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Caregiver-Mediated Intervention for Low-Resourced Preschoolers With Autism: An RCT

WHAT'S KNOWN ON THIS SUBJECT: Mixed results exist regarding the efficacy of caregiver-mediated interventions for children who have ASD. To date, randomized controlled studies have rarely compared 2 active interventions; none have focused on targeting families who are low-resourced in the community.

WHAT THIS STUDY ADDS: Significant improvements were found in social communication of children who have autism when caregivers received a hands-on caregiver training intervention in the home. These are the first data from a low-intensity, short-term intervention with low-resourced families.

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abstract

OBJECTIVES: To compare 2 short-term, community caregiver training interventions for preschool-aged children with Autism Spectrum Disorder who had low resources. Low resource was defined by the US Department of Housing and Urban Development low-income index or 1 "indicator," (eg, Medicaid eligibility). Child outcomes focused on joint engagement, joint attention, and play.

METHODS: Participants included 112 families of a child who had Autism Spectrum Disorder who met criteria for being low-resourced and who were randomly assigned to 1 of 2 3-month interventions, group caregiver education or individualized caregiver-mediated intervention (CMM). Children were assessed for social communication skills pre- and post-treatment, and followed up at 3 months.

RESULTS: All children improved in joint engagement and initiating joint attention, with significantly greater improvement by the CMM group. Outcomes on play skills were mixed, with improvement of symbolic play for the CMM group and no change in functional play skills. Joint engagement maintained over time for the CMM group, and initiating joint attention maintained for both groups over time.

CONCLUSIONS: This study is among the first randomized trials comparing 2 active interventions with a large sample of low-resourced families. Results suggest improvements in core autism deficits of joint engagement, joint attention, and symbolic play with relatively brief, caregiver-mediated interventions, but additional support is necessary to maintain and generalize these gains over time. *Pediatrics* 2014;134:e72–e79

Randomized controlled studies of early interventions for children who have Autism Spectrum Disorder (ASD) have yielded impressive, albeit varying, changes in child IQ, adaptive behavior, language, and social communication outcomes.[1–5] Over the past decade, we have amassed an evidence base of effective interventions that can be recommended to families. However, the evidence for the efficacy of these approaches is less established with low-income, low-resourced families in community settings, and when mediated by caregivers versus trained therapists.

One reason for our limited knowledge is that most ASD early intervention research studies have involved homogeneous participant populations. The evidence base is built primarily on participants who are more highly educated and more advantaged than families in the broader population. Low-income and minority families in particular have been underrepresented in these studies. Such underrepresentation is not surprising given data on later average age of ASD diagnosis in ethnic minorities, and greater difficulty these families have in accessing early intervention services.[6,7] Of concern is that once identified, these families often report more severe ASD symptoms in their children.[8,9]

Lower-resourced families also experience other barriers to participation in research. Most studies occur near large autism centers, often in clinical settings. For example, 4 of 5 randomized controlled trials of caregiver-mediated interventions were conducted in clinical settings, and not in homes.[2,10–13] The burden of travel and economic impacts of time off work may limit involvement of low-resourced families.[14] Some families also have difficulty obtaining information about potential studies, either because of language barriers or lack of knowledge about how to find information about research opportunities.

Finally, we have limited understanding of the effectiveness of early interventions.

Few interventions have been subjected to rigorous testing using randomized controlled designs, and there are limits to the outcomes measured. Often studies focus on change in IQ, which may not be appropriate as an outcome of short-term interventions given concerns over practice effects and the dissociation of IQ and ASD core deficits.[15,16] In the current study, our intervention was aimed at improving the types of core deficits that distinguish young children who have autism from children who have other developmental delays, and that are most challenging to change.[17] These core deficits include child initiation of joint attention, diversity of play acts, and joint engagement with caregivers.

The goal of the current multisite study was to determine if a short-term, low-intensity, caregiver-mediated intervention aimed at core autism deficits would be efficacious with low- resourced families. Our primary aim was to improve dyadic joint engagement between caregiver and child, and secondary aims were to improve child initiations of joint attention and play. Families of 2- to 5-year-old children who have ASD were recruited to participate if they met study criteria for being low-resourced. To compare efficacy, children were randomized to a caregiver-mediated joint engagement intervention carried out across daily home routines, or to a caregiver group intervention containing similar information. We expected superior outcomes from the caregiver-mediated group compared with the caregiver education group.

In this study, several design issues were considered to recruit low-resourced families. The study involved the possibility of receiving 1 of 2 potentially efficacious interventions rather than a "treatment as usual" group. The study was carried out in the homes and neighborhoods of participants. Effort was made to work within family schedules (eg, nights, weekends) and in the caregiver's preferred language. Finally,

we designed the intervention to be easily mediated in the home across everyday activities that were identified as important by the families themselves.

METHODS

Study Procedures

Children meeting inclusion criteria were randomized to 1 of 2 intervention groups: Caregiver-Mediated Module (CMM) or Caregiver Education Module (CEM). Examiners blind to treatment status conducted all pretreatment, post-treatment, and follow-up assessments. Randomization and analyses were conducted by an independent data-coordinating center.

Participants

Children were recruited from 5 study centers across the country and approved by local Institutional Review Boards. Given the geographic diversity of sites, being "low-resourced" was broadly defined by 1 of the following options: (1) low income as indicated by the US Department of Housing and Urban Development for reported family income, number of family members, and state of residence, or (2) 1 of the following indicators: mother held a high school diploma or lower; primary caregiver unemployed; government assistance (eg, Medicaid). Children were between age 2 and 5 years, with a Mullen mental age above 12 months; independent assessors confirmed the clinical diagnosis of ASD using the Autism Diagnostic Observation Schedule (ADOS). Children who had known genetic comorbidities were excluded (eg, fragile X). Recruitment occurred over 23 months (from August 2009 through July 2011). There were 147 families who participated in the initial assessment and were randomized to a treatment condition, 112 of which entered treatment. Thirty-five families never began intervention sessions (eg, changed mind, could not be located). There were no significant differences in child (age,

gender, ethnicity, primary language) or caregiver characteristics (income, education, and financial assistance) between those who withdrew and those who entered treatment. The final sample consisted of 112 preschoolers and their caregivers (see Fig 1).

Demographic characteristics for the 112 participants who entered treatment are presented in Tables 1 and 2. Nearly half had received no other intervention services before entering the study. The participants were diverse, with 66% identifying as a racial/ethnic minority and 15% who spoke languages other than English at home.

Intervention Groups

The CMM group involved 2 1-hour sessions per week for 12 weeks in the home. Caregivers were actively coached in the treatment model with their child by trained interventionists (established fidelity of >0.80 before beginning treatment). The interventionists followed a manualized intervention that was focused on establishing dyadic engagement during 3 routines at home; 1 routine involved play and 2 others involved "everyday activities," such as chores (eg, watering plants, helping with laundry) and grooming (eg, washing hands, brushing teeth) as requested by the family. The intervention followed the Joint Attention Symbolic Play Engagement and Regulation (JASPER) treatment, a manualized developmental and behavioral intervention involving active coaching of caregivers to use strategies for setting up the learning environment, modeling and prompting for joint attention, expanding play, and using developmentally appropriate language.[11] A new strategy is introduced each week. Weekly written materials were provided, and for the 15% of participants who spoke a language other than English at home, intervention was delivered in their preferred language. Fidelity was assessed on each therapist monthly for each child and av-
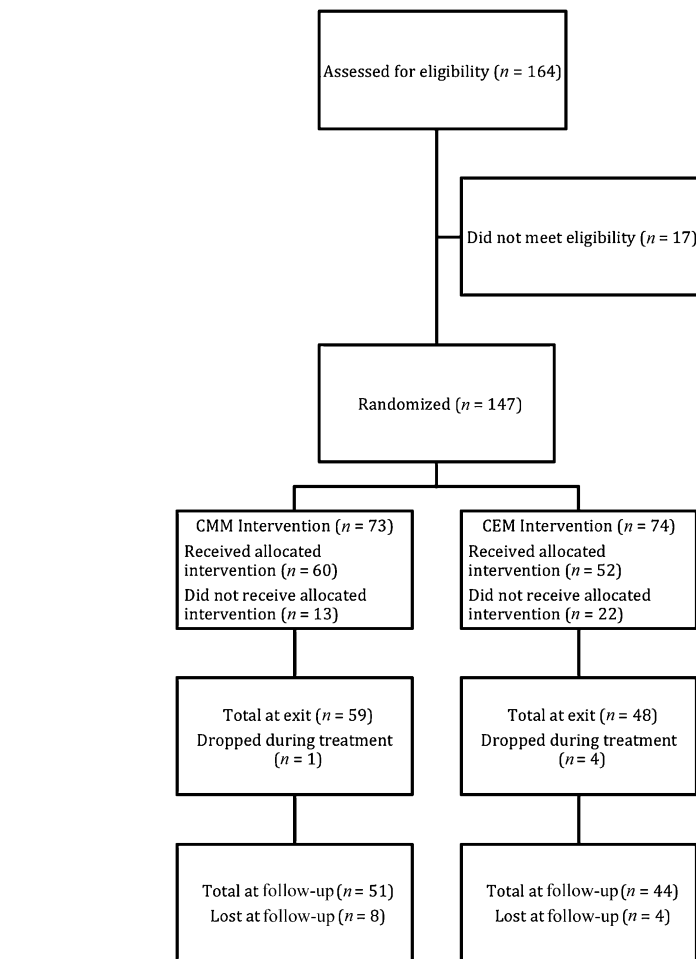

FIGURE 1
Recruitment flow diagram.

eraged 76%, with a range of 0.41 to 0.99. When therapists fell below 0.80 in fidelity, the lead site coordinator gave weekly feedback on sessions.

The CEM group involved small group-based caregiver training without the child being present. Caregivers gathered in neighborhood locations, such as homes, community centers, clinics, and schools. The caregivers attended 2-hour group sessions each week that covered similar material to the CMM intervention, with a focus on teaching communication to their children, the ABCs of behavior management, and developing routines. The CEM group followed a manualized intervention with informational handouts similar to CMM given out each week. Fidelity of therapist implementation was assessed on 20% of

sessions and averaged 0.97 with a range of 0.83 to 1.00.

Measures

Independent testers blind to study hypotheses conducted all assessments.

ADOS[18]

This semi-structured observational assessment employs a standard set of probes to measure autism symptoms in social behavior, communication, and repetitive behaviors generating algorithms for ASD cutoffs. The ADOS was used for eligibility.

Mullen Scales of Early Learning[19]

This standardized test of fine and gross motor, visual reception, and expressive and receptive language yields age-equivalent scores, and was used for eligibility.

TABLE 1 Child Characteristics at Baseline

Child Characteristics, N (%)	CEM, N = 52	CMM, N = 60
Chronological age, mo: mean (SD)	42.8 (10.21)	41.9 (10.0)
Gender		
Male	43 (82.7%)	50 (83.3%)
Female	9 (17.3%)	10 (16.6%)
Race/ethnicity		
White	16 (30.8%)	23 (38.3%)
Hispanic	7 (13.5%)	9 (15.0%)
African American	18 (34.6%)	13 (21.7%)
Asian	4 (7.7%)	5 (8.3%)
Multi-ethnic/other	7 (13.5%)	10 (16.7%)
Language child hears most at home		
Non-English	5 (9.6%)	10 (16.6%)
Receives other early intervention services		
No	10 (19.23%)	10 (16.67%)
Yes	42 (80.77%)	48 (80.0%)
Missing	0 (0%)	2 (3.33%)
Mullen age equivalency, mo: mean (SD)		
Mental age	26.3 (11.8)	23.6 (11.6)
Receptive language	23.3 (13.2)	22.1 (14.4)
Expressive language	24.1 (13.5)	20.1 (12.6)
Fine motor	29.1 (10.8)	25.5 (9.3)
Gross motor	28.8 (12.2)	26.4 (12.7)
ADOS severity score: mean (SD)		
Module 1 (0 to 10)	7.53 (1.8)	7.6 (2.3)
Module 2 (0 to 10)	6.3 (1.1)	6.4 (1.9)
Module 3 (0 to 10)	6.0 (0)	7.7 (0.6)

TABLE 2 Caregiver Characteristics at Baseline

Caregiver Characteristics	N (%)	
Maternal education		
<12th grade	3 (5.8)	4 (6.7)
High school diploma or GED	8 (15.4)	9 (15.0)
Some college/ college degree	29 (55.8)	36 (60)
Graduate work/ graduate degree	12 (23)	9 (15)
Unknown	0 (0)	2 (3.3)
Low income		
No	19 (36.5)	19 (31.7)
Yes	31 (59.6)	38 (63.3)
Unknown	2 (3.9)	3 (5.0)
Medicaid		
Yes	16 (30.8)	23 (38.3)
Any assistance		
Yes	27 (51.9)	35 (58.3)

Caregiver-Child Interaction

A 10-minute videotaped interaction between caregiver and child was collected at pre-, post- and follow-up to treatment. Caregivers were asked to play with their child as they normally would. 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). Caregiver interactions from the caregiver-child interaction sessions were coded for child play diversity types (coded the same as in the structured play assessment [SPA]), and joint engagement between caregiver and child. Joint engagement, our primary measure, was measured by continuously coding the caregiver-child interaction using a well-validated measure of joint engagement states.[20] Independent observers coded the beginning and end of joint engagement, defined as the child and caregiver engaged with the same activity and with both aware of the roles of the other. Inter-rater reliability among 9 independent raters was ICC = 0.89.

Caregiver Adherence Measures: Caregiver Diary and Caregiver Quality of Involvement Scales

The caregiver diary asks the caregiver to document the extent to which they are using the strategies they are learning each week (see Supplemental Information). Four questions address caregiver adherence and 2 address caregiver competence. Each is rated on a 1 to 5 scale and averaged across weekly sessions. Cronbach's α for the measure was 0.82.

Interventionists rated the caregiver's quality of fidelity to the intervention on the Caregiver Quality of Involvement Scale (CQI). This scale consists of 4 items relating to the caregiver's enthusiasm, comfort, confidence, and execution of specific strategies; each item is rated on a 1 to 5 scale, averaged across weekly sessions. Cronbach's α for CQI was 0.86.

The Early Social Communication Scales[21]

This experimenter-child assessment of nonverbal communication behaviors 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). Total frequency of initiating joint attention was a secondary variable. Inter-rater reliability among 8 independent coders blind to group status was ICC = .80.

SPA[22]

The examiner sequentially introduces 5 sets of toys designed to elicit play acts. The SPA is videotaped and coded for the diversity of play acts, defined as the number of different acts with toys within the same level of play (eg, doll feeds the dog and doll brushes the dog are 2 types within a symbolic level of play, "doll as agent").[23] Total functional and symbolic play diversity types were secondary variables of interest. Inter-rater reliability among 9 independent coders was ICC = 0.89.

Statistical Analyses

Generalized linear mixed models (GLMM) with main effects of treatment (CMM and CEM) and time (baseline, end of

treatment, and 3-month follow-up), treatment by time interactions, and subject-level random intercepts were used to model the longitudinal trajectories of the outcomes, employing an identity link for continuous outcome variables and a log link function for count outcomes (using SAS MIXED and GLIMMIX procedures, respectively). We used a hurdle model with random effects to assess the effects of treatment on symbolic play types across time (using SAS NLMIXED procedure) to adjust for the inflation of 0 counts. Bonferroni adjustment for multiple testing was employed, and tests that survived the Bonferroni adjustment were denoted with an asterick in the results section. Lastly, we reported the effect size by using Cohen's f in the results section where effect sizes of 0.10, 0.25, and 0.40 are generally regarded as small, moderate, and large, respectively (see Supplemental Information).[24]

RESULTS

Preliminary Analyses

There were no significant group differences in gender, siblings, ethnicities, chronological age, additional intervention services received, and family income at baseline (see Table 1). Although the CEM group had a slightly higher but non-significant average mental age compared with the CMM group, mental age at baseline was included in all regression models to adjust for potential confounding effects. Site main effects and interactions with time in the primary outcome models were checked and found insignificant; site was omitted from the final models. Treatment effect was defined as a significant interaction between the treatment groups and time during treatment (baseline to end of treatment) and maintenance of treatment effect was defined as a significant interaction effect between the treatment groups and time (baseline to the 3-month follow-up).

Attrition was high (35% by follow-up) but not significantly different by treatment group ($P = .40$). However, percentage of sessions completed did significantly differ by treatment group, with the CMM group completing 90% of sessions compared with 71% for CEM ($P < .001$). No significant differences in child or caregiver characteristics were found between caregivers who completed the required number of sessions (set at 80% of total, as the last 2 sessions were review) and those who did not.

The unadjusted means at each time point for the primary and secondary outcomes are presented in Table 3. The means and proportions within the table are not adjusted for any other covariates and are different from the predicted means (adjusted for mental age at baseline) presented in later sections.

Primary Outcome

Joint Engagement

Total time spent in joint engagement was modeled by using a linear mixed model. Both the CMM and the CEM group showed improvements in total time spent in joint engagement ($F[1,192] = 11.28; P < .001$) during the treatment period and a significant interaction between treatment group and time during treatment ($F[1,192] = 8.82; P = .003*$), with the CMM group (predicted mean baseline, 226.37 and predicted mean exit, 333.46) exhibiting a greater rate of improvement compared with the CEM group (predicted mean baseline, 253.66 and predicted mean at end of treatment, 260.24). The increase in joint engagement for the CMM group was clinically meaningful, with engagement improving to over half the interaction period, and a rate of difference between groups of 44.7%. The difference in joint engagement by the end of treatment corresponded to a moderate treatment effect size of 0.21 (Cohen's f).[24] The effect of treatment was maintained for the

CMM group ($F[1,192] = 5.85; P = .02$) by the 3-month follow-up (see Fig 2).

Secondary Outcomes

Early Social Communication Scales Initiating Joint Attention

Although both groups showed improvements in initiating joint attention (IJA) ($F[1,197] = 21.97; P < .001*$) during the treatment period, there was a significant interaction effect between treatment group and time ($F[1,197] = 3.74; P = .05$) with the CMM group (predicted mean baseline, 5.60 and predicted mean at end of treatment, 10.28) exhibiting a greater rate of improvement compared with the CEM group from baseline to end of treatment (predicted mean baseline, 7.67 and predicted mean at end of treatment, 9.86). The increase in IJA for the CMM group more than doubled but yielded a statistically significant small effect size (effect size = 0.14).[24] At the 3-month follow-up, the effect of treatment was maintained for both groups ($F[1,197] = 3.94; P = .05$), and both groups had significantly higher IJA at their follow-up compared with their entry ($F[1,197] = 2.09; P = .04$) and $F[1,197] = 4.63; P = .03$, respectively) (see Fig 3).

SPA Functional and Symbolic Play Types

Neither group exhibited significant improvements in functional play types during the treatment phase ($F[1,194] = 0.54; P = .46$), and there was no significant treatment ($F[1,194] = 0.08; P = .78$) or maintenance effect ($F[1,194] = 1.25; P = .26$).

Symbolic play types were modeled using a hurdle model in which the 2 processes were modeled simultaneously. The estimated parameters for the binary model were not significant except for mental age at baseline. Children who had higher mental ages at baseline had lower odds of having 0 symbolic play types ($F[1,109] = 29.26; P < .001$). The interaction between treatment group and time ($F[1,109] = 10.07; P = .002*$)

TABLE 3 Unadjusted Child Outcomes at Baseline, Exit (12 Wks), and Follow-up (24 Wks)

Assessments	CEM, $N = 52$	CMM, $N = 60$
	Mean (SD)	Mean (SD)
Early social communication scales		
Initiates joint attention		
Entry	14.65 (18.0)	9.4 (12.7)
Exit	19.08 (19.8)	16.6 (20.5)
Follow-up	17.84 (16.5)	15.4 (14)
Structured play assessment		
Functional play types		
Entry	16.69 (7.7)	15.6 (9.2)
Exit	17.46 (9.3)	16.9 (10.1)
Follow-up	18.68 (7.8)	17.0 (9.5)
Symbolic play types		
Entry		
Zeroes: n (%)	27 (52.9%)	30 (50.0%)
>Zeroes, mean (SD)	3.08 (2.1)	2.80 (2.8)
Exit		
Zeroes, n (%)	23 (47.9%)	24 (41.4%)
>Zeroes, mean (SD)	2.88 (2.0)	5.05 (6.0)
Follow-up		
Zeroes, n (%)	13 (28.9%)	17 (33.3%)
>Zeroes, mean (SD)	3.34 (3.0)	4.03 (3.1)
Parent child interaction		
Time joint engaged (sec)		
Entry	258.75 (137.1)	220.5 (150.1)
Exit	267.96 (138.1)	334.6 (144.7)
Follow-up	266.41 (126.5)	309.6 (154)
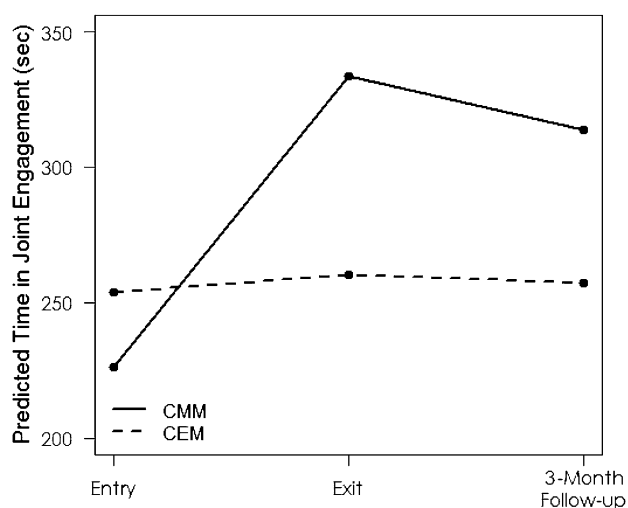
FIGURE 2
Primary aim: predicted time in joint engagement across groups and time for children who have average mental age (24.85 months).

was significant in the truncated Poisson model, indicating that, among the children who had a positive count for symbolic play types (those who crossed the "hurdle"), the children in the CMM group had significantly better rates of improvement (predicted mean baseline, 1.38 and predicted mean at end of treatment, 2.79) compared with the CEM group from baseline to the end of treatment (predicted mean baseline, 1.81 and predicted mean at end of treatment, 1.66). The difference in change in symbolic play between the 2 groups (more than doubling for the CMM group) yielded a moderate effect size, 0.30.[24] The effect of CMM on symbolic play was not maintained (F[1,109] = 2.35; $P = .13$) at the 3-month follow-up.

Caregiver Involvement and Adherence

Across both interventions, the majority of caregivers rated their use of strategies at home high, where lower scores indicated that caregivers have little difficulty carrying out the intervention strategies, CMM mean of 1.30 (SD, 0.56) and CEM mean of 1.53 (SD, 0.85), Wald's Chi-square, $x^2(1) = 1.47$; $P = .23$. The average CQI scores rated by the interventionist ranged from 3 to 5 with a mean of 4.28 (SD, 0.50) for the CMM group and 4.28 (SD, 0.49) for the CEM group, Wald's Chi-square, $x^2(1) = 0.01$; $P = .91$. Caregivers in both groups had high adherence as rated by interventionists, with higher scores indicating greater adherence.

DISCUSSION

This study is unique relative to previous intervention studies in children who have ASD in that it enrolled a large percentage of families who were non-white (66%) and disadvantaged. The current study also delivered intervention in homes, focused on core social communication skills, and employed a randomized, comparative efficacy study in 1 of the largest samples to date.

Both intervention groups improved over time but compared with the CEM caregiver education model, the CMM caregiver-mediated intervention was significantly more effective for improving the primary outcome measure of joint engagement, a measure of reciprocal and active engagement by both caregiver and child that yielded a moderate treatment effect.[24] CMM also resulted in small and significant improvements in secondary outcomes of initiating joint attention and symbolic play. These are some of the first data on a large sample of underserved families that indicate caregiver success in improving their children's joint attention and joint engagement, arguably
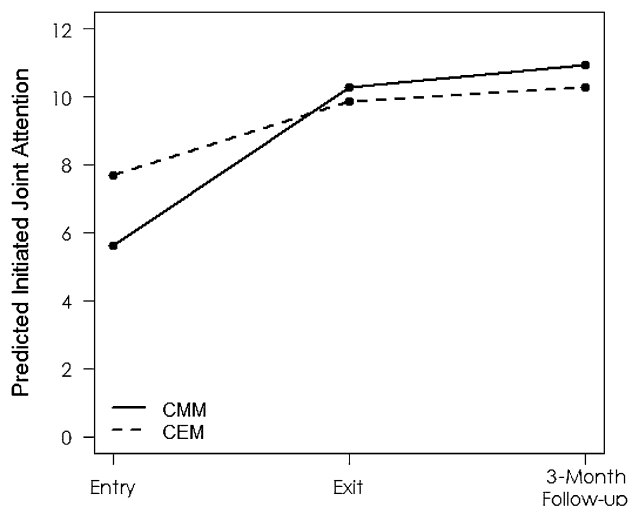
FIGURE 3
Secondary aim: predicted rate of initiating joint attention across groups and time for children who have average mental age (24.85 months).

among the most difficult impairments to change in children who have autism. Specifically, very few studies have measured change on initiating joint attention skills as a result of targeted interventions, regardless of approach.

Finally, maintenance of effects from end of treatment to follow-up was mixed. Children maintained their skill in initiating joint attention and joint engagement with their caregivers, particularly for the CMM group. Functional play did not change over treatment and follow-up, and symbolic play that improved over treatment of the CMM group was not maintained over the 3-month follow-up. These data highlight both the promise and the limitations of short-term intervention studies.

The promise of these data demonstrates that change can be made in core developmental problems for children who have ASD with a relatively brief but targeted intervention. These core areas of impairment are not easy to change, and the effect of the intervention was pro-nounced over an active comparator condition with similar intervention content. These data contribute to the literature on caregiver-mediated interventions with young children who have ASD that has yielded mixed results even when compared with treatment as usual samples. For example, 2 other caregiver-mediated interventions, 1 conducted in groups similar to CEM[10] and another similar to CMM conducted 1-on-1 with a therapist coaching model,[12] yielded non-significant differences from community control samples. However, another study found benefit to caregiver-mediated interventions compared with community controls on caregiver responsiveness, shared attention, and child social communication behaviors,[2] and along with the data from the current study underscore the importance of augmenting "treatment as usual" with caregiver-mediated interventions.[25,26]

The limitations, however, are related to the short-term nature of the interventions, and the difficulty continuing the intervention once active support is removed. Without continued support, caregivers may not know what to teach and how to teach it.[23,27–28] Thus, although short-term interventions can inform the field as to what is possible to achieve, children who have ASD need continued support as their developmental abilities change.

Another limitation is the relatively high percentage of families who did not complete the intervention (with the majority of dropped cases occurring before intervention began). Reasons for the lack of treatment uptake are unclear, but likely varied from caregivers not wanting the treatment to which they were allocated to difficulty scheduling time. For families who did enter the study, most completed the intervention, especially if they were in the CMM intervention carried out in the home. These data speak to a number of successful strategies used to maintain families in the study once they began, but raise issues about other factors not measured that may affect low-resourced families' ability to uptake and sustain interventions. These issues should be examined in future studies.

CONCLUSIONS

This multisite, randomized, comparative efficacy study of caregiver-mediated interventions was conducted with significant numbers of low-resourced children who have ASD. Results indicate significant improvement in child outcomes of joint engagement, initiating joint attention, and symbolic play. These interventions have promise for the wider community and require further study.

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