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PLAY Project Home Consultation Intervention Program for Young Children With Autism Spectrum Disorders: A Randomized Controlled Trial

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ABSTRACT: *Objective:* To evaluate the effectiveness of the Play and Language for Autistic Youngsters (PLAY) Project Home Consultation model, in combination with usual community services (CS), to improve parent-child interaction, child development, and autism symptomatology in young children with autism spectrum disorders (ASDs) compared with CS only. *Methods:* Children (N = 128) with autism or PDD-NOS (DSM-4 criteria) aged 2 years 8 months to 5 years 11 months and recruited from 5 disability agencies in 4 US states were randomized in two 1-year cohorts. Using videotape and written feedback within a developmental framework, PLAY consultants coached caregivers monthly for 12 months to improve caregiver-child interaction. CS included speech/language and occupational therapy and public education services. Primary outcomes included change in parent-child interactions, language and development, and autism-related diagnostic category/symptoms. Secondary outcomes included parent stress and depression and home consultant fidelity. Data were collected pre- and post-intervention. *Results:* Using intent-to-treat analysis (ITT), large treatment effects were evident for parent and child interactional behaviors on the Maternal and Child Behavior Rating Scales. Child language and developmental quotient did not differ over time by group, although functional development improved significantly. PLAY children improved in diagnostic categories on the Autism Diagnostic Observation Schedule (ADOS). PLAY caregivers' stress did not increase, and depressive symptomatology decreased. Home consultants administered the intervention with fidelity. *Conclusions:* PLAY intervention demonstrated substantial changes in parent-child interaction without increasing parents' stress/depression. ADOS findings must be interpreted cautiously because results do not align with clinical experience. PLAY offers communities a relatively inexpensive effective intervention for children with ASD and their parents.

(*J Dev Behav Pediatr* 35:475–485, 2014) **Index terms:** developmental outcomes, early intervention, parent-mediated intervention.

Autism spectrum disorders (ASDs), characterized by social communication deficits and repetitive/restrictive patterns of behavior,¹ affect 1 in 68 children.² Prognosis is often poor with high economic costs for families and society.^{3–5} Better developmental outcomes are associated with early intensive intervention.³ Prognosis improves when children initially demonstrate functional play

abilities, higher cognitive abilities, and less initial severity.^{3,5,6} The National Research Council recommends engaging, intensive (15–25 hr/wk, high teacher to pupil ratio), early (18 mo–5 yr) intervention that addresses the comprehensive needs of children with ASD.⁷

Most states in the United States that mandate autism intervention by law require applied behavioral analysis

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methods,⁸ which are based on operant conditioning.^{5,9} Behavioral intervention is effective but very expensive (\$30–\$60,000 per year per child), difficult to administer and sustain, and there is a shortage of trained personnel.¹⁰ Despite legal mandates, too many young children with ASD are not receiving needed early intervention services.^{10–13} Effective, less expensive, and more easily disseminated models are needed. Furthermore, with few exceptions, behavioral research on ASD has largely focused on language and cognition as primary outcomes.^{5,14,15} With the recent DSM-5 focus on social impairment,¹ research that emphasizes social reciprocity is needed.

Parent-mediated interventions^{16–26} often focus on social reciprocity. They are typically much less costly, more easily implemented, and could offer an important alternative or complement to professionally delivered interventions if they were shown to be effective. Recently parent-mediated programs for ASD have been recognized as evidence-based.¹⁶ In these programs, professionals train parents one-on-one or in group formats in home or community settings with methods that may include didactic instruction, discussion, modeling, coaching, or performance feedback. Once trained, parents implement all or part of the intervention(s) with their child.¹⁶ A majority of parent-mediated models emphasize social reciprocity and/or improvement in developmental measures.^{17–26}

A recent review of rigorously designed parent-mediated interventions for young children with ASD¹⁷ found strong evidence for improvement in short-term parent-child interaction but less robust evidence for longer term effects on language, IQ, and core autism symptoms. Only 3 studies were a year-long or longer. None of the larger longer studies showed objective changes in autism severity/symptomatology by using such measures as the Autism Diagnostic Observation Schedule.^{17,19,23} The review emphasized the need for parent-mediated programs to monitor parent stress. They concluded that high-quality randomized controlled trials (RCTs) were still needed.

In this article, we present results from a RCT of the Play and Language for Autistic Youngsters (PLAY) Project Home Consultation program for young children with ASD (using DSM-4 criteria²⁷). PLAY is parent-mediated, developmental, and focused on social reciprocity.²⁸ PLAY is based on Greenspan and Wieder's²⁹ developmental, individual differences, and relationship-based (DIR) theoretical framework. Greenspan's "affect diathesis hypothesis" maintains that when dyadic interaction is contingent, reciprocal, and affectively laden (i.e., enjoyable), the child's diathesis/inherent tendency is to progress through a series of increasingly functional (i.e., socially competent) developmental levels. PLAY operationalizes DIR through a structured approach that includes coaching, modeling, and video feedback. PLAY consultants make monthly 3-hour home visits; a 15-minute video of representative play interactions is recorded and analyzed. This analysis includes a written "PLAY Plan"

describing methods, techniques, and activities that fosters parents' interactional abilities and play skills to promote their children's functional development.

PLAY addresses National Research Council recommendations for intensity by supporting parents in engaging their children for a minimum of 2 hours/day (15 hr/wk) in addition to usual community services. It was hypothesized that, compared with a control group, PLAY parents would improve in their interaction skills that would result in concomitant improvements in their children's interaction skills, language, development, and autism symptomatology.

Caregivers of children with ASD are at high risk for clinical levels of stress and depression.^{30–32} Both parenting stress and depression are associated with the demands of caring for a child with ASD.³² Since PLAY places more demands on caregivers, it was hypothesized that PLAY parents would experience more stress and depression than control parents. Finally, we assessed whether PLAY consultants showed fidelity to the model. This is an important outcome given that the intervention was conducted across multiple sites with multiple providers.

METHODS

Study Design and Participants

Michigan State University's (MSU) Institutional Review Board (IRB) approved the study. The Community Evaluation and Research Collaborative at MSU served as the study's independent evaluation team. The study was funded through the National Institute of Mental Health (NIMH) Small Business Innovation Research (SBIR) grant and registered with clinicaltrials.gov. An NIMH SBIR grant funded an initial feasibility study in 2006–2008, implementing the same process and most of the same measures.³³

Power Analysis

To identify the appropriate size for recruitment, power analysis was conducted based on the results from the feasibility study and comparable studies.^{19,34,35} Sample sizes needed to achieve power set at 0.8 with levels (Type I error) set at 0.05, accounting for correlated measures in a repeated measures analysis of variance (ANOVA) design testing a within- or between-subject treatment interaction (time \times group) were Maternal Behavior Rating Scale (MBRS): responsiveness ($d = 0.8$), required $N = 52$; and achievement ($d = 0.43$), required $N = 172$; Parent-Child Interaction's Child Communication Acts ($d = 0.73$), required $N = 62$; MacArthur Communicative Development Inventory's (MCDD) language comprehension ($d = 0.67$), required $N = 72$; and expressive vocabulary ($d = 0.40$), required $N = 200$. To determine the final recruitment target, we considered (1) the range of required N identified through these power estimates, (2) capacity per site to recruit and serve study children, (3) the study cost per site and per child, and (4) the variability evidenced in severity, demographic characteristics, and outcomes. The final recruitment target for analysis was 96 children, 19 per site

for the 5 sites after accounting for estimated attrition. After oversampling for an estimate of 20% attrition, the final recruitment target was 120, 60 per group/cohort (12 per site, with 6 per site receiving PLAY therapy).

Families were recruited from April 2010 to June 2012 through local physician offices in 5 cities (Detroit, MI; Peoria and Bloomington, IL; Billings, MT; and Evansville, IN) and referred for enrollment to Easter Seals sites in those cities, respectively. Easter Seals (ES) is a national, private, nonprofit, disability service agency. Two consecutive cohorts participated for 1 year each. Inclusion criteria were age 3.0 to 5.11 years (actual 2 yr 8 mo–5 yr 11 mo) at the time of intervention and previous clinical diagnosis of autism spectrum disorder (ASD) according to DSM-4²⁷ criteria (i.e., autism vs PDD NOS) and meeting criteria for autism or ASD on the Autism Diagnostic Observation Schedule (ADOS)^{36,37} and Social Communication Questionnaire (SCQ).³⁸ Exclusion criteria included a diagnosis of Asperger syndrome, genetic disorders, severe medical conditions, a parent with severe psychiatric disorder or cognitive impairment, and/or families in which English was not the primary language. The *Peabody Picture Vocabulary Test—Fourth Edition*³⁹ was used to screen parents for cognitive functioning that would permit understanding of the intervention processes with a minimum requirement of sixth-grade vocabulary. ES administrators obtained written informed consent. Of the 148 families screened, 128 met criteria and chose to participate (Fig. 1).

Research risks related to privacy of research data (e.g., videos, health information, etc) were addressed through the original application and the MSU IRB. Other risks included the need for appropriate clinical support during the research time frame, which was supplied through ES. Parent stress and depression were measured both before and after and monitored clinically. Families were expressly allowed to obtain other interventions at any time during the research time frame.

Table 1 displays child and family demographic characteristics by group. At baseline, children's average age was around 50 months (range, 32–71 mo). In accordance with the prevalence of autism, the majority of children were male. About one quarter of children were African-American, Asian, and/or Hispanic. Most of them were from 2-parent families, and more than half reported family incomes less than \$60,000 (US median income in 2011 was \$51,100). Most primary parents (responsible for participating in the intervention) were mothers. About half of the primary parents had a bachelor's degree.

Randomization

Deidentified demographic and diagnostic data for enrolled families were sent to the MSU research team for randomization to usual community services (CS) intervention or PLAY plus CS. Randomization was computer-generated and occurred within sites using a matched pair design with primary blocking variables of age (younger than 4.49 yr vs 4.5 yr or older), ADOS-

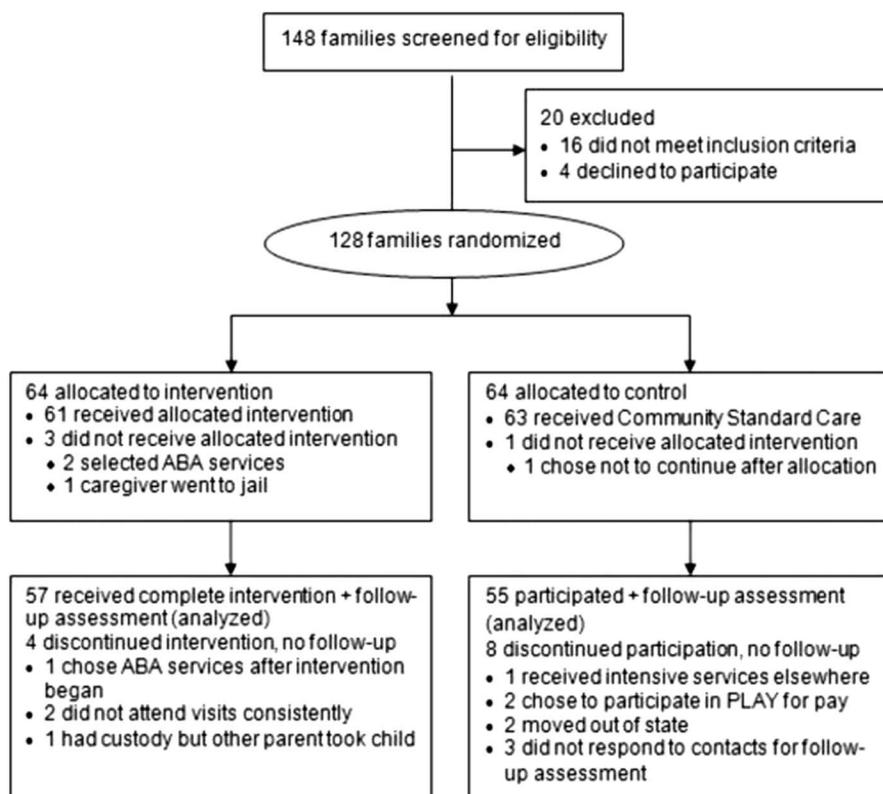


Figure 1. Participant enrollment and retention.

Table 1. Baseline Child and Family Characteristics

	Group		Test Statistics
	CS (n = 64), %	PLAY (n = 64), %	
Child			
Age, mo			0.38 ^a
Mean	50.53	49.85	
SD	10.07	10.43	
Male	84.4	79.7	0.48 ^b
Child of color	18.8	29.7	2.09 ^b
ADOS autism diagnosis (vs ASD)	68.8	70.3	0.04 ^b
Family			
2-parent household	87.1	90.5	0.36 ^b
Primary caregiver is mother	91.5	91.8	0.00 ^b
Primary caregiver's education, bachelor's degree or above	45.3	53.1	0.07 ^b
Income <\$60,000	54.0	56.3	0.07 ^b

^at, *df* = 126. Not significant. ^b χ^2 , *df* = 1. All values are not significant. ADOS, Autism Diagnostic Observation Schedule; ASD, autism spectrum disorder; CS, community services.

related autism categories (autism vs autism spectrum), and child's gender. Each group was allocated 64 families. PLAY and CS groups did not differ significantly on any demographic or outcome variables. Retention rate was 89.0% of PLAY families and 85.9% of control families for a total of 112 families. Retained and nonretained families did not differ significantly on demographic or outcome variables.

Intervention

The PLAY Project Home Consultation (PLAY) program is a well-established clinical model.²⁸ Since 2001, the PLAY Project training program has trained hundreds of masters/doctoral level consultants (SLP, OTs, MEd, PhD, and MD) reaching over a 1000 children nationally with dissemination in 27 states. PLAY typically supplements existing services (e.g., special education, language and occupational therapies, and/or applied behavioral analysis/behavioral interventions) but has been implemented as a primary intervention for ASD in early intervention settings. The average cost of PLAY is between \$3500 and \$4500 per year per child.

Treatment Group

In this study, 6 PLAY consultants (1 occupational therapist, 2 speech and language therapists, and 3 special educators) were employed at the 5 ES study sites and had 2 to 5 years experience as PLAY consultants. All had been trained to certification by attending a 4-day training seminar followed by 12 to 18 months of supervision. Supervision involved submitting 20 video write-ups

based on their clinical caseload to PLAY Project supervisors who evaluated their write-ups according to the PLAY Project fidelity manual.

PLAY services consisted of a 3-hour monthly home visit for 12 months (mean visits = 10.52; SD = 3.01). One week before the first visit, parents were encouraged (but not required) to review the PLAY Project DVD and written orientation materials. The 2-hour DVD introduced the parents to PLAY principles, methods, activities, and techniques through PowerPoint lecture slides combined with video examples. Written orientation materials (about 20 pages in total) described in detail the 6 functional developmental levels (FDLs) of Greenspan and Wieder's²⁹ developmental, individual differences, and relationship-based theoretical framework (see FEAS measure below) and provided descriptions and dozens of examples of PLAY techniques and activities based on the FDLs.

During the visits, the primary caregiver providing the majority of play interaction was targeted for instruction, but all caregivers were welcomed to attend monthly sessions. Consultants trained caregivers/parents through coaching, modeling, and video feedback. During *coaching*, consultants helped parents identify their child's subtle and hard to detect cues, respond contingently to the child's intentions, and effectively engage the child in reciprocal exchanges. Parents were taught to provide appropriate developmental challenges to promote progress in the child's FDLs.²⁹ During *modeling*, consultants played for 15 to 30 minutes with the child to demonstrate PLAY methods and techniques. During *video feedback*, the home consultant obtained a 10-minute representative sample of parent play, and the parent obtained a 5-minute representative sample of the home consultant modeling. A *written analysis of the video*, sent between visits, reviewed the parent-child and consultant-child video interactions, summarized the child's developmental profile, and recommended methods and techniques. The program was revised to address the child's evolving developmental profile. For example, as children became easier to engage, the intervention emphasized increasing the *length* of engagement, waiting for more *initiation*, and expecting more *reciprocal social exchanges*, thus increasing the complexity of interaction and helping the child move up FDLs. Consultants were available between visits as needed by e-mail or phone. Families were encouraged to engage their child in 15- to 20-minute play sessions and throughout daily for a total of 2 hours/day.

Control Group

Usual CS included special education public preschool services for 3 to 5 year olds that were free, typically composed of 4 to 5 half days of educational services and readily available in each of the study communities. The amount of these services was not consistently documented by parent report. Parents did report that on an average, they obtained approximately 100 hours/year (or approximately 2 hr/wk) of private speech and

language therapies. After randomization, 2 families from the CS group chose to pay for PLAY services rather than participating in the control group and left the study.

Measures

Measures were collected before randomization and 12 months after PLAY intervention began. Easter Seals (ES) site administrators collected demographic data for the child and family at the screening visit. ADOS evaluators were trained to research reliability. The ADOS and Mullen were administered in ES offices, and evaluators were blinded as to intervention status. Other parent-report measures were completed by parents in the home, collected, and reviewed for accuracy at ES offices. ES management and staff were trained according to training manuals by the central administrative office in Ann Arbor to use the various evaluation instruments. All interactional observation measures were video-recorded in the home, then scored by raters blinded to group, and time assignment. Each measure was deidentified and copied at the grant's central administrative office before being sent to MSU for data analysis. All measures were prespecified by grant aims according to the original NIMH grant protocol.

Intervention Hours

Parents completed monthly logs of time spent using PLAY and other types of interventions. Consultants collected logs at the PLAY home visit. Participation in other intensive interventions (i.e., at least 10 hr/wk) made families ineligible because of the potential confound with PLAY; 1 family from each group was removed for this reason.

Autism Diagnosis and Symptoms

The ADOS-generic³⁷ (ADOS-G) assesses social and communication behaviors representing ASD and was administered by independent assessors in ES offices. Assessors administered either Module 1 for children with little or no phrase speech or Module 2 for children who used phrase speech but did not speak fluently. Seventy participants were administered ADOS Module 1, and 26 participants were administered Module 2 at both pretest and posttest. The remaining 16 participants were administered Module 1 at pretest and Module 2 at posttest. Diagnostic classifications were based on research-derived cut points,³⁶ listed from the most to the least severe for *autism*, *ASD*, or *no autism* diagnosis (After pretest data collection on the ADOS-G, the revised ADOS-2 instrument was published.⁴⁰ This version includes an algorithm for a continuous calibrated severity score [CSS]. Since initial randomization was done using diagnosis from the original ADOS algorithms, replacing ADOS-G scoring with CSS algorithms resulted in participants being in different diagnostic groups for randomization or disqualifying them from the study, which would have invalidated the initial randomization. Thus, the continuous scores could not be used). At baseline, all children received ADOS classifications for either *autism* or *ASD*.

Parents also completed the SCQ,³⁸ a 40-item Yes/No measure of communication and social functioning that

aims to identify behaviors that would be rare in unaffected individuals ($\alpha = .79$ at baseline and $.85$ at follow-up).

Parent and Child Interactions

The MBRS⁴¹ and Child Behavior Rating Scale (CBRS)⁴² assessed parent and child interactional behaviors, respectively. Parent-child play with toys in the home was video-recorded for 7.5 minutes at pre- and post-assessment and coded by raters blind to group allocation and assessment time. Items were coded on a scale of 1 (none to minimal use of the interactive dimension) to 5 (high to continuous use of the interactive dimension). The MBRS assesses 4 interactive style dimensions: Responsive/Child Oriented (3 items, $\alpha = .87$ at baseline and $.91$ at follow-up), Affect/Animation (5 items, $\alpha = .85$ at baseline and $.89$ at follow-up), Achievement Orientation (2 items, $\alpha = .22$ at baseline and $.58$ at follow-up), and Directiveness (2 items, $\alpha = .64$ at baseline and $.53$ at follow-up). The CBRS is composed of 7 items, which assesses 2 interactive style dimensions for children: Attention (4 items, $\alpha = .88$ at baseline and $.89$ at follow-up) and Initiation (3 items, $\alpha = .70$ at baseline and $.83$ at follow-up). Interrater reliability was assessed through intraclass correlations (ICCs) for 20% of videos randomly selected and distributed over the time of the study. ICCs were moderate⁴³; ICCs for MBRS were $.64$ for Responsiveness/Child Oriented, $.70$ for Affect/Animation, $.73$ for Achievement Orientation, and $.61$ for Directiveness, and ICCs for CBRS scales were $.75$ for Attention and $.77$ for Initiation.

Child Developmental Outcomes

Developmental quotients were measured by *The Mullen Scales of Early Learning*⁴⁴ and calculated by dividing the child's age equivalent score by chronological age and multiplying by 100. Twenty percent of children at baseline and 17% at the second assessment either refused or were unable to complete the Mullen because of low levels of developmental functioning. These data were treated as missing and were not imputed. Children not completing the Mullen tended to be younger (47 vs 51 mo) ($F_{[1,110]} = 3.11, p = .081$) and more likely to be classified with Autism (vs ASD) on the ADOS at baseline (86% vs 68%) ($\chi^2_{[1, N = 112]} = 2.992, p = .084$).

Child language was also measured through parent report on the MCDI,⁴⁵ a standardized parent-report language measure for children from age 8 to 16 months (*Word and Gestures* Form: MCDI-WG) and 16 to 30 months (*Words and Sentences* Form: MCDI-WS). Since the children tended to evidence significant language delay, all parents completed the MCDI-WG form at each assessment point. Parents were asked to complete the MCDI-WS if the Easter Seals site administrator assessed the child's language development as appropriate for the questions. Parents completed the MCDI-WS for 30% of children at baseline and 51% of children at the second assessment. Reliabilities were as follows for MCDI-WG: Phrases understood (28 items) $\alpha = .95$ at baseline and

.94 at follow-up, Vocabulary (396 items) $\alpha = 1.00$ at baseline and 1.00 at follow-up, and Total gestures (63 items) $\alpha = .96$ at baseline and .97 at follow-up. Reliabilities for the MCDI-WS scales were as follows: Complexity (37 items) was $\alpha = .97$ at baseline and .95 at follow-up and Vocabulary (636 items) $\alpha = 1.00$ at baseline and 1.00 at follow-up.

The *Functional Emotional Assessment Scale*⁴⁶ is a video assessment of a child's interactional/social functioning. The FEAS has 6 sections and 34 items based on Greenspan's 6 FDLs,³³ which progress from simple attention (FDL 1) and engagement (FDL 2) to 2-way purposeful reciprocal exchanges (FDL 3), to problem-solving gestures (FDL 4), and then to the consistent use of words (FDL 5) leading to rich pretend play, emotional thinking, and complex interaction (FDL 6). Items are rated as 0 (not at all or very brief), 1 (present some of the time, observed several times), or 2 (consistently present, observed many times). Ratings were summed to compute scores. Higher raw scale scores indicate greater social-emotional development. Parent-child free play with toys in the home was video-recorded for 15 minutes at pre- and post-assessment and coded by raters blind to group allocation and assessment time. Internal consistency of the overall scale was .99 at pretest and .95 at posttest. ICCs for interrater reliability for videos randomized over time were .95, which is considered substantial.⁴³

Parent Outcomes

The Parenting Stress Index⁴⁷ (PSI), a 120-item screening and diagnostic instrument, identifies areas of stress from the domains of child characteristics, parent characteristics, and situational/demographic life stress. Parents completed these forms at home and then sent them to MSU for data analysis. Internal consistency for the total score was .94 at baseline and .95 at posttest. The PSI was analyzed both as a continuous score and as a binomial variable using the recommended cutoff for referral for clinical services of 260.

The Center for Epidemiologic Studies Depression Scale⁴⁸ (CES-D) is a 20-item questionnaire used to assess adult depressive symptoms. Parents were given these forms to complete at home and then sent to MSU for data analysis. Internal consistency was .93 and .92 at pretest and posttest, respectively. CES-D scores were analyzed continuously and as a binomial variable with scores of 16 and above categorized as at risk for clinical depression.⁴⁸

Consultant Fidelity

Two study supervisors, experts in PLAY methodology, trained to use the project's fidelity manual, and blinded to time, independently rated a random sample of consultant videos and write-ups. Supervisors agreed 100% on whether the consultants met or did not meet fidelity criteria.

Statistical Analysis

Apart from the Mullen and MCDI-WS, missing data were missing completely at random (Little's MCAR test $\chi^2_{[42, N = 112]} = 50.16, p = .181$). Data were imputed

forward for using the last observation carried forward method at the scale level. Although multiple imputation procedures are promising,⁴⁹ the field has not advanced to provide methods for addressing repeated measures ANOVA analysis,⁵⁰ as used in this article. A common alternative has been the use of last observation carried.^{51,52} Analyses used an intent-to-treat approach, which included all cases randomized to PLAY and CS groups including those that did not complete the intervention. Exceptions were the video-based MBRS, CBRS, and FEAS, which were rated only for cases that completed the intervention. To test for the effect of treatment group on ADOS classification, an ordered logistic regression was conducted predicting ADOS diagnosis at Time 2 controlling for initial diagnosis, child age, and site. Ordered logistic regressions were conducted for the PSI and CES-D binomial classifications at Time 2 controlling for site, child age and Time 1 classification on the measure. For all other outcomes, repeated measures univariate or multivariate analyses of covariance (analysis of covariance and MANCOVAs) were conducted on sets of variables with treatment group as a between-group variable. When MANCOVAs were significant, follow-up univariate analyses were conducted to identify the direction of the differences.

RESULTS

Dosage

PLAY families participated in an average of 10.52 visits (SD = 3.01) and reported using intervention with their children for 621.90 hours (SD = 273.64 hr) over the year (Table 2). In addition to usual community services (CS) (e.g., special education preschool), both PLAY and CS groups participated in about 100 hours of CS therapies (OT, Speech/Language, etc) per year. There were no group differences in CS therapies other than developmental, individual differences, and relationship-based/play-based interventions. In addition to PLAY consultation in the home, the PLAY group also received significantly more of these services in the community but they were infrequent (<10 hr/yr).

Autism Diagnosis and Symptoms

Table 3 displays the number of children by change in Autism Diagnostic Observation Schedule (ADOS) classification between Time 1 and Time 2 for each diagnosis and treatment group. Overall, 33% of CS children and 54% of PLAY children improved by at least 1 category. By Time 2, for children diagnosed with autism spectrum disorder, 41% of CS children and 53% of PLAY children improved, and for children diagnosed with *autism*, 29% of CS children and 55% of PLAY children improved.

Results of the ordinal logistic regression (controlling for child age, initial diagnosis, and site) predicting change in ADOS by treatment group indicated that the model was significant, $\chi^2_{(6, N = 128)} = 32.29, p < .001$,

Table 2. Total Hours of Intervention and Number of PLAY Visits

Intervention Type	CS (n = 64)		PLAY (n = 64)		t
	Mean	SD	Mean	SD	
Community services intervention, hr	101.87	98.14	110.15	152.19	-0.37
Occupational therapy	37.31	66.67	41.33	70.95	-0.33
Speech and language therapy	44.11	28.64	50.05	79.34	-0.56
DIR/play-based interventions	0.74	3.74	7.54	23.64	-2.27*
Behavioral intervention	19.70	61.40	11.24	38.50	0.93
PLAY intervention					
Parent-play interaction, hr	NA		621.90	273.64	NA
HC visits, N	NA		10.52	3.01	NA

* $p < .05$. CS, community services; DIR, developmental individual relationship; HC, home consultant; NA, not applicable.

with PLAY children more likely to improve in diagnostic classification than control children (Wald estimate = 5.91; location estimate = 0.87; 95% confidence interval [CI], 0.169-1.57; $p = .015$). The odds ratio of 2.39 indicates that PLAY children were more than twice as likely as control children to improve their diagnostic classification. Relative risk of no improvement was 32.30%, and absolute risk of no improvement was 21.66%.

Table 4 presents descriptive data, and repeated measure analysis of covariance and multivariate analysis of covariance (MANCOVA) results for time \times group analyses for all other outcomes for the intent-to-treat analysis. The Social Communication Questionnaire showed a positive effect for time, indicating that parents reported fewer symptoms over the time regardless of group but the time \times group effect was not significant.

Parent and Child Interactions

The repeated measures MANCOVA for parent interactions included the 4 Maternal Behavior Rating Scale scales and showed a significant and large time \times group effect. Univariate tests of each scale indicated that PLAY parents evidenced significantly greater change in interaction quality than CS parents. Effect sizes were moderate to large, especially for the Responsiveness/Child Oriented and Affect/Animation scales. Repeated measures MANCOVA results for the child interaction scales also evidenced a significant time \times group effect. Child Attention and Initiation improved in the PLAY

group, whereas remaining stable in the CS group with moderate to large effect sizes.

Developmental Outcomes

The Mullen developmental quotient results showed a trend for time \times group but no significant univariate effects. The parent-rated MacArthur Communicative Development Inventories (MCDI) had significant effects for time with all subscales except Vocabulary Understood demonstrating improvement. However, time \times group effects were not significant for either MCDI-WG or MCDI-WS. The FEAS video ratings showed a significant moderate time \times group effect with the PLAY group showing improvement in observed socioemotional behavior, whereas the CS group remained stable.

Parent Outcomes

Parenting stress levels decreased over time for both groups but did not differ by intervention group when analyzed continuously or categorically (Wald estimate = 0.65; $p = .42$; Exp(B) = 1.44; 95% CI, 0.591-3.508).

Depression scores of parents showed a trend for time by treatment group when measured on a continuous scale, with PLAY parents' depression scores tending to decrease more than that of CS parents. When classified as above or below, the threshold of "depressed," $\chi^2_{(6, N = 128)} = 30.86, p < .001$, with PLAY parents less likely to be classified as depressed over time than control parents (Wald estimate = 4.64; $p = .031$; Exp(B) = 3.02; 95% CI, 1.11-8.250).

Table 3. Number by Change in ADOS Classification from Time 1 to Time 2

Diagnosis Time 1	Diagnosis Time 2							
	Declined 1 Category (%)		No Change (%)		Improved 1 Category (%)		Improved 2 Categories (%)	
	CS	PLAY	CS	PLAY	CS	PLAY	CS	PLAY
ASD	3 (17.6)	2 (13.3)	7 (41.1)	5 (33.3)	7 (41.1)	8 (53.3)	NA ^a	NA ^a
Autism	NA ^b	NA ^b	27 (71.1)	19 (45.2)	6 (15.8)	13 (31.0)	5 (13.2)	10 (23.8)
Total	3 (5.0)	2 (4.0)	34 (61.8)	24 (42.1)	13 (23.6)	21 (36.8)	5 (9.0)	10 (17.5)

^aFor ASD, improvement of 2 categories was not possible. ^bFor autism, decline was not possible. ADOS, Autism Diagnostic Observation Schedule; ASD, autism spectrum disorder; CS, community services; NA, not applicable.

Table 4. Descriptives and Repeated Measures ANCOVA/MANCOVA Results for Outcome Variables

	Control					PLAY					Effects						
	N	Pre		Post		N	Pre		Post		df	Time			Time × Group		
		Mean	SD	Mean	SD		Mean	SD	Mean	SD		F	η^2	r	F	η^2	r
Autism symptoms																	
SCQ	60	21.65	4.77	17.98	6.04	62	21.19	5.16	17.92	5.73	1,114	3.22 ^a	.03	.17	1.03	.01	.09
Interactions						57											
MBRS	55					57					4,101	1.22	.05	.21	10.93***	.30	.55
Responsive/child oriented	55	3.13	0.90	3.18	0.99	57	3.14	0.93	4.19	0.75	1,104	1.72	.02	.13	18.00***	.15	.38
Affect/Animation	55	2.97	0.67	3.00	0.67	57	2.95	0.59	3.74	0.63	1,104	0.00	.00	.00	26.49***	.20	.45
Achievement orientation	55	2.72	0.75	2.85	1.05	57	2.82	0.83	2.26	0.66	1,104	1.02	.01	.10	11.75***	.10	.32
Directive	55	3.15	0.63	3.30	0.70	57	3.18	0.70	2.88	0.47	1,104	1.56	.02	.12	8.63**	.08	.28
CBRS	55					57					2,103	0.02	.00	.02	8.35***	.14	.37
Attention	55	3.21	0.75	3.22	0.95	57	3.28	1.01	3.91	0.73	1,104	0.05	.00	.02	8.15**	.07	.27
Initiation	55	2.83	0.66	2.96	0.92	57	2.96	0.89	3.81	0.91	1,104	0.02	.00	.01	16.67***	.14	.37
Developmental outcomes																	
FEAS	55	34.29	12.45	37.14	14.24	57	35.18	9.93	43.58	12.35	1,104	3.10 ^a	.03	.17	6.02*	.05	.23
Mullen developmental quotient	47					52					4,88	1.50	.06	.25	2.11 ^a	.09	.30
Visual reception	47	58.73	32.72	59.03	33.25	52	66.75	34.90	67.23	34.82	1,91	2.09	.02	.15	0.14	.00	.04
Fine motor	47	53.66	21.63	54.33	26.03	52	59.36	23.38	59.94	26.36	1,91	0.18	.00	.04	3.63 ^a	.04	.20
Receptive language	47	49.20	27.73	53.84	29.97	52	54.16	29.98	59.10	31.76	1,91	2.05	.02	.15	0.02	.00	.02
Expressive language	47	48.65	26.59	48.33	29.08	52	46.29	25.14	52.82	28.10	1,91	0.02	.00	.01	0.76	.01	.09
MacArthur Bates words and gestures											4,117	8.99***	.24	.48	0.49	.02	.13
Gestures	64	34.36	15.43	40.22	17.25	64	34.36	15.05	42.58	15.46	1,120	12.31***	.09	.31	0.10	.00	.03
Vocabulary understood	64	231.44	136.89	276.20	128.51	64	232.11	130.39	285.20	123.98	1,120	29.07***	.20	.44	0.02	.00	.01
Vocabulary produced	64	77.55	69.67	81.59	85.58	64	75.94	53.59	66.41	58.91	1,120	0.06	.00	.02	1.39	.01	.11
Phrases understood	64	19.09	8.69	22.27	7.32	64	19.16	7.52	23.09	6.54	1,120	28.52***	.19	.44	0.40	.00	.06
MacArthur Bates words and sentences	22					16					2,29	3.47*	.19	.44	1.43	.09	.30
Vocabulary produced	22	492.73	158.97	590.55	123.70	16	540.44	115.58	598.25	129.12	1,30	6.18*	.17	.41	0.64	.02	.14
Complexity	22	17.55	12.71	25.77	10.14	16	22.94	7.04	29.81	7.48	1,30	6.74*	.18	.43	0.06	.00	.55
Parent outcomes																	
PSI	63	270.57	41.27	249.97	40.35	62	263.28	48.60	237.00	45.48	1,117	3.72 ^a	.03	.18	0.00	.97	.00
Depression	64	11.91	9.56	11.43	9.42	64	12.08	11.42	8.69	8.98	1,120	0.01	.00	.01	3.14 ^a	.03	.16

Controlling for site, child age, and ADOS diagnosis at entry. * $p < .05$, ** $p < .01$, *** $p < .001$. ^a $p < .10$. ANCOVA, analysis of covariance; CBRS, Child Behavior Rating Scale; MANCOVA, multivariate analysis of covariance; MBRS, Maternal Behavior Rating Scale; PSI, Parenting Stress Index; SCQ, Social Communication Questionnaire.

Consultant Fidelity

Consultants completed 610 visits and submitted 138 (23%) videos and write-ups for review; each consultant was rated for at least 22 submissions. Nearly, all (97%) submissions reached criteria. Those that did not reach criteria received corrective feedback.

DISCUSSION

This randomized controlled trial (RCT) evaluated the PLAY Project Home Consultation (PLAY) program, a parent-mediated intervention model that uses a developmental relationship-based approach for young children ages 3 to 5 years old with autism spectrum disorder (ASD) (i.e., autism or PDD-NOS by DSM-4 criteria). After 12 months of intervention, the following aims, using an intent-to-treat analysis, were demonstrated: On the Maternal Behavior Rating Scale, PLAY parents significantly improved in their abilities to sensitively respond and effectively engage their child; on the Child Behavior Rating Scale, PLAY children's interaction skills within the home improved with increased shared attention and initiation; and as measured by the Functional Emotional Assessment Scale, PLAY children's social-emotional development significantly increased. Autism symptomatology, measured by the Autism Diagnostic Observation Schedule-Generic (ADOS-G), also improved significantly with PLAY children more than twice as likely to improve in their autism diagnostic category. Although the interactional and functional developmental outcomes were robust, the ADOS findings must be interpreted with caution.

Other studies have used the ADOS as an outcome measure with equivocal or negative results.^{19,23} To our knowledge, this is the first larger scale, longitudinal (12 mo) controlled study using a parent-mediated model to show improvement in autism symptomatology as measured by the ADOS. These ADOS results, however, have led to some incongruous results when interpreted clinically (Table 3). Forty-one percent of community service (CS) children and 53% of PLAY children in the "ASD" group improved significantly enough to be categorized clinically as no longer on the autism spectrum. Furthermore, 16% of CS and 31% of PLAY children categorized as being in the "Autism" ADOS category improved enough to move to the milder diagnosis of ASD. Finally, 24% of PLAY and 13% of CS children classified in the Autism category at pretest no longer were classified on the spectrum at posttest. This kind of dramatic improvement in 1 year is not in agreement with clinical experience.

The ADOS, according to the ADOS diagnostic manual, "is only one component of a full diagnostic evaluation for ASD... information from this instrument should never be used in isolation to determine an individual's clinical diagnosis."⁴⁰ The ADOS-G has been revised to improve diagnostic accuracy⁴⁰ (after pretest data collection on the ADOS-G, the revised ADOS-2 instrument was published.⁴⁰

This version includes an algorithm for a continuous calibrated severity score [CSS]. Since initial randomization was done using diagnosis from the original ADOS algorithms, replacing ADOS-G scoring with CSS algorithms resulted in participants being in different diagnostic groups for randomization or disqualifying them from the study, which would have invalidated the initial randomization. Thus, the continuous scores could not be used). Categorical cutoffs on the ADOS-G might have led raters to interpret the test items such that slight changes in score caused categories to be crossed leading to the incongruous results. Because of these concerns, the improvement of autism symptomatology in the PLAY group must be viewed very cautiously. Results need to be replicated in future studies and should include clinical correlation.

Parent-mediated intensive intervention models may present potential harms. Increasing demands on parents may add to parental levels of stress and depression.^{53,54} However, interventions that offer support and/or lead to improvement in children's symptoms have been shown to lower reported parental stress.^{55,56} Consistent with this, PLAY parents' stress did not increase. Parents of children with ASD also demonstrate more depression than parents of typically developing children,⁵⁷ yet PLAY parents showed a significant reduction in depressive symptomatology when compared with CS parents. These findings must be interpreted cautiously since improvement in depression resulted when established cutoffs (scores ≥ 16) for depression were used, whereas analysis of continuous depression scores showed no significant findings. Nonetheless, our study is one of the first rigorous long-term studies to show a reduction in depression after intensive intervention.⁵⁵⁻⁵⁷

Our study has limitations. Language, as measured by MacArthur Communicative Development Inventory, and developmental quotient, as measured by the Mullen, showed no differences between groups. These mixed findings improved parent-child interaction with less robust outcomes in language and IQ measures and are characteristic of the other RCTs of parent-mediated models.^{23,26} Longer term studies with children carefully enrolled by cognitive/language level may be necessary. Also, the intervention group received similar CS as the control group, making it difficult to assess PLAY in isolation. Combining parent-mediated interventions with other locally available services, however, may improve the comprehensiveness of services and might be preferred for local autism treatment provision so that the burden on parents is shared.¹⁷ Finally, parents in this study were better educated and of somewhat higher socioeconomic status than average, which may limit the generalizability of findings.

CONCLUSIONS

This study has implications for dissemination of ASD services. This was a community-based real-world implementation of the PLAY Project Home Consultation

intervention for young children with ASD, adding 3 hours/month of home visitation within the context of usual CS. PLAY consultants showed fidelity in implementing the model, and parents consistently and effectively applied the program, providing about 2 hours/day of engaging interaction with their children. PLAY children made greater improvements in their interaction, functional development, and autism symptomatology than CS children. PLAY offers communities a relatively inexpensive effective treatment for children with ASD and their parents.

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