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Randomized controlled trial of parental responsiveness intervention for toddlers at high risk for autism[☆]

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Abstract

This study tested the effects of a parent-mediated intervention on parental responsiveness with their toddlers at high risk for an autism spectrum disorder (ASD).

Participants included caregivers and their 66 toddlers at high risk for ASD. Caregivers were randomized to 12 sessions of an individualized parent education intervention aimed at improving parental responsiveness or to a monitoring control group involving 4 sessions of behavioral support. Parental responsiveness and child outcomes were measured at three time points: at beginning and end of the 3-month treatment and at 12-months post-study entry. Parental responsiveness improved significantly in the treatment group but not the control group. However, parental responsiveness was not fully maintained at follow up. There were no treatment effects on child outcomes of joint attention or language. Children in both groups made significant developmental gains in cognition and language skills over one year. These results support parental responsiveness as an important intervention target given its general association with child outcomes in the extant literature; however, additional supports are likely needed to fully maintain the treatment effect and to affect child outcomes.

Keywords

Early intervention; Parental responsiveness; Autism spectrum disorder; High risk infants

1. Background

Autism spectrum disorder (ASD) prevalence is now estimated at 1 in 68 children (CDC, 2014) and identification of children at-risk for an ASD is increasingly more common below the age of 2. These children are characterized by early atypical development in social-communication skills and object exploration (Zwaigenbaum et al., 2009). The American Academy of Pediatrics urges pediatricians to screen twice for autism prior to the age of 24 months; the expectation is that early screening will move identification of ASD closer to age

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2 (vs. the current average age of 4 years) (Johnson & Myers, 2007) and increase the opportunity for even earlier intervention. Widespread implementation of earlier screening and identification makes it imperative that vigorous, empirically supported early interventions are available to recommend to families of infants at high risk.

The obviously key role of parents in their children's lives supports parent-mediated intervention models for very young children with developmental deviations (Landry, 2008). Reviews of the few available randomized controlled and single subject design intervention studies concur that parent-mediated models have promise for implementation with young children at high risk for ASD (McConachie & Diggle, 2007; Patterson, Smith, & Miranda, 2012; Steiner, Koegel, Koegel, & Ence, 2012; Wallace & Rogers, 2010). The focus of these interventions on increasing parental responsiveness to children's social communication signals are especially relevant to children with ASD who exhibit early deficiencies in affective sharing and attention to others. Indeed, a prospective longitudinal study of infants at high risk for autism confirms that infants with parents who are more responsive to their attentional focus make larger subsequent gains in language (Baker, Messinger, Lyons, & Gantz, 2010). Conversely, parents who more often redirect their child's attention away from the child's focus of interest tax the child's attentional system and hinder the child's ability to connect the parent's words to their own activities (Morales et al., 2000). These data suggest the potential importance of increasing parental responsiveness to help promote improved developmental trajectories in high-risk children.

Interventions designed to increase parental responsivity have generally been focused on children with confirmed diagnoses who are over 24 months (Green et al., 2010; Siller, Hutman, & Sigman, 2013). There have been two recent randomized controlled trials for toddlers at high risk for autism who were under 24 months. One study compared the Hanen More Than Words intervention, delivered by speech and language therapists, to community practice as usual. The experimental intervention group failed to separate on parent and child outcomes from the community control group at the end of treatment and at follow-up five months later (Carter et al., 2011). One possible reason for this result is that the intervention was delivered in a group format with little hands-on, individualized intervention with parents and children. In comparison, a more hands-on parent coaching model was employed in 12 sessions over three months using the Early Start Denver Model (Rogers et al., 2012). This study also did not yield significant differences in parent responsiveness or child outcomes between the experimental group and community controls.

However in both the Carter et al. (2011) and the Rogers et al. (2012) studies, significant moderators or predictors of treatment outcome were reported. As reported by Carter et al. (2011) children who explored fewer toys during a play assessment at pre-treatment and received the Hanen More than Words treatment scored higher on weighted measures of communication post-treatment while children who explored more toys in this assessment had attenuated progress. Rogers et al. (2012) reported that children who were younger at study start, and who received more outside services made more progress on cognitive and language outcomes regardless of treatment assignment. The amount of community-based intervention that children receive varies across the United States, both in dose and type of services offered. Additional non-project services are important to document as they have

sometimes affected the outcomes of research interventions (e.g., Rogers et al., 2012) and other times have not (Kasari, Paparella, Freeman, & Jahromi, 2008; Kasari, Gulsrud, Wong, Kwon, & Locke, 2010; Kasari, Gulsrud, Freeman, Paparella, & Hellemann, 2012).

The published studies with children at high risk for ASD typically utilize a parent mediated intervention approach with the belief that even low doses of parent education and/or coaching of the parent can lead to significant benefit to both parent and child outcomes. The underlying premise is that because parents are with their children throughout the day, they can provide the necessary density and intensity of intervention that is needed to improve child outcomes (NRC, 2001). To date, few published studies on toddlers with ASD have found significant main effects on child outcomes of an experimental intervention (Kasari et al., 2010; Schertz, Odom, Baggett, & Sideris, 2013). In the Schertz et al. (2013) RCT of toddlers under 30 months of age meeting criteria for ASD on the ADOS, lower level child outcomes were improved (dyadic gaze, and responding to joint attention) while turn-taking and initiating joint attention were not significantly improved, again confirming the difficulty in improving joint attention initiations in young children.

The current study aimed to add to the intervention research base on very young children at high risk for autism by testing whether a weekly, individualized 1:1 parent education and coaching model of early intervention (Focused Playtime Intervention, FPI), delivered over 12 weeks, could enhance parental facilitating behaviors and improve children's developmental outcomes. The theoretical model for the intervention was based on improving shared engagement and enjoyment in interactions by teaching parents strategies for synchronizing their attention and language to their child's play actions (Siller & Sigman, 2002). There was some precedent for applying the intervention given positive effects on parent responsiveness with older children with ASD (Siller et al., 2013). In the current study, it was hypothesized that FPI would increase parental responsiveness as well as result in greater improvements in children's later communication and language outcomes. An exploratory aim was to determine if child or parent characteristics pre-treatment would moderate the effects of the intervention.

2. Method

2.1. Design

This study was a two-site randomized, comparative efficacy trial of parent education interventions with toddlers at high risk for ASD and their parents. Children were randomized in a balanced two group design using a 1:1 ratio within site to one of the two treatment groups via a centralized web-based system created by an independent data-coordinating center. A block randomization strategy was used to maintain balance throughout the trial; randomly selected blocks of lengths 4 and 6 were employed to help further preserve the blinding. Treatments were delivered over 3 months with assessments conducted before treatment, after treatment, and again twelve months later from the start of treatment (nine months post-treatment end).

2.2. Setting and participants

Assessments were conducted in University laboratories and interventions were carried out in the participants' homes. Participants between the ages of 15 and 31 months were recruited from the Los Angeles (site 1) and New York (site 2) metropolitan areas. Children were referred through pediatricians, early intervention programs, regional centers and autism evaluation clinics. A total of 123 children were *prescreened* for participation in this study using a structured interview (see below). Of these, 57 children declined participation or did not meet screening criteria, with the majority failing to exhibit sufficient behavioral features indicative of autism risk (see Fig. 1). Toddlers also were excluded if they presented with confirmed medical conditions (e.g., Fragile X) or with severe visual, hearing or motor impairments. The final sample consisted of 66 toddlers and their parents, 43 at Site 1 and 23 at Site 2.

Each of the enrolled participants met criteria on a three step screening procedure. Specifically, children had to (i) meet concern on the parent completed Modified Checklist for Autism in Toddlers (M-CHAT, Robins, Fein, Barton, & Green, 2001), (ii) continue to meet concern on the follow-up telephone interview to confirm parent flagged items on the M-CHAT and (iii) score 1 standard deviation below the mean on the social composite score of the Communication and Symbolic Behavior Scales Developmental Profile (CSBS DP, Wetherby & Prizant, 2002). At the one-year follow-up, children were assessed with the Autism Diagnostic Observation Schedule, Module 1, to determine whether they met full criteria for an Autism Spectrum Disorder.

The final sample of 66 high-risk children had a mean age of 22.37 months with a standard deviation of 3.8 months (Treatment: $Mean = 22.18, SD = 4.18$, Control: $Mean = 22.56, SD = 3.47$). Subjects were from diverse racial/ethnic backgrounds and were predominantly male (79%). Parents were mostly well-educated. Characteristics of the children and parents are presented in Table 1. Moreover, prior to treatment start, there were 20 (63%) toddlers in the treatment group and 24 (71%) toddlers in the control group who were already receiving outside early intervention services. At treatment end these numbers increased, with 25 (86%) toddlers in the treatment group and 28 (88%) toddlers in the control group receiving outside services. Use of external services and total number of hours of services received were not significantly different between groups.

The final sample consisted of 32 children randomized to the experimental group and 34 children randomized to the active control group. Five of the 66 families withdrew participation during treatment due to time conflicts. Twelve additional families could not be contacted or refused further research participation at the one-year follow up assessment (see Fig. 1).

2.3. Interventions

2.3.1. Focused playtime intervention, FPI (Siller et al., 2013)—FPI is a parent education program that involves 12 in-home training sessions (one session per week for 12 weeks, 90 min per session) on an ordered sequence of eight topics. The eight topics range from understanding child's communication skills, addressing parent's goals during play and

developing strategies to promote play. The primary goal is to promote coordinated toy play between parent and child. Trained interventionists delivered FPI; treatment fidelity was monitored on a random sample of 25% of intervention sessions and ranged from 72% to 100% with an average of 96% and no differences between sites.

Each treatment session consisted of two parts. The first approximately 45 min consisted of interactive play between the parent and child with interventionist demonstrated strategies related to the session's main topic and specific feedback on the parent's use of strategies and child's responses. All interactions between parent, child and interventionist were videotaped. The second part of each session (45 min) was an educational component that involved only the parent. During this time, the interventionist elaborated on each session topic using an illustrated workbook, video feedback, conventional teaching and review of weekly homework assignments. The FPI treatment manual and workbook are available as an electronic supplement from Siller et al. (2013). Treatment components are listed in Table 2.

2.3.2. Monitoring group intervention—The monitoring control group received four 90-min in-home training sessions equally spaced over the 12 weeks. Interventionists followed a standardized manual based upon teacher workshops created by the Center on the Social and Emotional Foundations for Early Learning (CSEFEL, Vanderbilt University). The parent and interventionist covered a hierarchy of topics, aimed at helping the parent promote the child's social and emotional competency. The first session involved reviewing the child's current social communication abilities. The second and third sessions were devoted to strategies for increasing social and emotional development and decreasing challenging behaviors. The last session included a behavior support plan. The monitoring sessions also involved video instruction on the specific topics above, but not specific feedback on parent-child interactions (see Table 2). Therapist fidelity was measured over the course of treatment on a random selection of 25% of sessions and ranged from 60% to 100% with an average of 94%.

2.4. Outcome measures

2.4.1. Parent-child play (PCX)—A 10 min videotaped interaction was collected for each child at entry, exit and follow-up to treatment. Caregivers were asked to play with their child as they normally would in their homes. A standard set of toys was provided so that all families would have similar materials available to them (including blocks, figurines, cars and shape sorters). Parental interactions from the PCX sessions were categorized as responsive, ignoring or directive to the child's object manipulation. That is, we first identified the child's play acts and then coded parental responses to the play acts. Parental interactions were considered responsive if the parent followed-in and joined their child's actions using non-demanding language or nonverbal actions. Parental interactions were considered *directive* if the parent commanded the child to do something with the object verbally or nonverbally and *ignoring* if the parent did not pay attention to what the child did with objects. We scored the entire 10-min window of parent-child interaction to obtain percentage scores for time spent in each of these three response modes. Our primary outcome, percent responsiveness, measures the proportion of times the parent responded to the child within the 10-min parent-child play. Average reliability between two independent

coders blind to child condition was .94 for children's play acts and .83 for parental responses.

2.4.2. The early social communication scale (ESCS)—ESCS (Seibert, Hogan, & Mundy, 1982) is a semi-structured experimenter-child procedure used to assess nonverbal communication behaviors, which typically emerge between 8 and 30 months. The ESCS is videotaped and coded for the frequency of initiations of joint attention (coordinated looks between person and objects, pointing to share, showing toys, joint attention language) and responses (to examiner's points and gaze). It was administered at entry, exit and follow-up. The overall frequencies of initiating joint attention and responding to joint attention were the primary outcomes from the ESCS. Interrater reliability was assessed with intraclass correlation coefficients between 2 independent coders blind to group status (average ICC = .91).

2.4.3. The Mullen scales of early learning (MSEL)—MSEL (Mullen, 1997) provide a standardized assessment of a child's overall cognitive and language abilities. In this study we assessed the visual reception, fine motor skills and receptive and expressive language domains of the MSEL. The receptive and expressive language subscales were administered at entry, exit and follow-up; the visual reception and fine motor subscales were administered at entry and follow up. Developmental quotient (DQ) and age equivalents were calculated.

2.5. Procedure

The University Institutional Review Boards at each site approved the research. After informed consent, parents and children were randomly assigned to the FPI or Monitoring Intervention group. An independent data-coordinating center administered the random assignment using generated lists of random numbers for each site. Entry data were entered for each participant into a centralized database, and the participant was randomized by the system if all inclusionary criteria were met. Entry, exit and follow up assessments were carried out at the University, and interventions were carried out in the home.

2.6. Statistical analyses

T-tests, Chi-square tests and permutation tests were used for baseline comparisons by site, treatment group (to assess the success of randomization) and completer status (to check for evidence of differential dropout). Generalized linear mixed models (GLMM) with main effects for group (FPI, control) and time (in weeks from study entry), a group by time interaction, and subject level random intercepts were used to model the longitudinal trajectories of the primary and secondary outcomes. An identity link for continuous outcome variables and a logistic or multinomial link for categorical outcomes were used (employing SAS Proc Mixed and Glimmix respectively). Time was modeled using linear splines to allow the rate of improvement (slope) over the treatment period to differ from that over the follow-up period. GLMM account for correlations between repeated measures within subjects, easily allow for both fixed and time-varying covariates and automatically handle missing data, producing unbiased estimates as long as observations are missing at random (Fitzmaurice, Laird, & Ware, 2012). Hence, all available observations from each subject were utilized in modeling via the GLMM.

In addition, we checked for violations of distributional assumptions and the presence of missing data. Three of the main outcomes (percent responsiveness, receptive language and expressive language) exhibited moderate deviations from normality. Both receptive and expressive language were successfully normalized using a square root transformation, but this technique did not work for percent responsiveness due to a high prevalence of zeroes. Consequently, we used the two-stage approach to analyze percent responsiveness, first assessing whether there was any responsiveness and if there was then examining its magnitude using a mixed model as described above. This approach parallels the standard Poisson hurdle model which is used for count data with a higher than expected proportion of 0's. (Littell, Milliken, Stroup, Wolfinger, & Schabenberger, 2006).

3. Results

3.1. Preliminary analyses

3.1.1. Equivalence at study start—There were no significant differences between the treatment groups at study start on demographic, cognitive, language, joint attention, or parental responsiveness variables except for a slight difference in income levels; this indicates the success of the randomization. Moreover, in subsequent models, income was not a significant predictor of outcome. Descriptive statistics for child and parent variables at study start are presented in Table 1. At enrollment, the only observed site difference was in chronological age (site 1 children were younger by 2.55 months); however, age at study start was not associated with any of the outcome measures. We also checked for site main effects and interactions with time in the primary outcome models. Percent responsiveness was the only outcome variable for which site effects were found (see details below).

3.1.2. Study completion—We tested for differences between toddlers who discontinued the study and those who completed it. Overall there were 17 families that had incomplete data. Of these, only 5 withdrew during treatment (due to time conflicts); follow up assessments one year post-treatment were missing for 12 families who could not be contacted or refused further research participation (see Fig. 1). There were no significant differences between subjects who did and did not complete the study.

3.2. Effect of treatment on the primary outcome of parental responsiveness

Due to the high prevalence of zeroes, percent responsiveness was analyzed using a two-part model. We first examined the likelihood of having any responsiveness (change from zero to some) using a logistic mixed model. There was overall evidence of a significant treatment effect (overall likelihood ratio test $\chi^2(3) = 32.32$; $p < 0.001$) with the FPI group having greater improvement from treatment start to end ($F(1,89) = 7.32$; $p = 0.008$) than the controls. However, this effect was not maintained as the FPI group was no longer significantly better than controls at follow-up ($F(1,89) = 1.32$; $p = 0.25$) (see Fig. 2). Finally, we note that there was a significant site effect ($F(1,89) = 5.83$; $p = 0.02$) in this model with site 1 showing greater increases in the probability of responsiveness from treatment start to treatment end.

For the second stage of this analysis, we used a standard linear mixed model to assess the magnitude of the responsiveness for those observations in which the parents showed any amount of responsiveness at baseline. There was a significant treatment effect from start to end of treatment ($F(1,41) = 6.16; p = 0.02$) with the FPI group showing a significant increase in amount of responsiveness and the effect was maintained at follow-up ($F(1,41) = 6.16; p = 0.02$). See Table 3.

3.3. Effect of treatment on secondary outcomes of child joint attention and language

Next, we modeled the changes in visual reception, expressive and receptive language scores from the Mullen and joint attention from the ESCS using linear mixed models (see Table 4). Visual reception and language scores were collected only at treatment start and follow up time points. Although overall visual reception, expressive and receptive language scores significantly increased from treatment start to follow-up ($F(1,47) = 106.62; p < 0.001$ for visual reception; $F(1,105) = 58.31; p < 0.001$ for expressive language and $F(1,105) = 23.55; p < 0.001$ for receptive language), there were no significant group by time interaction effects (see Fig. 3). No significant changes were noted in joint attention.

3.4. Parental responsiveness and its relationship with language and joint attention

Given the lack of treatment effects on joint attention and language, we combined the two treatment groups to check for associations between parental responsiveness and child outcomes. Specifically, percent responsiveness was included as a time varying predictor in the GLMMs for the child outcomes. Results did not yield statistically significant associations between parent responsiveness and concurrent expressive language, receptive language or responding to joint attention.

3.5. Parental responsiveness and its relationship with DQ, session dose, and non-project intervention services

The Mullen was given at treatment start and follow up assessments only. Percent responsiveness was not associated with DQ across time points ($F(1,37) = 1.04; p = 0.32$). Additionally, number of sessions completed was not associated with any of the outcome measures with the exception of a significant positive correlation between the amount of response to joint attention (RJA) and number of sessions for the FPI group ($p = 0.04$).

We also examined the relationship between the total hours of outside services received with concurrent percent responsiveness, child language, initiating joint attention, and responding to joint attention by adding services as a time-varying predictor in the previous mixed models. No significant results were found (see Table 5).

3.6. Diagnostic outcome

The Autism Diagnostic Observation Schedule assessment (ADOS; Lord, Rutter, DiLavore, & Risi, 2001) was administered at the one-year follow up visit. Ten children did not meet criteria for ASD on the ADOS at follow up, five in each group. The 10 children were considered delayed based upon developmental measures. There were no significant differences by diagnostic status (ASD vs. Delay) in responsiveness, improver status, IJA,

RJA, and receptive language. Children with delay only vs. ASD had a greater rate of improvement in expressive language ($F(1,97) = 4.17, p = 0.04$).

3.7. Moderators

Five potential moderators (i.e., mother's age, child's age, child's ethnicity, IJA at entry, and RJA at entry) of treatment effect were evaluated for the primary and secondary outcomes (percent responsiveness, expressive language, and receptive language). None of the potential moderators significantly moderated the effect of treatment on the primary and secondary outcomes.

4. Discussion

Early screening and identification of toddlers at high risk for ASD necessitates the development of effective interventions to ameliorate risk. The goal of this study was to determine whether a developmentally informed, low intensity parent–education intervention would improve parental responsiveness and child developmental outcomes, and thus fulfill a pressing need for efficacious interventions for this group of children. Our analyses yielded three main findings.

First, as hypothesized, there was a significant effect of our intervention on parental responsiveness. Nearly eighty percent of parents in the FPI group improved in responsiveness compared to only half that many in the monitoring group. This is one of the first studies demonstrating a significant effect from a controlled test of an intervention aimed at this unique aspect of parent–child behavior in parents of toddlers *at high risk for ASD*.

Second, we predicted that there would be a differential treatment effect on children's joint attention and language skills at one year follow up, reflecting the treatment-related facilitation of parental responsiveness and its impact over time on child developmental trajectories. This hypothesis was not supported, as there was no evidence of a significant difference between groups on these outcomes. These findings are consistent with a study of older children with ASD using the same intervention approach in which parent responsiveness was improved, without concurrent benefit to child outcomes (Siller et al., 2013).

Why did the predicted increases in parental responsiveness take place without corresponding differential treatment effects on communication and language outcomes one-year post-baseline? There are several possible explanations. One is that the treatment lacked sufficient *durability* to affect longer-term outcomes. Although there was a significant increase in the likelihood of any parental responsiveness at 12 weeks for the FPI group, level of responsiveness was not maintained. Since parents only received the full dose of the intervention by treatment end, a shorter follow up interval may have yielded greater maintenance. Only those parents who showed some responsiveness at baseline maintained their responsiveness to follow up. Treatment modification may be necessary, including extending the duration of the intervention to improve responsiveness, or supplying “booster” sessions to maintain positive changes in parental behavior over time. It also suggests that

changes in responsiveness are not sufficiently learned or reinforced to drive their maintenance.

Another possibility relates to the challenge of demonstrating benefit of a low-intensity, short-term intervention. Early parent mediated interventions are designed to fill a service gap for families prior to receiving more intensive interventions should they be needed. More recently, given heightened attention to early interventions for ASD, many families begin receiving services even without a definite diagnosis. Thus, research studies must design interventions that can be an augmenting treatment, with expected benefit above and beyond the effects of the participants' ongoing interventions. In this study, dose of non-project services was examined before the study began, during the course of the intervention study, and during the follow up period. While children varied in amount of intervention received, over 80% of toddlers were receiving additional services by study end. The number of hours of intervention toddlers received was not associated with joint attention, cognitive or language outcomes. In particular, these data differ from a recent report in which sheer amount of intervention was associated with more positive outcomes in toddlers at high risk for ASD (Rogers et al., 2012). Findings suggest that we have much more to learn about the additive value of parent-mediated interventions against the backdrop of non-project services.

Despite the non-significant effects of outside services on the outcomes of our study, we also note that there were significant developmental changes in language and cognition for the entire sample of children. Over a 12-month period, children had average gains of approximately 16 standard points in their DQs, 15 months in their mental ages and 16 months in their language ages. Similarly their cognitive scores also improved by 12–13 months over the year. On the whole, subjects continued to show delays despite these gains, but their substantial progress, presumably in part reflecting the impact of other ongoing interventions and family supports, requires that any adjunctive intervention possesses a large effect in order to be detectable. While our sample may have been underpowered to reveal a differential long-term effect at one year, examination of one-year gains in cognition and language do not suggest trends of differential treatment outcomes. These findings are similar to the one other published randomized trial targeting high-risk toddlers that has follow up data (Carter et al., 2011).

Perhaps a more relevant explanation for the lack of treatment effects on child outcomes relates to the actual target of the intervention, parental responsiveness. Increasing parental responsiveness is a place to begin in working with parents, but not enough to move child outcomes by itself, particularly for core areas of social communication that are significantly impaired in children who are at high risk for ASD. Indeed, 80% of the toddlers in our study met criteria for ASD at follow-up. However, parental responsiveness intervention did not improve children's initiating and responding to joint attention, regardless of their diagnostic status at follow-up. These core deficits in young children at high risk for ASD are arguably difficult to improve. However, when these core areas of development are improved in children with confirmed diagnoses of ASD, language outcomes are significantly improved suggesting they are important targets of early interventions (Kasari et al., 2008, 2012). Thus, the current intervention likely did not provide enough direct targeting of these core areas of development to precipitate improvement.

A third finding is that we did not find significant moderators of treatment outcome. Several candidates were examined including child baseline skill in joint attention and language, parent and child age, and amount of non-project interventions. These data are different from several recent studies in which both significant moderators (Carter et al., 2011; Siller et al., 2013; Yoder & Stone, 2006) and predictors of treatment outcomes were found (Rogers et al., 2012). It may be that there are other factors that are associated with our treatments, and that were not measured in the current study. Moderators are important to consider especially since a single treatment is not expected to be similarly beneficial to all, and studies will want to continue to consider moderators in future trials.

The current study is one of only a handful on interventions for toddlers at high risk for autism. A limitation is that while only 8% of subjects dropped out of treatment (experimental or monitoring), another 20% of the sample did not maintain participation through the follow up assessments. The difficulty in recruiting and then keeping families in interventions when at high risk at this young age has been highlighted as a concern for toddler risk studies (Morgan, Turner-Brown, Siller, Baranak, & Kasari, 2011). Another low intensity parent-mediated intervention for toddlers at high risk also had attrition of 20% (Carter et al., 2011). These percentages are higher than what we typically see in more intense interventions, or in interventions with older children for whom the dropout rate is typically around 10% (Kasari et al., 2010, 2008). There are several possible contributing factors that should be examined in future studies including the possibility that the intervention is too brief or not culturally sensitive enough to keep parents involved, parent denial of toddlers 'autism' symptoms or the fact that children are progressing well and treatment is not viewed as necessary.

5. Conclusions

Toddlers at high risk for autism require early effective interventions. To date, intervention studies for toddlers at the youngest ages have mostly failed to detect significant effects on child outcomes. While we could improve parental responsiveness in the current study, these improvements were not significantly associated with child social communication and language outcomes. Notably, toddlers in this study improved significantly on standardized cognitive and language scores but showed no improvement in joint attention. We conclude that increasing parental responsiveness over a short period of time is not enough to improve core deficits in autism. To affect these core areas of development other intervention models are indicated, perhaps including a combination of therapist plus parent intervention, as well as more direct focus on child joint attention and joint engagement.

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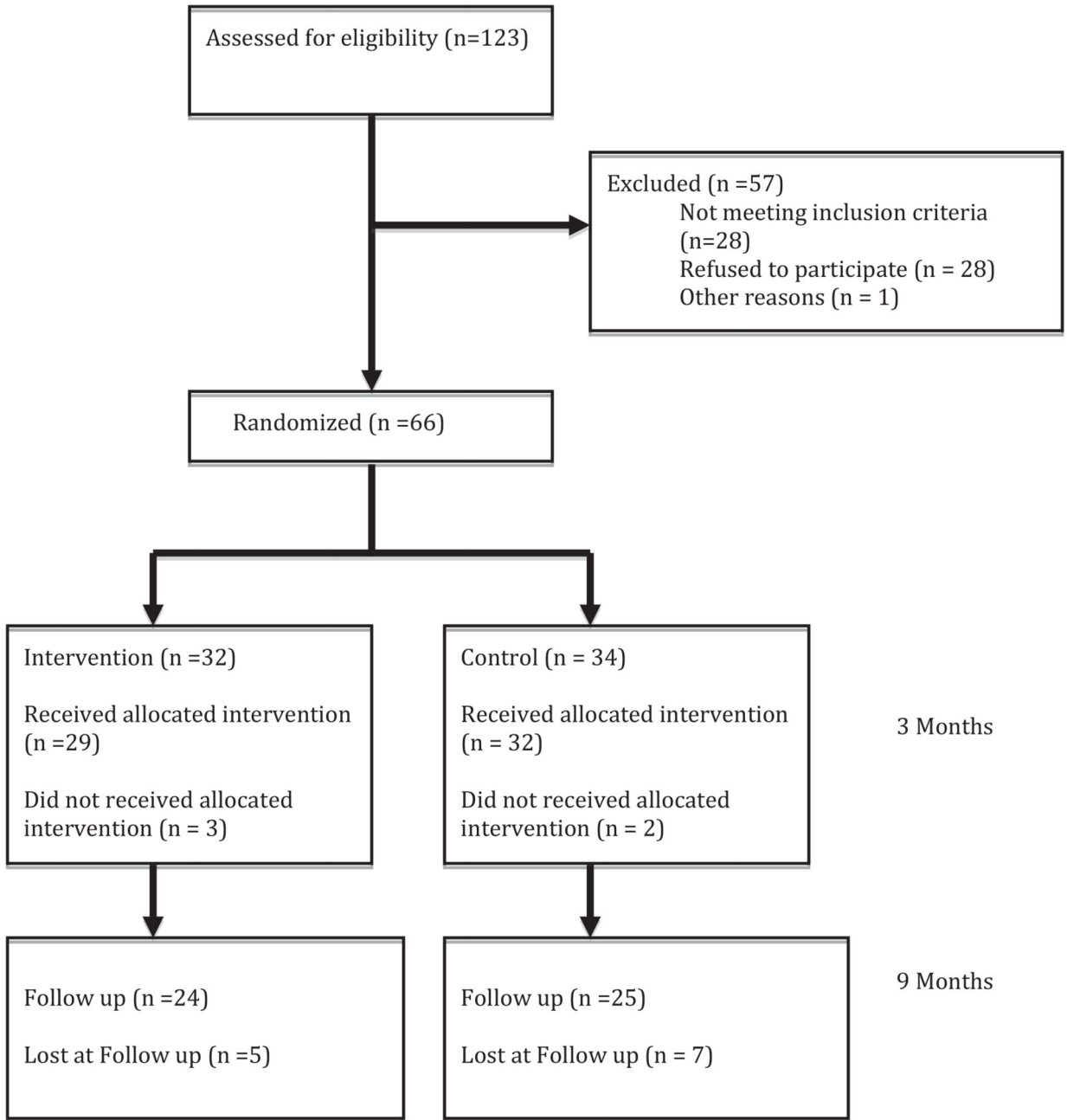


Fig. 1.
Toddler recruitment flow diagram.

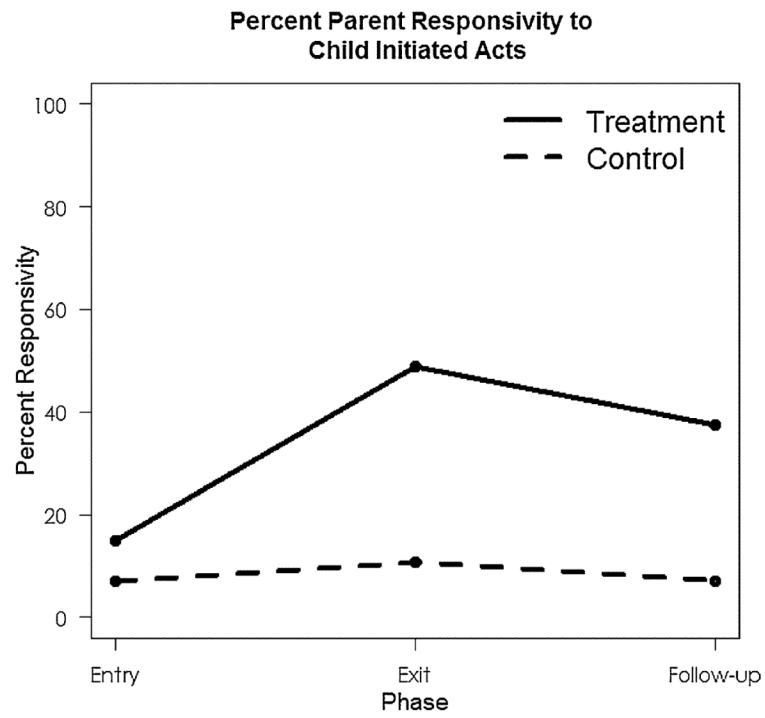


Fig. 2.
Percent parent responsivity for experimental and control groups over time.

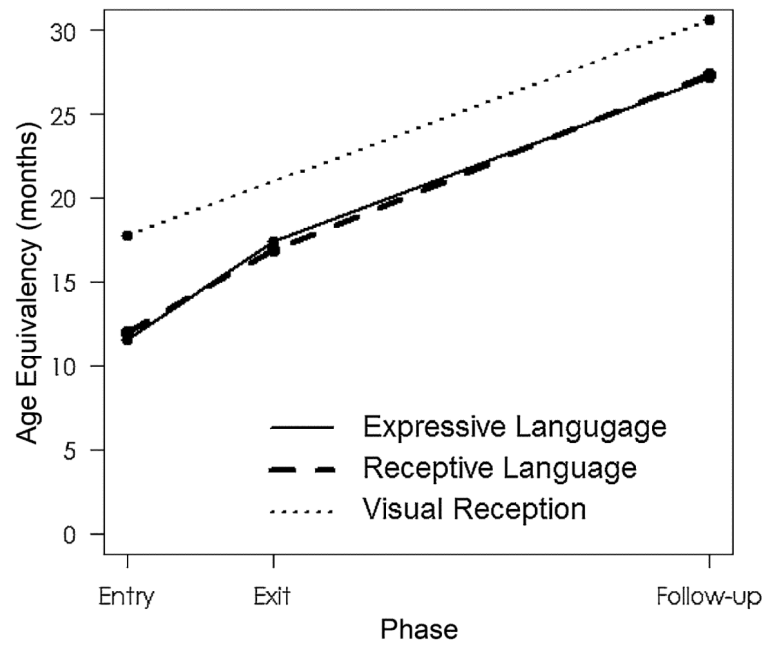


Fig. 3. Visual reception and language (Mullen) growth for all children.

Table 1

Child and parent entry demographic characteristics.

	Controls N = 34	Treatment N=32	p-Value	 Cramer's V
<i>1. Child characteristics</i>				
Gender(%)			0.28	0.13
Male	73.53%	84.38%		
Female	26.47%	15.63%		
Ethnicity (%)			0.23	0.22
White	46.88%	28.57%		
Hispanic	18.75%	35.71%		
Other/mixed	34.38%	35.71%		
	Mean (SD)	Mean (SD)	p-Value	 Cohen's d
Chronological age (months)	22.56 (3.48)	22.19(4.18)	0.70	0.10
Mental age (months)	15.05 (5.78)	14.32(4.81)	0.58	0.14
CSBS behavior				
Weighted raw score	44.35 (26.42)	41.75 (26.34)	0.69	0.10
Standard score	70.12(7.89)	70.81 (8.76)	0.74	0.08
Developmental quotient	66.66 (22.77)	65.78(20.51)	0.87	0.04
<i>2. Parent demographics</i>				
Gender(%) Male	8.80%	0%	0.24	0.21
Female	91.20%	100%		
Education (%)			0.72	0.18
Less than HS	3.57%	0%		
High school	3.57%	7.14%		
Some college	17.86%	25%		
College/professional school	75%	67.86%		
Income (%)			0.024	0.37
Below 40,000	7.41%	37.04%		
40,001–70,000	22.22%	22.22%		
70,001–above	70.37%	40.74%		

Table 2

Topics covered in FPI and monitoring treatments.

FPI treatment		Monitoring treatment	
Week	Topic	Week	Topic
1	Topic 1: When and how does my child communicate	1	Module 1: Reviewing current social communication abilities
2	Topic 2: What do I hope to accomplish during play?		
3	Topic 3: How do I develop a special play time routine		
4	Topic 3: Coaching	4	Module 2: Promoting children's success: Building relationships and creating supportive environments
5	Topic 4: How to tackle play one-step at a time? Topic 5: Who gets to pick the toys?		
6	Topics 4 and 5: coaching		
7	Topic 6: Who decides the 'Correct' way of using the toys?		
8	Topic 6: Coaching	8	Module 3: Determining the meaning of challenging behavior
9	Topic 7: How do I speak to my child during play?		
10	Topic 7: Coaching		
11	Topic 8: How do I make play more balance between me and my child?		
12	Topic 8: Coaching and wrap up	12	Module 4: Developing a behavior support plan

Table 3

Parent outcomes at pre, post and follow up assessments.

Parent outcomes	Controls <i>N</i> = 34 Mean (SD)	Treatment <i>N</i> = 32 Mean (SD)	<i>p</i> -Value*	Cohen's <i>d</i>
<i>Percent responsiveness</i> **				
Entry	0.07(0.12)	0.15(0.22)	0.07	0.44
Exit	0.11 (0.18)	0.49 (0.24)	0.002	1.81
Follow-up	0.07(0.16)	0.37(0.41)	0.003	0.98
<i>% of play acts parent directs</i>				
Entry	0.56(0.35)	0.48 (0.35)	0.38	0.23
Exit	0.62 (0.35)	0.31 (0.26)	<0.001	0.99
Follow-up	0.68 (0.26)	0.50 (0.39)	0.09	0.54
<i>% of play acts parent ignores</i>				
Entry	0.22 (0.28)	0.35 (0.33)	0.12	0.40
Exit	0.21 (0.28)	0.18(0.21)	0.60	0.14
Follow-up	0.25 (0.24)	0.12(0.19)	0.06	0.59
High/improved parental responsiveness	<i>N</i> (%)	<i>N</i> (%)	<i>p</i> -Value*	Cramer's <i>V</i>
Entry to exit	11(37.9%)	23(79.3%)	0.001	0.42
Exit to one year	7(31.8%)	10 (43.5%)	0.42	0.12

* *N* varies for parent behaviors depending on whether child showed any child play with objects. If child did not show play, parent could not respond and dyad was removed from analysis.

** *p*-Value calculated from permutation test.

Table 4

Child outcomes at pre, post and follow up assessments.

Clinical characteristics	Controls N=34 Mean (SD)	Treatment N=32 Mean (SD)	p-Value*	Cohen's d
<i>Mental age (months)</i>				
Entry	15.05 (5.78)	14.32(4.81)	0.58	0.14
Follow-up	29.78(11.39)	26.90 (9.32)	0.34	0.28
<i>Developmental quotient</i>				
Entry	66.66 (22.77)	65.78(20.51)	0.87	0.04
Follow-up	84.52 (32.57)	80.04(28.91)	0.61	0.15
<i>Initiated joint attention</i>				
Entry	5.85 (5.23)	7.13(7.02)	0.42	0.21
Exit	7.56 (5.91)	7.07 (8.08)	0.79	0.07
Follow-up	9.00 (8.95)	10.00(10.15)	0.72	0.11
<i>Responding to joint attention (%)</i>				
Entry	39.35% (0.310)	34.13% (0.25)	0.46	0.18
Exit	45.92% (0.290)	38.37% (0.30)	0.33	0.26
Follow-up	51.71% (0.299)	36.90% (0.34)	0.110	0.48
<i>Visual reception (age equivalency)</i>				
Entry	17.47 (6.84)	18.00 (6.65)	0.75	0.08
Follow-up	31.72(12.81)	29.46(10.78)	0.51	0.19
<i>Expressive Language (age equivalency)</i>				
Entry	12.50(8.37)	10.53 (5.94)	0.27	0.27
Exit	18.45(10.67)	16.28 (7.09)	0.35	0.24
Follow-up	29.08(12.32)	25.21 (10.92)	0.25	0.33
<i>Receptive language (age equivalency)</i>				
Entry	12.85(8.33)	10.97 (6.05)	0.30	0.26
Exit	17.90(11.52)	15.86 (9.06)	0.45	0.20
Follow-up	28.76(13.74)	25.88(11.72)	0.43	0.23

* Cramer's V.

Table 5

Outside services received at each time point.

Hours of non-project services received	Overall Mean (SD)	Control Mean (SD)	Treatment Mean (SD)	p-Value
Entry	7.51 (10.20)	5.40(5.81)	9.70(13.07)	0.55
Exit	13.42(11.37)	13.96(10.53)	12.86(12.34)	0.38
1 year	16.41 (9.78)	18.88(9.69)	13.94 (9.44)	0.09

Entry: 30 days prior to entry.

Exit: Between entry and exit.

1 year: between entry and 12 months.