ASD toddlers receiving community intervention and their parents as controls. We hypothesized that the P-ESDM intervention delivered at home by parents using therapists' low-intensity modeling and coaching would improve developmental outcomes and ASD severity. We selected this intervention because we felt the style of P-ESDM would be acceptable for Chinese parents and parent-implemented early intervention in natural, home-based environment is an appropriate approach for application and popularization in China, where there is a severe shortage of professionals in early intervention.

Effects of P-ESDM on Child Developmental Outcomes and ASD Severity

Our results illustrated that relatively high-intensity P-ESDM intervention for 26 weeks had positive effects on general developmental outcomes of Chinese toddlers with ASD, especially on their receptive and expressive language skills, which was consistent with the developmental results of the original ESDM study

[Dawson et al., 2010]. In general, the results met our expectations that low-intensity P-ESDM intervention over a 26-week period would improve the developmental outcomes of toddlers with ASD.

In an early case study of P-ESDM [Vismara et al., 2009], after completing 1-hr parent coaching once a week for 12 weeks, parents of the 6 ASD toddlers showed improvement in mastery of key techniques of ESDM. Parallel with that, frequency of children's spontaneous functional verbal utterances and imitative behaviors had also been increasing during the treatment and subsequent follow-up periods. However, the following randomized controlled trial of P-ESDM using the same intervention procedures demonstrated no significant effects of P-ESDM on developmental outcomes, adaptive behaviors, severity of ASD symptoms, and parent-child interactions compared with community group [Rogers et al., 2012]. The discrepancy between the results of the two studies demonstrated that P-ESDM has the potential to improve toddlers' developmental outcomes. However, the majority of parents in the case study acquired the techniques of ESDM at around weeks 8–9 of parent coaching. Thus, 12-week period might be not enough for parents to implement the intervention with sufficient intensity and quality [Rogers et al., 2012]. A retrospective study in Italy [Devescovi et al., 2016] demonstrated that 3-hr/week ESDM intervention with monthly meeting among professionals, parents and teachers improved language and cognition of children with ASD. The results also supported that higher-intensity P-ESDM intervention for longer duration helped enhance developmental outcomes of ASD toddlers. Furthermore, we thought that the 12-week period of intervention in the original study of P-ESDM [Rogers et al., 2012] might also be insufficient to cause significant changes on standardized measures of developmental and adaptive behaviors, which integrate many behavioral changes into overall improved performance. Therefore, P-ESDM intervention for 26 weeks in the current study was considered most appropriate for parents to acquire ESDM techniques and for toddlers to gain improvements in standard developmental measures.

Furthermore, authors of the original P-ESDM study [Rogers et al., 2012] considered that other responsible reasons might include that toddlers in community group received almost twice intensity of intervention as much as those in P-ESDM group did, and the community intervention might include similar services to the P-ESDM [Rogers et al., 2012]. However, in the present study, the difference of intervention intensity between P-ESDM and community group was not as significant as the previous study (almost half), which alleviated the effect of that factor. Moreover, it should be noted that the shortage of professionals and underdeveloped early

intervention of ASD in China lead to lower quality of community intervention compared with in U.S. This might be one of factors leading to more significant effects of P-ESDM than that of community intervention on child developmental outcomes.

Although longer duration of P-ESDM intervention showed positive effects on development of toddlers with ASD, their severity of ASD symptoms measured with ADOS was not reduced. This might be related to the reliability and stability of ADOS. As a diagnostic schedule, the result of ADOS assessment should be relatively stable, especially in a short period. Even after high-intensity ESDM intervention (20 hr/week for 2 years) delivered by trained therapists, toddlers still did not gain significant improvement in ADOS severity score [Dawson et al., 2010]. However, Devescovi et al. [2016] indicated that although no significant difference was found in the entire group between pre- and post-interventions, most toddlers younger than 27 months at baseline got reduced ADOS severity score after ESDM intervention. A logistic analysis further supported that younger age at the beginning of intervention was positively related to greater improvement in ASD severity (OR = 15, $P = 0.028$). Several studies [Howlin, Moss, Savage, & Rutter, 2013; Vivanti et al., 2016] have also reported similar results. However, the age-range of toddlers recruited in our study was relatively small between 18 and 30 months. We had not found the similar trend of change in ASD severity score with age.

It was still encouraging that parents in the both groups reported improvement in social, speech and symbolic play of their children, and P-ESDM intervention was positively associated with greater improvement. It indicated that ASD toddlers still made some gains in social communication and interaction after receiving early intervention, especially for the toddlers with P-ESDM intervention. We speculated that CSBS-DP-ITC measures behaviors that were more detailed and specific with a less integrated mode, compared with ADOS. Nevertheless, it is necessary to note that parent's involvement in intervention may affect their perceptions of their children's behaviors in positive ways. Thus, as a parent-rated scale, the scores of CSBS-DP-ITC may be liable to be affected by parent involvement in the intervention. In further studies, we will select some rating scales and observation instruments completed by teachers or professionals who are not directly involved in the intervention with the child, to evaluate and compare the change of children's behaviors as objectively as possible.

Effects of P-ESDM on Parenting Stress of ASD Toddlers

In terms of parenting stress, analysis of group difference demonstrated significant improvement in parents of P-

ESDM group and the opposite trend in the community group, as was also reported by Estes et al. [2014]. However, our linear model analyses did not result in any associations between group assignment and differences in stress over time.

There was a main difference in our intervention design compared with the original P-ESDM study [Rogers et al., 2012], which may be responsible for these contrasting findings. In our study, therapists spent a whole hour interacting with the child while parents were observing and half an hour discussing with parents about the topic of each session and videotapes of intervention activities at home. Even during the 15th to 26th week of P-ESDM intervention, parents only had 15 min to interact with their children directly under therapist coaching. However, in the previous study [Estes et al., 2014], therapists spent less than 10 min while parents spent 30–40 min directly interacting with the child in each 1-hr session, because they emphasized the collaborative coaching process and parental learning within the sessions. We thought that more modeling from therapists to parents would improve parent's mastery of techniques, but neglected the possible stress-reducing effects of collaborating and guided intervention practice, which have been reported in several earlier studies [Brookman-Frazer, 2004; Gray, Msall, & Msall, 2008; Moh & Magiati, 2012; Warfield, Chiri, Leutz, & Timberlake, 2014; Russa, Matthews, & Owen-DeSchryver, 2015].

Evaluation of Parents' Satisfaction with P-ESDM Intervention

For evaluating parents' satisfaction and feedback to our P-ESDM intervention, we performed a feedback questionnaire (Supplementary material 1) in parents of the P-ESDM group. We noted with pleasure that over 80% of the parents felt satisfied with our P-ESDM intervention, and over 90% of them thought they had mastered at least some techniques of ESDM intervention. From their feedback, we also consider it necessary to extend ESDM intervention to community health centers and kindergartens to help more children with ASD.

Limitations and Future Direction

The present study built upon on our early screening study (Li et al, under review). Toddlers aged between 18 and 24 months in our targeted areas underwent a standardized 3-step screening, referral, and diagnostic procedure. Toddlers who were evaluated as "positive" in screening test by CHAT-23 [Wong et al., 2004; Wu et al., 2010] received a typical diagnostic evaluation by developmental and behavioral pediatricians. Children who were diagnosed with ASD were listed as candidates for our P-ESDM early intervention study. In order to

improve the compliance of screening and follow-up, we considered all toddlers diagnosed with ASD through screening-referral procedure as potential subjects of the P-ESDM group, and recruited children with ASD for the community (control) group from clinics. Therefore, we designed and conducted a non-randomized controlled trial resulting in minor baseline differences between the two groups in some characteristics of child and parent. Although the retention rates for the two groups were similar, it was noted that parents of four children in the P-ESDM group who were excluded because of poor reporting of home interventions had less education than the others (primary/middle/high school). Thus, we speculated that parents who have lower education might have more difficulty carrying out the requirements of a research study. Besides, quality of community interventions in Shanghai might be higher than that in other areas, especially in less urban, lower resource areas. However, it would be difficult for us to quantify the quality of community interventions. In the future, we will continue recruiting more subjects and perform stratified analyses to explore the role of living areas in intervention outcomes. Another limitation was the lack of examination of parental fidelity of implementation of P-ESDM. Without knowing how well the parents delivered the model and how many hours weekly, we cannot assess the relationship between treatment administered and resulting effects.

In the future, we plan to carry out a long-term longitudinal follow-up study in the current cohort to evaluate long-term effects of P-ESDM compared to community treatment. Moreover, the level of evidence of the present study is obviously lower than that of a randomized controlled trial. Therefore, we also plan to conduct a multisite randomized controlled trial with a modified study design in China, to examine the effects of P-ESDM further on Chinese ASD toddlers.

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Conflict of interest

Dr. Rogers receives royalties from texts on the Early Start Denver Model. The other authors have no proprietary, financial, professional or other personal interests

of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled "Effects of Parent-implemented Early Start Denver Model Intervention on Chinese Toddlers with Autism Spectrum Disorder: A Non-Randomized Controlled Trial".

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Supporting Information

Additional Supporting Information may be found in the online version of this article.