

Early Intervention for Toddlers With Language Delays: A Randomized Controlled Trial

Megan Y. Roberts, PhD, CCC-SLP^a, Ann P. Kaiser, PhD^b

abstract

OBJECTIVE: Early interventions for toddlers with expressive and receptive language delays have not resulted in positive expressive language outcomes. This randomized controlled trial tested the effects on language outcomes of a caregiver-implemented communication intervention targeting toddlers at risk for persistent language delays.

METHODS: Participants included 97 toddlers, who were between 24 and 42 months with language scores at least 1.33 SDs below the normative mean and no other developmental delays, and their caregivers. Toddlers were randomly assigned to the caregiver-implemented intervention or a usual-care control group. Caregivers and children participated in 28 sessions in which caregivers were taught to implement the intervention. The primary outcome was the Preschool Language Scale, Fourth Edition, a broad-based measure of language. Outcome measurement was not blinded.

RESULTS: Caregivers in the intervention improved their use of all language facilitation strategies, such as matched turns (adjusted mean difference, intervention-control, 40; 95% confidence interval 34 to 46; $P < .01$). Children in the intervention group had significantly better receptive language skills (5.3; 95% confidence interval 0.15 to 10.4), but not broad-based expressive language skills (0.37, 95% confidence interval -4.5 to 5.3; $P = .88$).

CONCLUSIONS: This trial provides preliminary evidence of the short-term effects of systematic caregiver instruction on caregiver use of language facilitation strategies and subsequent changes in children's language skills. Future research should investigate the ideal dosage levels for optimizing child outcomes and determine which language facilitation strategies are associated with specific child outcomes. Research on adaptations for families from culturally and linguistically diverse backgrounds is needed.



WHAT'S KNOWN ON THIS SUBJECT: Early language delay is common in toddlers and is associated with poor academic outcomes, reading difficulties, and persistent communication problems. Despite these long-term sequelae, few interventions for toddlers with early language delays yield positive expressive and receptive language results.

WHAT THIS STUDY ADDS: A 28-session program delivered over 3 months can enhance parent language facilitation strategies. Unusually, the small short-term benefits were mainly in receptive, rather than expressive, language and vocabulary. Extended follow-up could determine the costs versus benefits of this promising approach.

^aRoxelyn and Richard Pepper Department of Communication Sciences and Disorders, School of Communication, Northwestern University, Evanston, Illinois; and ^bDepartment of Special Education, Peabody College, Vanderbilt University, Nashville, Tennessee

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Address correspondence to Megan Y. Roberts, PhD, CCC-SLP/L, The Roxelyn and Richard Pepper Department of Communication Sciences and Disorders, School of Communication, Northwestern University, 2240 Campus Dr, Evanston, IL 60208. E-mail: megan.y.roberts@northwestern.edu

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Early language delay is common in toddlers and is associated with reading difficulties,¹ persisting communication problems,² and poor school readiness.³ Approximately 15% of 24-month-old children have language delays that are not due to any identifiable etiology.⁴ Although the majority of toddlers with expressive language delays are likely to recover without intervention (60%), toddlers with receptive and expressive delays are substantially less likely to recover spontaneously (25%).⁵ Despite this increased risk, toddlers whose developmental delay is restricted to language and who are between 25% and 50% delayed in that domain are not eligible to receive early intervention services in half of US states.⁵

Only 3 intervention studies examining children with receptive and expressive language delays have been published.⁶⁻⁸ In the largest randomized controlled trial of a therapist-implemented intervention for toddlers with language delays, modest effects were found for receptive language, and no effects were found for expressive language.⁶ However, the large range in intensity, frequency, duration, and type of therapy provided in the community-based intervention limited the interpretation of the results. Caregiver-implemented interventions for children with expressive and receptive language delays have not resulted in positive effects for receptive and expressive language skills.^{7,8} The lack of effects in child outcomes may be attributed to failure to achieve differences in caregiver use of language facilitation strategies between intervention and control groups⁷ or the absence of systematic caregiver instructional procedures and measures of intervention fidelity.⁸

Given limitations in extant research, the purpose of this study was to test whether a 3-month caregiver-implemented intervention targeting

toddlers at risk for persistent language delays improved language outcomes immediately after the end of intervention. Identified evidence gaps were addressed by targeting toddlers with receptive and expressive language delays, including systematic caregiver instructional procedures and measuring caregivers' use of language facilitation strategies continuously during intervention to ensure that caregivers were at high levels of fidelity.

We hypothesized that toddlers in the intervention group, relative to toddlers in the control group, would have higher scores on (1) standardized measures of expressive and receptive language (primary outcome), (2) standardized caregiver-report and observational measures of expressive vocabulary (secondary outcome), and (3) standardized measures of receptive vocabulary (secondary outcome) immediately after the end of the 3-month intervention. We also hypothesized that caregivers in the intervention group would use more language facilitation strategies than caregivers in the control group (primary outcome) and that the stress level of caregivers in the intervention group would not be greater than caregivers in the control group (secondary outcome) immediately after the end of the 3-month intervention.

METHODS

Trial Design

The Working on Rapid Language Development project was a randomized controlled trial (NCT01975922). The study was conducted in Nashville, Tennessee. The trial was approved by Vanderbilt University's Institutional Review Board (090904), and all caregivers provided written informed consent.

Participants

Toddlers and their caregivers were recruited through the Tennessee Early Intervention System, local

pediatricians' offices, and advertisements placed in the local *Nashville Parent*. Recruitment occurred continuously from October 2009 to October 2013. Toddlers were eligible for the trial if they were between 24 and 42 months of age and their expressive and/or receptive language scores were at least 1.33 SD below the normative mean of 10 on the Bayley Scales of Infant and Toddler Development, Third Edition⁹ (scaled score ≤ 6). This score corresponds to an expressive vocabulary of < 8 words for a 24-month-old. Exclusion criteria included intellectual disability, hearing loss > 40 dB, a major medical condition, or a diagnosis of autism spectrum disorder. Caregivers were informed immediately after the eligibility assessment if their children met the inclusion criteria.

Randomization

Eligible toddlers were randomly assigned to intervention or usual-care control arms with a 1:1 ratio by using a computer-generated random number sequence. The randomization sequence was concealed from the study coordinator, who enrolled participants and assigned participants to study arms. Random assignment occurred immediately after the eligibility assessment.

Intervention

Once randomly assigned, participants could not be naïve to the trial arm. Caregivers in the control group did not receive the intervention. Information about the type and amount of community-based language intervention was collected for all participants and is provided in Table 1. All children in both trial arms who had not previously been evaluated were referred to the Tennessee Early Intervention System to determine their eligibility for community-based services. The intervention (Enhanced Milieu Teaching¹⁰) was designed to promote early language acquisition in

TABLE 1 Participant Characteristics at Baseline

Variable	Trial Arm	
	Intervention	Control
<i>n</i>	45	52
Age, months	30.3 (5.0)	30.6 (5.1)
Receiving additional speech therapy	20	14
Male	82	80
Race		
African American	18	13
White	78	85
Other	4	2
Having receptive and expressive delay	69	72
Income	71 000 (35 000)	60 000 (52 000)
Mother's education		
High school	39	44
Undergraduate degree	37	27
Graduate degree	24	29
Baseline scores		
Cognitive skills, BSID-3 ⁹	91.3 (8.4)	88.6 (7.6)
Expressive language, PLS-4 ¹²	75.2 (7.9)	75.0 (7.2)
Receptive language, PLS-4 ¹²	76.5 (17.3)	73.8 (15.2)
Expressive vocabulary, EOWPVT-3 ¹³	60.9 (11.5)	59.8 (10.7)
Expressive vocabulary, NDW	19.0 (17.9)	17.2 (17.5)
Expressive vocabulary, MCDI ¹⁴	92.1 (105.1)	94.4 (97.2)

Data are expressed as mean (SD) or %. BSID-3, Bayley Scales of Infant Development, Third Edition; PLS-4, Preschool Language Scale, Fourth Edition; EOWPVT-3, Expressive One-Word Picture Vocabulary Test, Third Edition; NDW, number of different word roots in a 20-minute play interaction; MCDI, MacArthur Bates Communication Development Inventories.

everyday interactions. The intervention included 2 components: caregiver instruction and child intervention. First, the caregiver received individual instruction by using the teach-model-coach-review method (described below) to learn how to use specific language facilitation strategies at home with their toddlers. Second, the caregiver used 6 language facilitation strategies during intervention sessions and throughout the day with their child. A summary of these intervention components is provided in Fig 1. A complete description of the intervention is available in the manualized intervention protocol.¹¹

Caregivers received 28 individual instructional sessions (4 workshops, 24 practice sessions). One clinic session and 1 home session occurred weekly for 3 months. Missed sessions were rescheduled. The format of each session was standardized and included (1) review of the strategy taught in the workshop, (2) modeling of the strategy by the interventionist with the child, (3) caregiver practice

of the strategy with their child while the interventionist provided coaching, and (4) review of the session. Modeling and practice occurred in play interactions and routines such as reading a book or eating a meal. A video example of practice with coaching is provided in Fig 2. Sessions lasted ~1 hour.

Because early language delay is highly variable at young ages and caregivers vary in their use of language facilitation strategies, the intervention was individualized in 2 ways. First, specific language targets were chosen for each child based on performance during the baseline assessments. All toddlers had either (1) single word targets if they used <50 total words and 10 verbs during baseline or (2) early word combination targets if they used >50 total words but were not combining words regularly. Second, caregivers were taught the language facilitation strategies in sequential order. Performance was measured and instruction continued to criterion performance levels established for each strategy. A new strategy was

taught after the caregiver reached criterion levels on the previous strategy. Criterion levels are provided in Fig 1.

Trained interventionists provided the caregiver instruction. The 2 interventionists received 30 hours of individual instruction from M.Y.R. and practiced implementing the child intervention and the caregiver instruction over a 6-month period before beginning the intervention. Fidelity of the implementation of the intervention delivered by the interventionists was recorded for 20% of sessions. The average fidelity was 94% and exceeded 90% for all intervention components across all sessions.

Outcomes

Table 2 shows the primary and secondary caregiver and child outcomes. All outcome data were collected at baseline and immediately after the end of intervention (~3 months). Outcomes were assessed in a clinic by a speech language pathologist or a special education teacher trained to fidelity. These assessors were not naïve to the trial arm; because of the behavioral nature of the intervention, caregivers knew the trial arm to which they were assigned and made comments during assessments that indicated their trial arm assignment. To reduce the potential for bias, procedural fidelity was completed for 20% of all assessments. In addition, all norm-referenced assessments were scored by 2 raters. Procedural fidelity and scoring agreement exceeded 95% for all assessments and did not vary by trial arm, suggesting that the potential for bias was low.

Caregivers' use of language facilitation strategies was measured during a 20-minute play-based caregiver-child interaction in which the caregiver and child played with a standard set of toys in the clinic. Interactions were coded for the caregiver strategies listed and defined

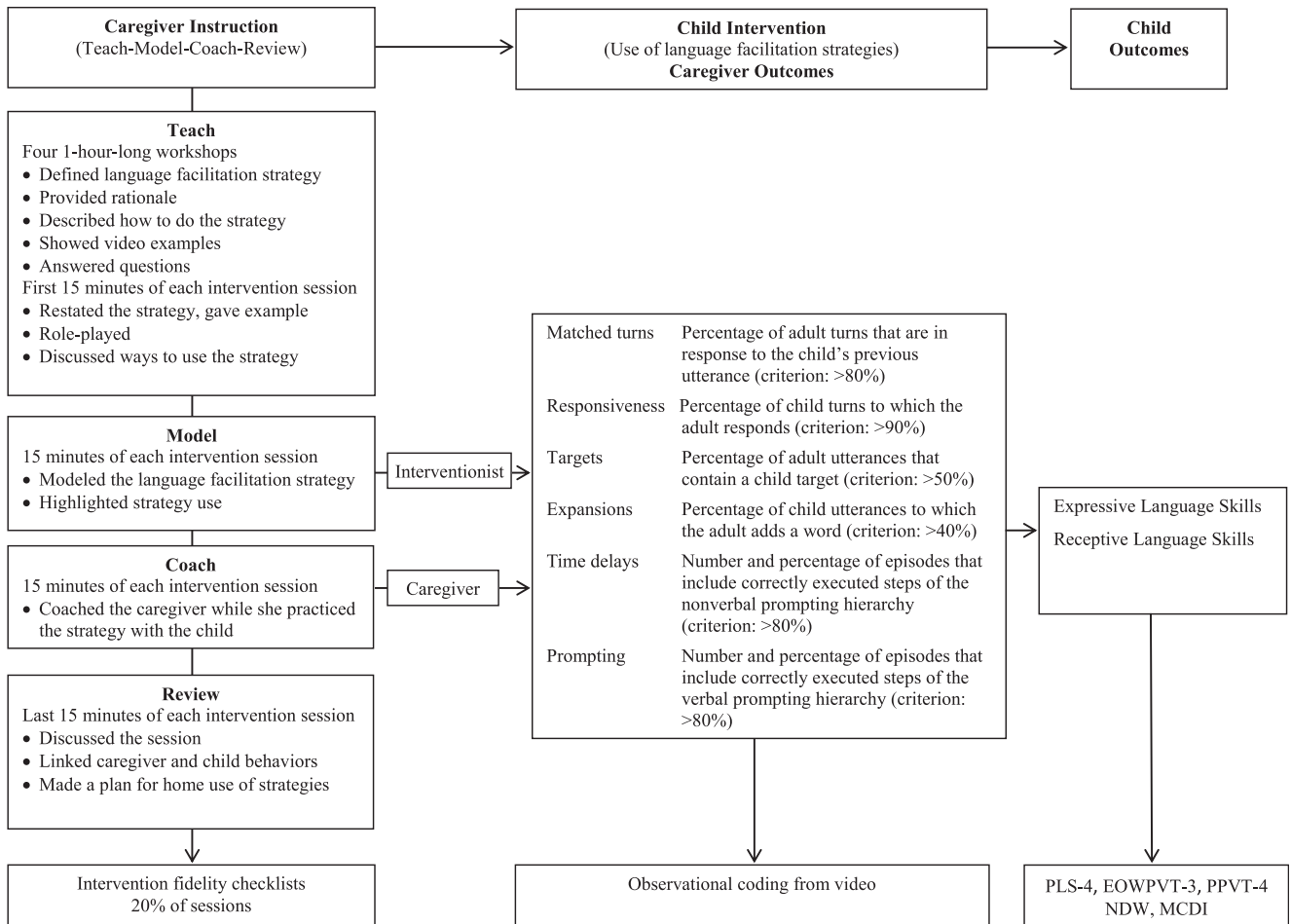


FIGURE 1 Pictorial design of the Working on Rapid Language Development trial. PLS-4, Preschool Language Scale, Fourth Edition; EOWPVT-3, Expressive One-Word Picture Vocabulary Test, Third Edition; PPVT, Peabody Picture Vocabulary Test, Fourth Edition; NDW, number of different words in a 20-minute play interaction; MCDI, MacArthur Bates Communication Development Inventories.

in Table 2. Reliability was calculated for 20% of all interactions, and point-by-point interobserver agreement exceeded 90% for each caregiver behavior. Caregivers in the intervention arm completed a questionnaire related to the structure and content of the intervention and their perception of the effect of the intervention on their children’s communication skills.

Sample Size

We anticipated that 120 toddlers would be eligible for the trial with 10% attrition. Assuming a baseline covariate of 0.70 between the primary outcome measure at baseline and at the end of intervention, a difference of 0.43 SD could be

detected with 90 toddlers (45 in each arm) with 80% power at the 5% significance level.

Statistical Analyses

An intent-to-treat analysis was used to analyze data in both randomization arms. Mean outcomes were compared between arms using linear regression adjusted for the baseline measure of the outcome variable, family income, and child cognitive skills at baseline. Differences in the rate of language delay were compared by using χ^2 analysis.

RESULTS

Figure 3 summarizes the flow of participants through each stage of the

trial. Table 1 summarizes the participant characteristics. Baseline differences in group characteristics were not large but generally favored the intervention arm. As such, final analyses were adjusted for baseline characteristics. Of the 97 eligible toddlers, 45 were assigned to the intervention group and 52 to the control group. All toddlers in the intervention group ($n = 45$) and 83% of toddlers in the control group ($n = 43$) were retained after the 3-month intervention period.

Child Outcomes

The analyses provided evidence for improvement in all measures of receptive language. The differences in receptive language between the



FIGURE 2
Video example of a parent practicing responding to and expanding child communication with coaching from a therapist (Supplemental Video).

intervention and control arms were small, with effect sizes ranging from 0.27 to 0.35 ($P = .04$). Differences in expressive language skills were not consistent across measures. There were only positive effects for the observational measure of expressive vocabulary ($P = .01$, effect size 0.38). No positive effects for overall expressive language skills, parent report of expressive vocabulary, or norm-referenced expressive

vocabulary were found. χ^2 Analyses indicated that toddlers in the intervention arm were less likely to meet the criterion for language delay after intervention than toddlers in the control arm ($\chi^2 = 3.8$, $P = .05$). After the 3-month intervention period, 71% of toddlers in the control arm were delayed, compared with 51% of toddlers in the intervention arm. Toddlers who did not receive intervention had a 1.4 times greater

risk of having a language delay than toddlers who received intervention.

Caregiver Outcomes

Table 3 shows that caregivers in the intervention arm improved their use of all language facilitation strategies. The differences in caregiver use of language facilitation strategies between the intervention and control arms were large, with effect sizes ranging from 0.43 to 3.19 ($P < .01$). There were no differences in the amount of total stress reported by caregivers in the intervention and control arms ($P = .15$, effect size -0.16).

Intervention Evaluation

There were no known adverse events or side effects for those children enrolled in the intervention group. The majority of caregivers (98%) reported that the strategies helped their children's language skills. When asked how comfortable they felt using the strategies, 92% of caregivers reported that they were very comfortable and 8% were somewhat comfortable. Caregivers reported using the strategies an average of 17 hours per week (range 2–77 hours,

TABLE 2 Primary and Secondary Outcome Measures for the Working on Rapid Language Development Trial

Outcome	Measure	Description
Primary		
Receptive and expressive language	Preschool Language Scale, Fourth Edition ¹²	Expressive score: Expressive Communication subscale; Receptive score: Auditory Comprehension subscale; both yield a standard score of 100 (SD 15)
Caregiver use of strategies	Observational coding of a 20-min play-based caregiver-child interaction	Matched turns: percentage of adult utterances in response to a child's utterance; Responsiveness: percentage of child utterances to which the adult responded; Targets: percentage of adult utterances that contained the child's language target; Expansions: percentage of child utterances to which the adult imitates and adds a word; Time Delays: percentage of nonverbal prompting sequences that were used correctly; Prompting: percentage of verbal prompting sequences that were used correctly
Secondary		
Caregiver stress	Parenting Stress Index, Fourth Edition ¹⁵	Total Stress score
Receptive vocabulary	Peabody Picture Vocabulary Test, Fourth Edition ¹⁶	Standard score with a normative mean of 100 (SD 15)
Expressive vocabulary	MacArthur-Bates Communicative Development Inventories: Words and Sentences ¹⁴	Total number of 680 words the caregiver reports that the child says
	Number of Different Word Roots	Total number of different word roots the child says in a 20-min play interaction with a research assistant
	Expressive One-Word Picture Vocabulary Test, Third Edition ¹³	Standard score with a normative mean of 100 (SD 15)
Presence of language delay	Preschool Language Scale, Fourth Edition ¹²	Total standard score <85

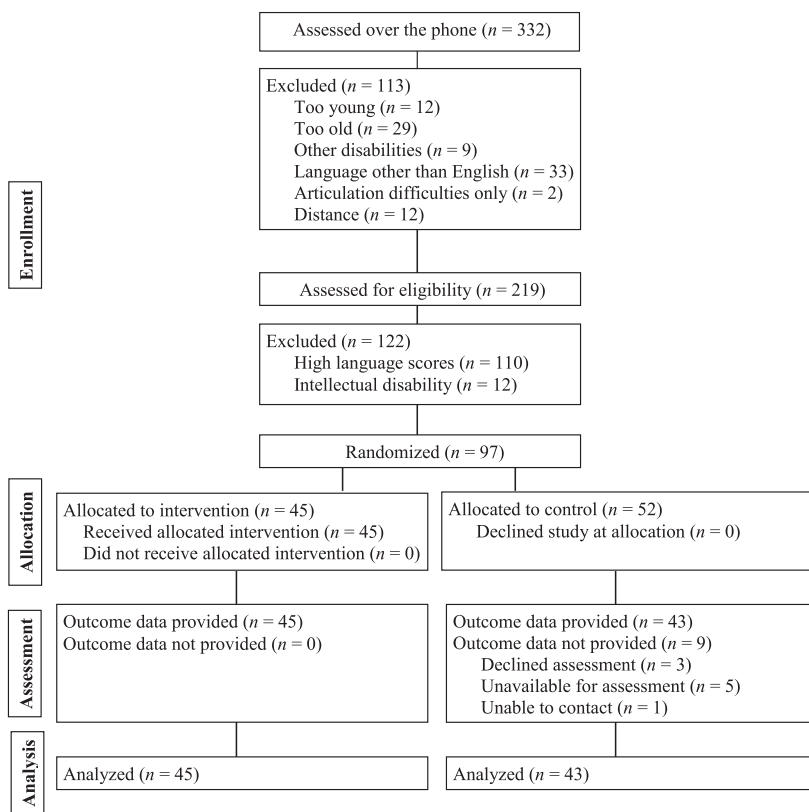


FIGURE 3 Participant flow chart for the Working on Rapid Language Development trial.

SD 18). The majority of caregivers (98%) reported teaching the language facilitation strategies to

another caregiver. The majority of caregivers (98%) reported that they preferred the home and clinic

location to home only or clinic only. Caregivers ranked the strategies they found most helpful in the following order: (1) responsiveness, (2) matched turns, (3) expansions, (4) targets, (5) prompting, and (6) time delays. Caregivers reported that observing the interventionist model the strategies and practicing the strategies with coaching from the interventionist were the most helpful instructional methods. The average cost of intervention was \$3861 per child, with a range of \$2767 to \$5653. Intervention costs included travel costs (\$0.55/mile) and therapist salary (\$65/hour) for time spent in instruction, traveling, preparing for, and delivering the intervention sessions.

DISCUSSION

Main Findings

This is the first trial to include specific criterion levels for caregiver use of language facilitation strategies and to continuously monitor caregiver use of these strategies. High fidelity in caregiver use of language facilitation strategies resulted in

TABLE 3 Outcome Comparisons

Outcome	Mean (SD) for Trial Arms		Adjusted			
	Intervention (n = 45)	Control (n = 43)	Mean Difference (Intervention – Control)	95% Confidence Interval	P	Effect Size
Primary child outcomes						
Expressive language, PLS-4 ¹²	84.0 (13.9)	80.2 (12.0)	0.37	–4.5 to 5.3	.88	0.03
Receptive language, PLS-4 ¹²	86.3 (19.4)	77.3 (20.4)	5.3	0.15 to 10.4	.04	0.27
Secondary child outcomes: Expressive Vocabulary						
MCDI ¹⁴	263.7 (172.6)	214.5 (146.3)	32.8	–17.3 to 83.0	.20	0.21
NDW	54.9 (30.2)	38.0 (30.3)	11.4	2.5 to 20.4	.01	0.38
EOWPVT-3 ¹³	75.7 (16.3)	70.0 (17.7)	3.5	–4.2 to 11.12	.40	0.21
Secondary child outcomes: Receptive Vocabulary						
PPVT-4 ¹⁶	94.3 (13.6)	85.6 (16.7)	5.3	0.4 to 10.5	.04	0.35
Primary caregiver outcomes, %						
Matched turns	74 (13)	32 (15)	40	34 to 46	<.01	2.86
Responsiveness	85 (9)	80 (14)	5	1 to 10	.05	0.43
Targets	47 (21)	3 (4)	39	33 to 45	<.01	2.55
Expansions	42 (18)	4 (4)	42	35 to 48	<.01	3.19
Time delays	42 (38)	0 (0)	29	18 to 40	<.01	1.07
Prompting	50 (38)	3 (9)	35	17 to 53	<.01	1.25
Secondary caregiver outcomes						
Stress, PSI ¹⁵	194.2 (43.4)	216.6 (38.2)	–6.7	–16 to 2.6	.15	–0.16

Effect size calculated by dividing the adjusted mean difference by the pooled SD of the intervention and control arms. Adjusted analyses include baseline scores, household income, and child cognitive scores as covariates. PLS-4, Preschool Language Scale, Fourth Edition; MCDI, MacArthur Bates Communication Development Inventories; NDW, number of different words in a 20-minute play interaction; EOWPVT-3, Expressive One-Word Picture Vocabulary Test, Third Edition; PPVT, Peabody Picture Vocabulary Test, Fourth Edition; PSI, Parenting Stress Index, Fourth Edition.

small benefits to receptive language but not to the primary expressive language outcome, although 1 of the 3 expressive vocabulary measures did seem to benefit. These results differ from previous studies,^{7,8} which did not report positive expressive language outcomes. Toddlers in the intervention arm used 11 more different words in a 20-minute structured play interaction than toddlers in the control arm. However, differences between the intervention and control arms were not observed for other measures of expressive language skills. Given the relatively brief nature of the intervention (3 months), it is not surprising that only changes in the proximal measures were evident immediately after the end of intervention. Over time, changes in these proximal measures (number of different words in the language sample) may result in changes in the distal measures (norm-referenced tests) of expressive language. These positive outcomes were achieved during 28 intervention sessions over the course of the 3-month intervention with a total delivery cost of \$3861 per family. This cost and limited duration of intervention are relatively modest given the promising results.

Strengths

The components of the intervention were naturalistic language facilitation strategies similar to those commonly used in speech-language therapy and early intervention. Caregivers rated the intervention strategies as easy to use throughout the day. The intervention approach was individualized to accommodate different rates of caregiver learning and child targets, yet standardized sufficiently that all caregivers and children received the same intervention. The length and frequency of the intervention were compatible with community-based early intervention service delivery models. Unique features of this trial include systematic and continuous monitoring

of caregiver use of language facilitation strategies, inclusion of children with receptive and expressive language delays, and a standardized protocol for teaching caregivers.

The research design included random assignment, low attrition, and careful and continuous monitoring of caregiver use of the language facilitation strategies. Intervention fidelity was measured for the therapist and for the caregiver, ensuring a high level of quality control. The manualized intervention program included a replicable yet individualized protocol. Taken together, these methodological strengths indicate high internal and external validity, increasing the likelihood that these positive results will generalize to similar samples.

Limitations

The current findings should be considered in the context of several limitations. First, the long-term outcomes remain unknown. Longer-term outcome measures may produce different results. Follow-up is ongoing and will provide additional information about spontaneous recovery rates and maintenance of language facilitation strategies by caregivers. Second, the majority of participants were from mainstream US cultures. Thus, it is unclear whether the results of this study would generalize to caregivers from other cultures with different beliefs about child-rearing practices.¹⁴ Third, participant recruitment took place over 4 years and included a variety of sources (self-referral, pediatrician referral, early intervention referral). It is possible that families who chose to participate in a research study may have been more motivated than families from the general population. Fourth, because assessors and caregivers could not remain naïve to the trial arm, the potential for bias exists.

Interpretation

The instruction to caregivers had the greatest effects on matched turns,

targets, and expansions. These language facilitation strategies in turn had the largest impact on receptive language skills and expressive vocabulary. Results of this study have several important clinical implications. Children with expressive and receptive language delays are likely to benefit from early intervention. This is the second trial to find positive effects on expressive vocabulary outcomes for toddlers with receptive and expressive language delays.⁶ Results from the current trial indicate that the effects of early intervention may be maximized when the caregiver is included in the intervention. Teaching caregivers to use language facilitation strategies is a cost-effective way to provide early intervention to this population. However, teaching caregivers is a complex process that requires ongoing monitoring and coaching. The current trial is the first step in investigating effective interventions for a population of children with language delays who are at risk for persistent communication difficulties.

CONCLUSIONS

Given the long-term negative academic and social effects of persistent communication difficulties, the outcomes of this trial provide preliminary support for early intervention for toddlers with language delays. This trial provides rigorous evidence of the effects of systematic instruction to caregivers on their use of language facilitation strategies and subsequent changes in their children's receptive and expressive language skills. The outcomes are particularly promising given the modest cost and limited duration of the intervention. Long-term follow-up of intervention effects is ongoing and will assess the long-term impact of early intervention on child language skills. Whereas caregiver use of language facilitation

strategies resulted in positive receptive language and some expressive vocabulary outcomes, the amount and total dosage of caregiver

strategy use needed to optimize language outcomes remains unknown. Future research should investigate specific caregiver

language facilitation strategies and the amount of caregiver strategy use that maximizes child language outcomes.

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