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Parent-mediated intervention tends to improve parent-child engagement, and behavioral outcomes of toddlers with ASD-positive screening: A randomized crossover trial

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ABSTRACT

Background: By participating in parent-mediated interventions, parents develop skills to promote their toddler's development. Knowing that the potential mediating role of a parent's behavior has been poorly assessed, our objective was to measure the effects of a parent-mediated intervention on the developmental outcome of toddlers (12–30 months) at risk for autism spectrum disorder (ASD), and on parent-child interactions.

Methods: Randomized crossover trial using a 12-week parent-mediated intervention (adapted from the parent delivery of the Early Start Denver Model and the Social Communication Emotion Regulation Transaction Support) and measuring its impact on parent-child dyadic engagement and child development.

Results: The intervention resulted in improved toddlers' motor skills ($p = .005$; $ES = .60$) and a trend toward improvement in social adaptive behaviors ($p = .053$; $ES = .45$) compared to the Waitlist group. There was also a trend toward improved parent-child engagement during the Intervention ($p = .010$; $ES = .77$), that did not significantly differ from the change in the Waitlist group ($p = .221$).

Conclusions: This study highlights potential benefits in motor and social skills for children at risk of ASD, as well as in parent-child engagement.

1. Introduction

Now that it is possible to detect a high risk of autism spectrum disorder (ASD) in children during the first two years of life (Zwaigenbaum, 2005), efforts are being made to develop effective early interventions for toddlers at high risk of ASD. In this regard, it is important to emphasize that toddlers are more influenced by their caregivers than their peers, their learning is very contextualized, and they have poorer communication and symbolic skills than preschoolers (Zwaigenbaum et al., 2009). Thus, developmentally appropriate interventions have to be used to offer effective early intervention including parent involvement to toddlers with a diagnosis or risk of ASD (Rogers & Wallace, 2011).

Parent-mediated interventions that focus on joint attention, imitation and play (Aldred, Green, & Adams, 2004; Carter et al.,

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2011; Drew et al., 2002; Green et al., 2010; Kasari, Gulsrud, Wong, Kwon, & Locke, 2010; Landa, Holman, O'Neill, & Stuart, 2011; Mahoney & Perales, 2003, 2005; Oosterling et al., 2010) can capitalize on teachable moments as they occur, create learning opportunities during daily routines, and facilitate the generalization of learned skills across environments (Zwaigenbaum et al., 2015). Based on Bearss et al.'s (2015) taxonomy, parent-mediated interventions for core symptoms of ASD "are *technique-focused* interventions where the parent is the agent of change and the child is the *direct* beneficiary of treatment" (Bearss, Burrell, Stewart, & Scahill, 2015). In other words, parents are taught how to promote social interaction, communication, imitation and play skills to stimulate their child's development (Bearss et al., 2015). Based on this definition, parent-mediated interventions for core symptoms are well suited for targeting young children with ASD (Rogers & Wallace, 2011). In fact, they are based on the assumption that parents will implement within their daily interactions with their child strategies learned through the intervention, which will increase the time the child is stimulated in their natural environment, and optimize the opportunities to stimulate the child's socio-communicative skills in their daily routines (Siller, Hutman, & Sigman, 2013). Moreover, it seems that children with ASD who have communication skills below 12 months of developmental age may benefit more from these parent-mediated interventions compared to older children (Siller et al., 2013), highlighting the need for early intervention in toddlers at risk of ASD (Siller & Morgan, 2018).

Knowing that parents are the primary agents of caregiver-mediated interventions (Ingersoll & Wainer, 2013; Koegel, Bimbela, & Schreibman, 1996), the potential remediating role of parental interventions in the improvement of the behavioral outcomes of children should be assessed (Green & Garg, 2018). The investigation of proximal outcomes within the parent-child dyad offers opportunities to gain a better understanding of the mechanism of change of parent-mediated interventions that ultimately aims to decrease core ASD symptoms in toddlers (Green & Garg, 2018; Siller & Morgan, 2018). Although several articles reported the effects of parent-mediated interventions for toddlers with ASD on parent-child interactions, most studies reported inconsistent results with either no improvement or a trend toward an amelioration of the interaction (Mahoney & Perales, 2005, 2010, 2015, Carter et al., 2011; Green et al., 2013; Gulsrud, Jahromi, & Kasari, 2010; Kasari et al., 2014; Mahoney & Perales, 2003; Oosterling et al., 2010; Vismara, Colombi, & Rogers, 2009). Moreover, previously published studies mostly used distinct tools to assess parent *versus* child behaviors during interactions (Beaudoin, Sébire, & Couture, 2014) rather than using a tool that assesses simultaneously the parent's and child's influence highlighted by the transactional process in which each partner's behavior influences the other's (Sameroff, 1993). Based on the hypothesis that parent-child interactions potentially mediate child-related outcomes (Green & Garg, 2018; Mahoney & Perales, 2003), this study aims to evaluate the effects of a parent-mediated intervention for toddlers with a risk or diagnosis of ASD on the quality of parent-child interactions and children's developmental outcomes using a crossover randomized controlled trial (Intervention and Waitlist groups). The hypothesis is that families receiving the 3-month parent-mediated intervention would show an improvement in the quality of parent-child dyadic engagement, and increased child development, compared to those having to wait three months before obtaining the intervention.

2. Methods

2.1. Participants

Potential participants aged between 12 and 30 months who were at risk for ASD were referred to the research team by community health care services or by a regional screening program for ASD from July 2013 to March 2016. After referral, all families completed an eligibility screening questionnaire, the *Infant-Toddler Checklist* (Wetherby, Brosnan-Maddox, Peace, & Newton, 2008) for children aged between 12 and 17 months or the *Modified Checklist for Autism in Toddlers—Revised* (Robins et al., 2014) for children aged between 18 and 30 months. All potential participants who scored at risk for ASD on the screening questionnaire then completed the *Autism Diagnosis Observation Schedule—Toddler Module* (Luyster et al., 2009), and the evaluator used the ADOS-T algorithm to identify children of concern (eligibility criteria: "mild-to-moderate" or "moderate-to-severe" concern). The *Autism Diagnostic Interview-Revised* (Rutter, Le Couteur, & Lord, 2003) was then completed with at least one parent to get a better understanding of each child's developmental trajectory and current symptoms. Based on these assessments, children at risk of ASD and their families meeting eligibility criteria (parents understanding and speaking English or French adequately to benefit from the intervention whereas another language could be used predominantly at home) were included in the study.

After the initial assessment, families were randomly assigned either to the Intervention Group, which would receive the parent-mediated intervention right away, or the Waitlist Group, which had to wait three months before getting access to the intervention. The randomization was done in blocks of four based on the age of the child at recruitment (12–17 months; 18–30 months). However, only three participants were aged between 12 and 17 months, keeping the research team from conducting age-block analysis in terms of response to intervention. Depending on group allocation, participants completed three (Intervention Group) to four (Waitlist Group) assessments at different time points, each of them three months apart: see Fig. 1 for more details on the evaluation timeline.

Considering the absence of longitudinal data available for children with ASD on the *Engagement State, Child and Caregiver Behavior and Shared Topic Rating* (Adamson, Bakeman, Deckner, & Nelson, 2013), the sample size was calculated after completing the intervention with the first three families. Based on this preliminary data, the sample size required to detect a significant change after participating in the intervention (14.66 point changes on the *Engagement State, Child and Caregiver Behavior and Shared Topic Rating* with a standard deviation of 13.31, an α value of 0.05 and power of 0.80) was estimated at 16 families. Even though the expected drop-out rate was low (Carter et al., 2011; Drew et al., 2002; Landa et al., 2011; McConachie, Randle, Hammal, & Le Couteur, 2005; Rogers, Dawson, & Vismara, 2012; Rogers, Estes et al., 2012; Wong & Kwan, 2010), 20 families were targeted for recruitment.

Among the 20 parent-child dyads recruited, 19 consented to participate and were included in this study. Nine of these were randomized in the Intervention Group, and ten were allocated to the Waitlist Group. Table 1 summarizes the developmental status

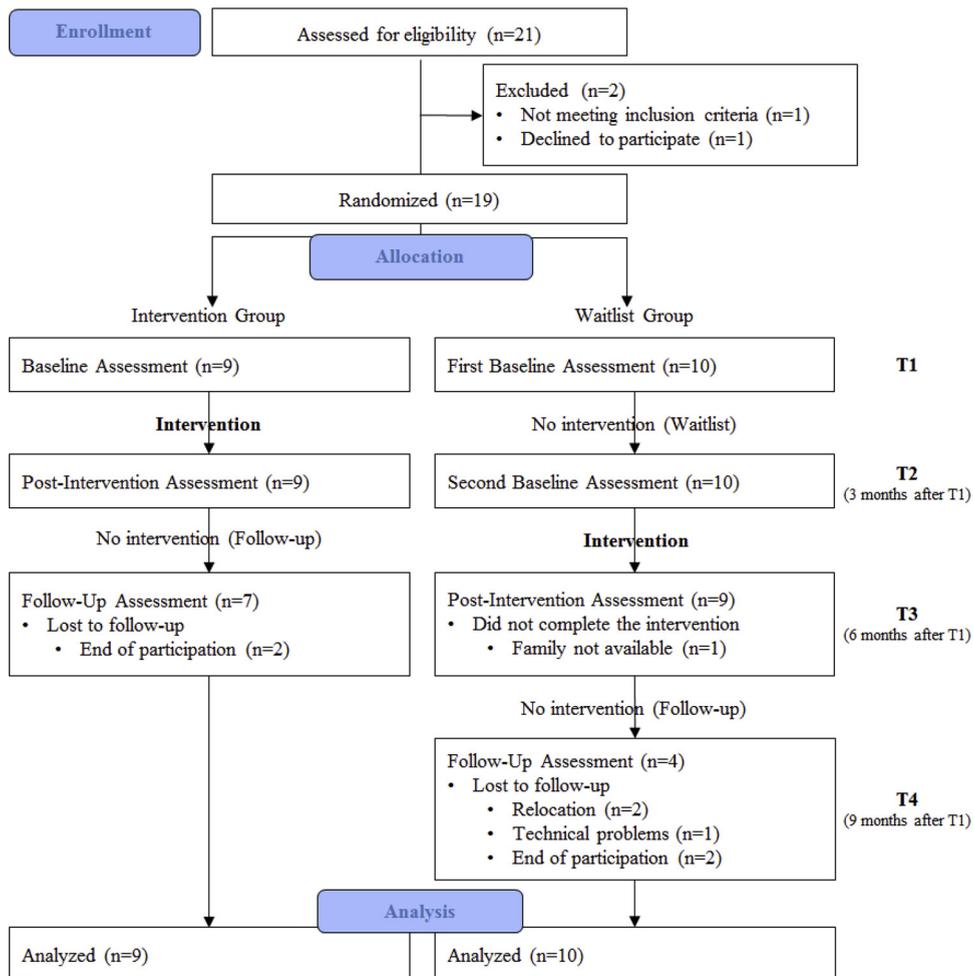


Fig. 1. Flow Diagram.

and sociodemographic data of both study groups. The groups were similar on all variables at baseline assessment. The total sample included 15 boys (78.9%). Toddler median age was 26 months (range: 13–30 months). The main caregivers involved in the parent-mediated intervention were mostly mothers ($n = 14$; 73.7%). Caregiver median age was 36.1 years (range: 23.0–46.5). All participants were in the low-to-moderate ($n = 7$; 36.2%) or moderate-to-severe ($n = 12$; 63.2%) ADOS range of concern. Based on developmental assessments, toddlers included in the study had significant developmental delays, as indicated by median standard scores in cognitive abilities (median score: 70; range: 55–95), motor skills (median score: 76; range: 55–103) and adaptive behaviors (median score: 65; range: 52–100). Sociodemographic data indicated that most families participating in this study were in the low-to-moderate socioeconomic status with 14 families (73.7%) having a household income of less than Can\$65,000 and nine primary caregivers (47.4%) who had been neither working nor studying. In addition, participants were from various cultural backgrounds, including 8 families (42.1%) with a cultural background other than Canadian, namely African ($n = 2$; 10.5%), Arabic ($n = 2$; 10.5%), Latin-American ($n = 3$; 15.8%) and Russian ($n = 1$; 5.3%), and 5 families (26.3%) primarily used a language other than French or English at home.

As reported in Fig. 1, one family (5.3%) did not complete the intervention phase; the family dropped out after four intervention sessions because of changes in the mother's socio-professional status that limited the family's availability to participate in the project. Seven families (two from the Intervention Group and five from the Waitlist Group) did not complete the follow-up assessment three months after the end of the intervention: two participants (10.5%) were not assessed at follow-up because they moved to another country; four families (21.1%) did not want to participate in this last assessment 3 months after receiving their last intervention session; and for one family (5.3%) there was a technical problem with the video camera that should have recorded an interaction between the child and parent, which prevented us from assessing their interactions.

2.2. Materials and design

Study procedures were approved by the Research Ethics Board of the Research Center of the Centre hospitalier universitaire de

Table 1
Developmental status and sociodemographic data at baseline.

	Intervention Group (n = 9)	Waitlist Group (n = 10)	Cross-Group Comparison <i>p</i> -value
Child sociodemographics			
Gender (boys) ²	8 (88.9%)	7 (70.0%)	.582
Age (months) ¹	25 (16–30)	26 (13–29)	.887
Prematurity ²	0 (0%)	0 (0%)	1.000
Family sociodemographics			
Caregiver (mothers) ²	8 (88.9%)	6 (60.0%)	.303
Age (years) ¹	35.5 (26.5–46.5)	26.8 (23.0–39.3)	.704
Number of children ¹	2 (1–4)	2 (1–3)	.510
Family income (< \$65,000) ²	7 (77.8%)	7 (70.0%)	1.000
Occupation (working/studying) ²	5 (55.6%)	5 (50.0%)	1.000
Education (years) ¹	16 (12–21)	16 (11–18)	.857
Ethnicity (Caucasian) ²	5 (55.6%)	6 (60.0%)	.857
Main language (French/English) ²	6 (66.7%)	8 (80.0%)	.628
Developmental status			
Autism symptoms severity (raw score /28) ¹	16 (10–21)	19 (10–26)	.344
Cognitive skills (standard score) ¹	70 (55–95)	72.5 (55–85)	.982
Motor skills (standard score) ¹	70 (58–97)	76 (55–103)	.984
Fine motor skills (scaled score) ¹	5 (2–11)	5 (1–15)	.734
Gross motor skills (scaled score) ¹	5 (4–9)	6 (4–7)	.853
Adaptive behaviors (standard score) ¹	63.5 (53–100)	66.0 (52–78)	1.000
Conceptual score (standard score) ¹	62.0 (57–97)	65.0 (52–90)	.683
Social score (standard score) ¹	72.5 (56–99)	74.0 (59–80)	.684
Practical score (standard score) ¹	65.0 (55–105)	71.5 (53–77)	.596

¹ Numerical data: Median (Range); Mann-Whitney U test.

² Categorical data: Frequency (Percentage); Fisher exact test.

Sherbrooke and carried out following the ethical standards of the Declaration of Helsinki as revised in 2000.

2.2.1. Parent-mediated intervention

The 12-session parent-mediated intervention was done in the family home with the therapist, at least one parent (identified as the primary caregiver considering that they were present at all 12 sessions) and the child with a diagnosis or risk of ASD. Sessions were all videotaped to code parent and child behaviors. Similarly to Rogers et al.'s adaptation (2018) of the Parent Implemented Early Start Denver Model (P-ESDM; Rogers, Dawson et al., 2012; Rogers, Estes et al., 2012), the parent-mediated intervention was an adaptation of the parent delivery of P-ESDM. In this non-official adaptation of the P-ESDM, the original ten P-ESDM sessions (addressing mostly social interaction and communication skills) were combined with two additional sessions (first and fourth sessions) based on the Social Communication Emotion Regulation Transaction Support (SCERTS; Prizant, Wetherby, Rubin, & Laurent, 2003) which focused on emotion regulation. These additions emphasized the recognition of children's arousal states, potential threats to emotional regulation, and ways to optimize their availability before and during parent-child interactions. All 12 intervention sessions were structured on the P-ESDM's 5-step procedure, including 1) a discussion about the past week between the parent and therapist, 2) a 10-minute free play period between the child and their parent that provided data on parent-child interactions and the parent's use of strategy, 3) the introduction of a new strategy by the therapist using discussion, a written handout and examples, 4) an opportunity for parents to practice the strategy with feedback from the therapist, and 5) a final discussion about the opportunities for parents to practice the strategy in the following week during routines with their child (Rogers, Dawson et al., 2012; Rogers, Estes et al., 2012; Vismara et al., 2009; Vismara & Rogers, 2008). Any other parental concerns were also addressed during the intervention sessions. When parents reported concerns or asked questions that were not planned in the parent-mediated intervention, the therapist took the time to give information to or refer parents to other resources, if available. Most intervention sessions lasted between 45 and 90 min, depending on concerns and questions raised by parents.

Two therapists taught the intervention to the 19 families. The primary therapist (n = 16 families, 84%) received training (three-day workshop) in the use of the ESDM (but did not complete the ESDM fidelity procedure) and attended a seminar on an adaptation of the SCERTS model. Based on her experience, the leading therapist adapted the parent-mediated intervention and created a comprehensive intervention manual. The other therapist (n = 3 families, 16%) was previously trained in the ESDM, and also received training by the main therapist to ensure the reliability of the adapted parent-mediated intervention.

Parents were encouraged to use the strategies in their daily routines with their child. However, there were no requirements in the time, frequency or duration that parents should use to implement these strategies. The parent's implementation of strategy during a 10-minute free play videotaped session between the child and their parent at each assessment time was coded with the *ESDM Fidelity Checklist* (Rogers & Dawson, 2010) by the primary therapist.

2.2.2. Treatment as usual

Participants were encouraged to use other services available as they would have done if not participating in the research project. However, all families that participated in the study were waiting for public-funded intensive behavioral intervention and thus received very few, if any, public-funded services. No families were receiving intensive early intervention at the time of recruitment, and only two families started intensive early intervention during the follow-up period. Private services (e.g., intensive early intervention, speech-language therapy, occupational therapy) could also be used by any family who could afford the cost associated with these services, but only two families ($n = 1$ in the Intervention Group; $n = 1$ from the Waitlist Group) purchased services from a speech-language pathologist.

Globally, during the first three months, families received a median of 0 h/week of other interventions ranging from 0 to 2.5 h/week in the Intervention Group and from 0 to 1 h/week in the Waitlist Group. Interventions that were most popular included early stimulation groups ($n = 4$; from 0.5 to 1.5 h/week), speech-language therapy ($n = 3$; from 0.2 to 1 h/week), and babysitting services ($n = 2$; from 0.6 to 0.8 h/week).

2.2.3. Data collection

Assessments were completed either at home ($n = 5$; 26.3%) or in a clinical setting ($n = 14$; 73.7%), depending on the proximity of one of the clinical settings to the family's home (i.e. 20 km or less). In all contexts where data collection took place, all families completed the same assessment procedures, including observational measures of parent-child interactions in a free play period, a direct assessment of the child's cognitive and motor development, and a parent-reported questionnaire on their child's adaptive behaviors.

2.2.4. Measures

The primary outcome was the quality of dyadic engagement between the child and their parent, as measured by the total score of the *Engagement state, Child and Caregiver Behavior, and Shared Topic* (Adamson et al., 2013). Based on Adamson et al.'s protocol (Adamson et al., 2013), four cluster scores were also analyzed, as follows: 1) Child Joint Engagement, 2) Child Behavior, 3) Caregiver Behavior, and 4) Shared Topic. Originally developed to be used with structured 6-minute play sessions in six different contexts (Adamson, Bakeman, Deckner, & Rowski, 2009; Adamson, McArthur, Markov, Dunbar, & Bakeman, 2001), the 17 items were used in this study to code a 10-minute unstructured play period between the child and their parent at each assessment time. This modification of the protocol was done with the approval of the author of the assessment tool (L. Adamson). Previously used with children aged between 18 and 30 months with typical development, ASD and Down Syndrome, the *Engagement State, Child and Caregiver Behavior and Shared Topic Rating* can be used to evaluate the quality of dyadic engagement in parent-child interactions for toddlers with or without neurodevelopmental disabilities (Adamson, Bakeman, Deckner, & Nelson, 2012). The 10-minute play periods were coded by two evaluators blinded to group allocation and time of evaluation, who then compared their scores. If a difference of more than 1 point on any of the 17 items rated on the 7-point Likert scale was reported between the two evaluators, they looked back at the videotaped play period and reached a consensus on these items.

Secondary outcomes were related to children's development. These outcomes included cognitive abilities, motor skills, and adaptive behaviors, all assessed via the *Bayley Scales of Infant Development—3rd edition* (Bayley, 2006).

Cognitive and motor skills were assessed via direct evaluation with children through a standard set of age-appropriate activities. Whereas the first assessment was completed by the primary therapist in order to get to know the child and facilitate individualization of care, all other assessment times were completed by one of two independent evaluators trained in the *Bayley Scales of Infant Development—3rd edition* (Bayley, 2006). These evaluators were blinded to group allocation and time of assessment. Raw scores were converted into standard scores (mean = 100; standard deviation = 15) for both scales (i.e., cognitive abilities and motor skills) and into scaled scores (mean = 10; standard deviation = 3) for the two subscales of motor skills (i.e., fine motor skills and gross motor skills) according to the age-based norms available.

Parents completed the Primary Caregiver/Parent form of *Adaptive Behavior Assessment Scale—2nd edition* (Harrison & Oakland, 2003) for children from birth to 5 years, which is included in the *Bayley Scales of Infant Development—3rd edition* (Bayley, 2006). In this questionnaire, parents indicated the extent to which the child performed a variety of adaptive behaviors on a 4-point Likert scale, from 0 (is not able) to 3 (always when needed). English and French versions of the questionnaire were available for parents according to their preferred language. Results on the total score and three subscales (i.e., conceptual, social, and practical) were converted into standard scores (mean = 100; standard deviation = 15) according to the age-based norms available.

2.3. Analysis

Planned data analysis for the total score, the four scaled scores for parent-child dyadic engagement (primary outcome), and child development (secondary outcome) were analyzed using non-parametric analyses (based on data distribution). Firstly, looking at the direct effect of the intervention separately for both groups, we conducted the following: i) Wilcoxon signed-rank tests separately for both groups to evaluate if there was a significant change in parent-child interactions between T1 and T2 independently for the Intervention Group, which received the intervention between these two assessments times, and for the Waitlist Group, which was waiting for the parent-mediated intervention and receiving treatment as usual, and: ii) a Mann-Whitney *U* test between groups to evaluate if change was greater in the Intervention Group than in the Waitlist Group during this 3-month interval. Secondly, considering that participants in the Waitlist Group received the parent-mediated intervention after T2, the research team conducted: iii) a Mann-Whitney *U* test on the difference score during the intervention period for the Intervention Group (T1 and T2) and the Waitlist

Group (T2 and T3). If no significant gap was found between differences in score during the intervention period between groups, both groups were merged into a single and larger group, and: iv) a Friedman ANOVA and Wilcoxon signed rank tests with Bonferroni correction to adjust multiple comparisons (p-value for Wilcoxon signed rank test: $.05/3 = .017$) were used for testing change in parent-child interactions between baseline, post-intervention and follow-up in the entire sample.

Baseline data from families with missing data ($n = 8$) were compared to the 11 families for which data was available for all assessment times. Families who dropped out of the study ($n = 8$) did not differ from those with complete data ($n = 11$) on parent sociodemographics (p-value between 0.262 and 1.000), child sociodemographics (p-value between 0.247 and 1.000), child developmental status (p-value between 0.172 and 0.806), and quality of parent-child interaction (p between 0.171 and 0.961) at baseline. The research team also compared post-intervention scores of families with complete data ($n = 11$) to those of the seven families who dropped out the study between post-intervention and follow-up assessments. Families did not differ in terms of parent-child dyadic engagement ($p = .801$) and children's cognitive abilities ($p = .693$), motor skills ($p = .218$), and adaptive skills ($p = .544$). Only post-intervention fidelity of implementation level was slightly higher in parents who completed the follow-up assessment (median: 70/100) compared to those dropping out at follow-up (median: 52.3/100), but this difference did not reach statistical significance ($p = .094$). Considering that no statistical differences were observed at baseline between participants who completed all assessments and those with missing data at one or more assessment time, statistical analyses were conducted on all available data, deleting missing data when occurring. Thus, analyses between T1 and T2 were conducted on all 19 participants, whereas comparison between pre-intervention and post-intervention results were conducted on 18 families (excluding the family who dropped out during the intervention phase) and analyses including the follow-up assessment were conducted with the 11 participants with complete data.

Excellent inter-rater reliability was achieved on the primary outcome, including the total score of the *Engagement State, Child and Caregiver Behavior and Shared Topic Rating* (ICC = .957) and each of its four subscales (ICC from .963 to .984).

3. Results

3.1. Parent fidelity of implementation

Parent implementation fidelity refers to the percentage of *ESDM* strategies used correctly in their interactions with their child. Based on these results, a significant increase was observed in the Intervention Group (median change: 10.3; $p = .006$, $ES = .81$), but no change was observed in the Waitlist Group (median change: -1.5; $p = .922$; $ES = .04$), between Time 1 and Time 2. The difference noted in the Intervention Group was statistically greater than the evolution observed in participants waiting for services during the same period, as reported by Mann-Whitney U test comparing changes in both groups between Time 1 and Time 2 ($p = .013$; $ES = .51$). Globally, parents implemented strategies with a median score of 68.5% after the intervention, compared to 58.5% before any training was provided. The improvement noted during the intervention period was maintained at follow-up (post-follow-up median change: -1.9; $p = .878$, $ES = .05$). Also, as reported in Table 2, only participants ($n = 3$) who had received the intervention reached the fidelity threshold for trained therapists (i.e., 80% of strategy implementation) while none of the participants had reached this threshold before receiving the intervention.

3.2. Parent-child interactions

Comparison of Time 1 versus Time 2 differential for the Intervention Group and the Waitlist Group showed that the parent-child dyadic engagement significantly increased in the Intervention Group (median change: 10.50; $p = .010$, $ES = .77$) but not in the Waitlist Group (median change: 6.88; $p = .250$; $ES = .40$) (Table 3). Results on three of the four subscales of the *Engagement state, Child and Caregiver Behavior, and Shared Topic* indicated a similar trend, including changes in Joint Engagement (median change in the Intervention Group: 3.09 $p = .012$; $ES = .75$), Child Behavior (median change in the Intervention Group: 2.13 $p = .004$; $ES = .85$), and Shared Topic (median change in the Intervention Group: 2.54 $p = .004$; $ES = .84$), which were statistically higher at Time 2 compared to Time 1 in the Intervention Group, but not in the Waitlist Group. Despite significant changes noted in the Intervention Group between Time 1 and Time 2, this improvement in parent-child dyadic engagement in the Intervention Group is not statistically greater than the maturation effect seen in the Waitlist Group between Time 1 and Time 2 (p values from .050 to 1.000; effect sizes from .00 to .45) as reported in Table 4.

Table 2
Parent fidelity of implementation.

	Intervention Group (n = 9)		Waitlist Group (n = 10)		Total (n = 19)	
	median score (range)	n (%) of score \geq 80	median score (range)	n (%) of score \geq 80	median score (range)	n (%) of score \geq 80
1st baseline	- -	- -	60.0 (35.4; 70.8)	0 (0%)	60.0 (35.4; 70.8)	0 (0%)
Pre-intervention	56.2 (45.4; 73.1)	0 (0%)	58.5 (36.9; 77.7)	0 (0%)	58.5 (36.9; 77.7)	0 (0%)
Post-intervention ¹	68.5 (47.7; 87.7)	2 (22%)	67.7 (49.2; 83.1)	1 (11%)	68.5 (47.7; 87.7)	3 (17%)
Follow-up ²	64.6 (43.1; 89.2)	1 (14%)	70.8 (52.3; 93.8)	2 (40%)	68.5 (43.1; 93.8)	3 (25%)

¹ Post-intervention assessment: $n = 18$ in total sample ($n = 9$ in the Intervention Group; $n = 9$ in the Waitlist Group).

² Follow-up assessment: $n = 12$ in total sample ($n = 7$ in the Intervention Group; $n = 5$ in the Waitlist Group).

Table 3

Change in parent-child and child outcomes between T1 and T2 for both groups separately.

	Intervention Group (n = 9)			Waitlist Group (n = 10)		
	T1 median (range)	T2 median (range)	p-value (ES) ¹	T1 median (range)	T2 median (range)	p-value (ES) ¹
Parent-child dyadic engagement (raw score /119)	47.8 (33.8; 67.3)	62.0 (36.0; 77.3)	.010* (.77)	47.3 (26.5; 66.5)	59.0 (30.3; 68.0)	.250 (.40)
Joint engagement (raw score /28)	10.0 (8.0; 14.8)	13.8 (8.0; 17.5)	.012* (.75)	10.3 (5.0; 13.0)	11.9 (6.8; 14.0)	.102 (.53)
Child behavior (raw score /35)	12.0 (7.5; 23.0)	15.5 (9.5; 24.8)	.004* (.85)	10.0 (7.0; 21.5)	13.8 (7.0; 21.5)	.117 (.51)
Caregiver behavior (raw score /28)	17.5 (6.8; 23.3)	21.0 (6.0; 24.0)	.172 (.34)	19.5 (8.0; 23.0)	20.8 (8.0; 23.0)	.813 (.11)
Shared topic (raw score /28)	8.2 (4.5; 13.3)	11.0 (6.5; 15.0)	.004* (.84)	6.8 (4.0; 11.0)	9.5 (4.8; 11.3)	.250 (.40)
Cognitive abilities (standard score) ²	70.0 (55; 95)	75.0 (55; 115)	.086 (.47)	72.5 (55; 85)	65.0 (55; 90)	.109 (.45)
Motor skills (standard score) ²	70.0 (58; 97)	73.0 (58; 110)	.375 (.18)	76.0 (55; 103)	61.0 (55; 88)	.016* (.74)
Fine motor skills (scaled score) ²	5.0 (2; 11)	5.0 (1; 13)	.931 (.03)	5.0 (1; 15)	5.0 (1; 10)	.257 (.40)
Gross motor skills (scaled score) ²	5.0 (4; 9)	6.0 (4; 11)	.570 (.19)	6.0 (4; 7)	4.0 (4; 8)	.194 (.46)
Adaptive behaviors (standard score) ³	63.5 (53; 100)	62.0 (45; 99)	.320 (.20)	66.0 (52; 78)	60.5 (53; 63)	.078 (.65)
Conceptual subscale (standard score) ³	62.0 (57; 97)	64.0 (50; 99)	.203 (.32)	65.0 (52; 90)	64.0 (52; 79)	.375 (.17)
Social subscale (standard score) ³	72.5 (56; 99)	72.5 (52; 105)	.422 (.29)	74.0 (59; 80)	62.0 (54; 71)	.031* (.84)
Practical skills (standard score) ³	65.0 (55; 105)	61.5 (49; 98)	.137 (.42)	71.5 (53; 77)	66.0 (53; 71)	.094 (.61)

ES: Effect size; * Significant change (p < 0.05).

¹ Wilcoxon signed-ranked test.² Bayley Scales of Infant Development—3rd edition: n = 18 in total sample (n = 9 in the Intervention Group; n = 9 in the Waitlist Group).³ Adaptive Behavior Assessment Scale—2nd edition: n = 14 in total sample (n = 8 in the Intervention Group; n = 6 in the Waitlist Group).**Table 4**

Cross-group comparison of parent-child and child changes between T1 and T2.

	Intervention Group (n = 9) median ⊗T1–T2 (range)	Waitlist Group (n = 10) median ⊗T1–T2 (range)	Cross-Group Comparison p value (ES) ¹
Parent-child dyadic engagement (raw score /119)	10.500 (–4.50; 22.0)	6.875 (–12.50; 22.50)	.221 (.19)
Joint engagement (raw score /28)	3.085 (–2.0; 5.50)	1.750 (–2.50; 4.50)	1.000 (.00)
Child behavior (raw score /35)	2.125 (–0.75; 5.50)	2.125 (–2.75; 8.00)	.673 (.12)
Caregiver behavior (raw score /28)	1.335 (–4.00; 9.25)	0.250 (–13.0; 6.0)	.167 (.34)
Shared topic (raw score /28)	2.540 (0.25; 5.00)	1.125 (–1.75; 5.00)	.050 (.45)
Cognitive abilities (standard score) ²	5.0 (–15.0; 30.0)	0.0 (–15.0; 15.0)	.182 (.22)
Motor skills (standard score) ²	3.0 (–6.0; 16.0)	–6.0 (–15.0; 0.0)	.005* (.60)
Fine motor skills (scaled score) ²	0.000 (–3.0; 4.0)	0.000 (–5.0; 2.0)	.423 (.22)
Gross motor skills (scaled score) ²	1.0 (–3.0; 4.0)	0.0 (–3.0; 2.0)	.236 (.30)
Adaptive behaviors (standard score) ³	–4.5 (–19.0; 12.0)	–6.0 (–16.0; 1.0)	.463 (.03)
Conceptual subscale (standard score) ³	–5.0 (–18.0; 10.0)	–3.0 (–11.0; 12.0)	.342 (.12)
Social subscale (standard score) ³	1.0 (–14.0; 18.0)	–9.0 (–26.0; 0.0)	.053 (.45)
Practical skills (standard score) ³	–7.0 (–16.0; 9.0)	–7.0 (–11.0; 7.0)	.489 (.01)

⊗: Change; ES: Effect size; * Significant change (p < 0.05).

¹ Mann-Whitney U test.² Bayley Scales of Infant Development—3rd edition: n = 18 in total sample (n = 9 in the Intervention Group; n = 9 in the Waitlist Group).³ Adaptive Behavior Assessment Scale—2nd edition: n = 14 in total sample (n = 8 in the Intervention Group; n = 6 in the Waitlist Group).

Using a Mann-Whitney U test to evaluate the change from Baseline to Post-Intervention in the two groups (T1–T2 for the Intervention Group; T2–T3 for the Waitlist Group), all participants evolved similarly in response to intervention regarding the parent-child dyadic engagement total score (p = .083) and the four parent-child interaction subscales (p values from .153 to .589), regardless of their group allocation. Thus, data from both groups were combined into a single group to analyze the effects post-intervention (T2 for the Intervention Group; T3 for the Waitlist Group) and at follow-up (T3 for the Intervention Group; T4 for the Waitlist Group) with a larger sample size. Friedman's non-parametric ANOVA (Table 5) showed no significant change when analyzing the effect of the intervention on total parent-child dyadic engagement (p = .256) nor on any subscale of the *Engagement state*, *Child and Caregiver Behavior*, and *Shared Topic* (p values from .062 to .265), at baseline, post-intervention and follow-up, for the 11 participants who completed all assessment times. However, Wilcoxon signed-rank tests with Bonferroni correction (p-value < .017) comparing assessment times 2 × 2 showed a significant increase during the intervention period in parent-child dyadic engagement total raw score (median change = 4.92; p = .012; ES = .51) and two of the four subscales, including Child Behavior (median change = 1.75; p = .016; ES = .49) and Shared Topic (median change = 1.46; p = .005; ES = .57). A moderate increase was also observed in the Joint Engagement subscale; however, it was not statistically significant (median change = 1.63; p = .022; ES = .46) during the intervention phase. At follow-up, none of the parent-child interaction outcomes significantly changed; a nonsignificant moderate increase in Caregiver Behavior subscale (median change = 2.17; p = .039; ES = .63) was observed at the three-month follow-up compared to the baseline score.

Table 5
Evolution of child and parent-child outcomes for all participants (both groups merged).

	Pre-int. (n = 19) median (range)	Post-int. (n = 16) median (range)	Follow-up (n = 11) median (range)	Pre-Post-FU (n = 11) <i>p-value</i> ¹	Pre-Post (n = 16) median ⊗ <i>p</i> (ES) ²	Post-FU (n = 10) median ⊗ <i>p</i> (ES) ²	Pre-FU (n = 11) median ⊗ <i>p</i> (ES) ²
Parent-child dyadic engagement (raw score /119)	54.0 (30.3; 68.0)	64.0 (31.5; 87.5)	48.0 (27.5; 68.5)	.256	4.915 .012* (.51)	-5.125 .947 (.03)	4.500 .320 (.32)
Joint engagement (raw score /28)	10.8 (6.8; 14.8)	13.8 (6.0; 17.5)	11.0 (7.5; 18.0)	.265	1.625 .022 (.46)	-0.125 .313 (.32)	1.250 .238 (.38)
Child behavior (raw score /35)	12.0 (6.8; 25.0)	15.5 (3.3; 28.5)	12.0 (7.5; 25.0)	.141	1.750 .016* (.49)	-1.250 .846 (.08)	-0.250 .043 (.61)
Caregiver behavior (raw score /28)	19.5 (6.8; 24.0)	21.0 (6.0; 25.5)	24.0 (6.5; 26.0)	.062	1.085 .212 (.19)	1.250 .278 (.35)	2.170 .039 (.63)
Shared topic (raw score /28)	8.5 (4.5; 13.3)	11.3 (5.5; 17.0)	8.0 (4.0; 17.0)	.071	1.460 .005* (.57)	3.415 .155 (.44)	0.330 .992 (.01)
Cognitive abilities (standard score) ³	67.5 (55; 95)	77.5 (55; 115)	80.0 (50; 95)	.011*	5.000 .010* (.57)	0.000 .633 (.17)	5.000 .137 (.48)
Motor skills (standard score) ³	70.0 (55; 97)	73.0 (55; 110)	70.0 (55; 94)	.232	1.500 .071 (.38)	-6.000 .063 (.57)	-3.000 .328 (.33)
Fine motor skills (scaled score) ³	4.5 (1; 11)	6.0 (2; 13)	6.0 (1.0; 10)	.508	1.000 .132 (.28)	0.000 .656 (.18)	1.000 .992 (.01)
Gross motor skills (scaled score) ³	5.0 (4; 9)	6.0 (3; 11)	4.0 (2.0; 8)	.011*	0.500 .116 (.31)	-1.000 .016* (.72)	-1.000 .133 (.47)
Adaptive behaviors (standard score) ⁴	64.0 (45; 100)	62.0 (56; 99)	60.0 (51; 89)	.932	0.000 .312 (.09)	1.000 .719 (.16)	-1.000 .938 (.06)
Conceptual subscale (standard score) ⁴	66.0 (50; 97)	65.0 (53; 99)	69.0 (50; 99)	.477	2.000 .472 (.14)	2.000 .344 (.38)	4.000 .547 (.25)
Social subscale (standard score) ⁴	75.5 (52; 99)	69.5 (62; 105)	65.0 (59; 93)	.818	0.000 .205 (.06)	-3.000 .828 (.10)	-6.000 .570 (.22)
Practical skills (standard score) ⁴	68.0 (49; 105)	66.0 (58; 98)	65.0 (50; 79)	.989	0.000 .446 (.13)	0.000 .406 (.15)	-3.000 .945 (.05)

⊗: Change; ES: Effect size; * Significant change.

¹ Friedman's non-parametric ANOVA test.

² Wilcoxon signed-ranked test (Bonferroni correction).

³ *Bayley Scales of Infant Development—3rd edition*: n = 18 at pre-intervention; n = 16 at post-intervention; n = 11 at follow-up.

⁴ *Adaptive Behavior Assessment Scale—2nd edition*: n = 14 at pre-intervention; n = 13 at post-intervention; n = 7 at follow-up.

3.3. Child development

A trend toward the amelioration of cognitive abilities between T1 and T2 was observed in the Intervention (median change = 5.0; $p = .086$) but not in the Waitlist Group (median change = 0.0; $p = .109$) (Table 3). Interestingly, the stability observed in motor skills in the Intervention Group (median change = 3.0; $p = .375$) was statistically different compared to the decrease in the Waitlist Group (median change = -6.0; $p = .016$) (Table 4). Similarly, the stability in parent-reported social adaptive behaviors in the Intervention Group (median change = 1.0; $p = .422$) contrasts with the decrease in the Waitlist Group (median change = -9.0; $p = .031$) (Table 4).

Comparison between merged Intervention and Waitlist groups after crossover (Table 5) showed significant change over time for cognitive abilities ($p = .011$) and gross motor skills ($p = .011$). Specifically, Wilcoxon signed-rank tests reveal a significant moderate increase in cognitive skills during the intervention period (median change in standard score = 5.0; $p = .010$; ES = .57), with a trend toward a moderate amelioration—not attaining statistical significance—between scores before the intervention and at the 3-month follow-up (median change in standard score = 5.0; $p = .137$; ES = .48). For gross motor skills, a significant decrease is reported after the end of the intervention (median change in scaled score = -1.0; $p = .016$; ES = .72).

4. Discussion

Before looking at the primary (parent-child interactions) and secondary (child development) outcomes, we explored parent fidelity of implementation after the intervention as a prerequisite to changes in proximal and distal outcomes. Preliminary analyses revealed an increase in parents' use of strategy learned during the 12-session parent-mediated intervention that was significantly different from the natural trend (no change) observed in the Waitlist Group. Knowing that significant relationships were previously found between the use of ESDM strategy by parents and their child's rate of development in proximal measures, parent improvement and maintenance after the intervention phase is promising regarding the level of integration of these strategies by parents, and potential effects on their child's development later on (Rogers et al., 2018). However, the percentage (16%) of parents reaching the fidelity threshold (80% or more) is lower than what was previously published concerning the parent delivery of the ESDM (between 36% to 100% of parents reaching the fidelity threshold; Rogers, Dawson et al., 2012; Rogers, Estes et al., 2012; Vismara et al., 2009; Vismara & Rogers, 2008; Vismara et al., 2018), but the median percentage of implementation after receiving the intervention (68.5%) is similar to Rogers, Dawson et al. (2012), Rogers, Estes et al. (2012) mean percentage of implementation (65%). A possible explanation for this reduced, but still significant, effect of the parent-mediated intervention on parents' use of strategies may be the unusually vulnerable sample of this study. In fact, most participants were in the low-to-moderate socioeconomic status, with a vast majority of the sample below the median household income for Quebec (Canada), i.e. Can\$73,870 (Statistics Canada, 2016). Also, the sample was culturally diversified, as illustrated by the proportion of the sample that indicated a cultural background other than Canadian (42.1%) and use of a language other than French or English (26.3%). By comparison in the general population, only 14.8% of families with a child under five years of age in Quebec speak a language other than French or English (Lavoie & Fontaine, 2016).

Results in the primary outcome showed that parent-child dyadic engagement increased during the intervention process, but this improvement was not sufficient to differ statistically from the maturation effect observed in the Waitlist Group. Interestingly, parent-child dyadic engagement in both groups increased significantly more than what was previously published in Adamson et al.'s (2012) paper. For example, higher scores in parent-child dyadic engagement for participants in the Waitlist Group at Time 2 (median age: 30 months; median score: 59.0) compared to age-matched children with ASD in the original data (54.8) from Adamson et al. (2012) might explain, at least in part, the lack of significant difference observed between groups in parent-child dyadic engagement change during the first 3-month period.

Even though multiple studies previously explored the effects of parent-mediated interventions on parent-child interactions, most have looked at parent-child interactions from distinct parental and children's perspectives (Beaudoin et al., 2014). Although Sameroff's *Transactional Model* (Sameroff, 1993) highlights the importance of dynamic interactions between children and their parents, only three studies (2015, Green et al., 2013; Kasari, Gulsrud, Paparella, Helleman, & Berry, 2015) used a global measure to assess parent-child interactions. From these three studies, only Kasari et al.'s (2015) used a similar tool to ours; a previous version of Adamson's tool targeting the first subscale (joint engagement) of the *Engagement state, Child and Caregiver Behavior, and Shared Topic* (Adamson et al., 2013) uniquely. Interestingly, Adamson et al. (2013) reported a significant improvement in parent-child interactions. Based on the change observed in parent-child dyadic engagement total and scale scores, Adamson et al. (2013) *Engagement state, Child and Caregiver Behavior, and Shared Topic* tool seems to be an interesting tool to evaluate the change in parent-child interactions after a parent-mediated intervention and may have an adequate sensitivity to change. However, further studies are needed to explore the psychometric properties of this assessment tool and the minimal clinically significant change over time.

Parent-child dyadic engagement scores at follow-up are difficult to interpret due to our small sample size and high rate of loss to follow-up. Despite the limited capacity for statistical analyses, higher parent-child scores were also observed at the end of follow-up (T3 for the Intervention Group; T4 for the Waitlist Group) compared to pre-intervention level. In fact, moderate-to-large effect sizes between pre-intervention and follow-up scores reveal maintenance over time of parent-child dyadic engagement, except for the subscale Shared Topic, which returned to the initial level at follow-up. Future studies including a larger sample are necessary to better understand the evolution of parent-child dyadic engagement in toddlers with ASD receiving intervention targeting this proximal outcome. Also, considering the possible attrition bias related to the high rate of loss to follow-up (Jüni, Altman, & Egger, 2001), future studies should integrate specific components for limiting loss to follow-up. In fact, the research team had expected low drop-out rates based on previous studies with pre-intervention and post-intervention assessments only. However, this study highlights the

need to address high drop-out rates at follow-up. Thus, it is crucial to integrate strategies to maintain the families' participation during the follow-up phase, such as limiting the duration of assessments or offering a report to parents about their child's development at the end of the 3-month follow-up period.

For the study's secondary outcomes, differential developmental trajectories were observed for three developmental areas typically limited in children with ASD, including cognitive abilities, motor skills, and social adaptive behaviors (American Psychiatric Association, 2013; Jasmin et al., 2009). Firstly, we observed a decrease in standard scores in the Waitlist Group between Time 1 and Time 2 with moderate effect sizes, but with a relative stability in raw scores. These results in the Waitlist Group indicate that toddlers at risk of ASD who did not receive the parent-mediated intervention (Waitlist Group) reported no-to-few gains in cognitive abilities, motor skills, and social adaptive behaviors, which were manifested by an increase in their developmental gap compared to age-matched typical peers. This stagnation in toddlers' development is congruent with previously published results highlighting the association between regression in cognitive standard scores, caused by declining or plateauing raw scores, and ASD in toddlers (Brian et al., 2014). Secondly, even though toddlers in the Intervention Group did not statistically improve their developmental scores, the relative stability of age-normed standard scores for children's cognitive abilities, motor skills, and adaptive behaviors indicate that these toddlers developed at a similar rate to age-matched typically developing peers. Even though previously published effects of parent-mediated interventions on developmental outcomes are very heterogeneous both for toddlers (Beaudoin et al., 2014) and older children (Oono, Honey, & McConachie, 2013), these results are congruent with the hypothesis that very early interventions for infants and toddlers at risk for ASD may offer a "normal trajectory and remit or reduce the expression of symptoms" (Webb, Jones, Kelly, & Dawson, 2014). However, improvements in children's outcomes were not maintained at 3-month follow-up in the current study. Interestingly previous papers reported that even moderate and non-significant gain in ASD symptom severity post-intervention could result in a significant reduction of symptom severity one year (Green et al., 2017) and two years (Estes et al., 2015) after the intervention ended. Although positive long-term effect of parent-mediated interventions can sustain up to 6 years after the end of the treatment (Green et al., 2017; Pickles et al., 2016), the use of booster sessions to optimize the long-term effect of parent-mediated interventions should be evaluated in future studies. Progressive intervention fade-out using booster sessions (e.g. Oosterling et al., 2010) has the potential to continue improving parent-child engagement which mediates child symptom change (Aldred, Green, & Adams, 2004; Pickles et al., 2016). Including individual or group booster sessions every few weeks or months might help parents remember some essential components of the program and give them the opportunity to share their feelings and experiences.

Interestingly, there was a significant effect of the parent-mediated intervention on children's motor skills, even though strategies discussed with parents focused mostly on communication and social interaction. This improvement in child motor skills is possibly an indirect effect. By facilitating interactions between parent and child, the parent-mediated intervention might have produced indirect effects on motor skills through stimulation from play (Ginsburg, 2007).

4.1. Strengths and limitations

A major limitation of this study was its small sample size, which limits the possible statistical analyses. In fact, the presence of moderate and large effect sizes, in the absence of statistical significance, is often an indication of low power. Also, considering data distribution, the research team had to analyze data with non-parametric tests limiting the ability to control for other outcomes such as the hours of other interventions received, age, or level of child development at recruitment. Moreover, the sample size is considerably reduced in relation to follow-up data, due to the 42% rate of loss to follow-up, which may impact the results. However, it is worth noting that participants who completed all assessment times did not differ from those who dropped out, based on baseline socio-demographics and post-intervention results in parent-child interaction and child development.

On the other hand, the main observational measures (dyadic engagement, cognitive abilities, and motor skills) were blind-coded, which enhances the credibility of results. Only the parent fidelity of implementation measure was not coded by blinded evaluators, because external evaluators were not trained in ESDM procedures, which could have limited the validity of their coding more than by using non-blinded, but trained evaluators.

Another strength of this study is the use of parent-child interactions and child development outcomes to assess the effect of the parent-mediated intervention on proximal and distal outcomes. As highlighted by Green and Garg (2018), parent dyadic behavior with their child is the proximal outcome that is theoretically linked in development to positive child outcomes. Thus, collecting and analyzing data on parent-child dyadic engagement and more distal child development allows a better understanding of the mechanism of change associated with parent-mediated interventions.

Finally, the sample recruited was highly diversified. This culturally and socioeconomically diversified sample is a major strength of this study. In fact, being able to use a parent-mediated intervention and observe clear trends toward amelioration in a sample that represents a diversity of families having a toddler with ASD is closer to the results that can be obtained in real-life settings. However, future studies assessing the effects of parent-mediated interventions should explore the effects of such interventions in a real implementation setting, by offering the intervention through service providers rather than a research team.

5. Conclusion

Promising effect sizes (with few statistically significant results) indicate trends toward a moderate-to-large improvement in parent-child dyadic engagement and a mild-to-moderate normalization of children's developmental outcomes after a 12-week parent-mediated intervention. However, results at the 3-month follow-up were inconclusive due to the high rate of loss to follow-up. These results also show greater benefits on proximal outcomes, specifically in the way parent and child interact with one another in play,

compared to more distal child-related outcomes (Helm & Kozloff, 1986; Mahoney & Perales, 2003, 2005; Oono et al., 2013). Future studies should explore the effects of this intervention on parental well-being, which can also influence the effect of a parent-mediated intervention (Baker-Ericzén, Brookman-Frazee, & Stahmer, 2005; Vismara et al., 2009) on more distal outcomes such as child development.

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Declaration of Competing Interest

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