



Effects of Early Literacy Promotion on Child Language Development and Home Reading Environment: A Randomized Controlled Trial

James P. Guevara, MD, MPH^{1,2,3}, Danielle Erkoboni, MD^{1,4}, Marsha Gerdes, PhD¹, Sherry Winston, MS¹,
Danielle Sands, MPH¹, Kirsten Rogers, BS⁵, Trude Haecker, MD⁵, Manuel E. Jimenez, MD, MSHP⁶,
and Alan L. Mendelsohn, MD⁷

Objective To determine if early literacy promotion, which consisted of board books and reading promotion beginning with newborns, is more effective than standard literacy promotion beginning at 6 months.

Study design Hybrid type 1 randomized controlled implementation trial of Medicaid-eligible newborns. Prior to 6 months of age, early literacy promotion participants received board books and reading promotion at well visits plus weekly text messages on reading, while standard literacy promotion participants only received weekly text messages on safety. Both groups received board books and reading promotion at well visits after 6 months as part of Reach Out and Read. Measures included proportion who received board books to assess implementation and StimQ Read Subscale (SQRS) scores and Preschool Language Scale-Fifth Edition (PLS-5) scores at 6 and 24 months to assess outcomes. Differences in measures were assessed using intention-to-treat analysis.

Results Of 120 newborns enrolled, most were African American, resided with a single parent, or had a parent with \leq high school education. Overall 82% of early literacy promotion participants received books/counseling at well visits <6 months old. Children in the early literacy promotion arm had greater SQRS scores (11.0 vs 9.4, $P = .006$) but similar PLS-5 scores at 6 months, but there were no differences in SQRS or PLS-5 scores between groups at 24 months.

Conclusions Implementation of a literacy promotion program early in infancy was associated with richer home reading environments at 6 months but did not improve language development. Although an early literacy program was feasible, additional study may be needed to assess other potential benefits. (*J Pediatr*: X 2020;2:100020).

Trial registration [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02713659): NCT02713659.

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Early childhood is a sensitive period in which early stimulation of brain centers involved in language leads to the development and maintenance of neuronal connections critical for language functioning.¹ Unfortunately, language delays are common among children under age 3 years residing in impoverished communities.²⁻⁵ Differences between poor and advantaged children in language processing skills and vocabulary are evident by 18 months of age.⁶ Reduced parent-child verbal interactions in the context of poverty-related stressors has been shown to be an important contributor.⁷⁻⁹

The home reading environment, including both the frequency of parent-child shared reading and the number of books available in the home, provides an important opportunity for language stimulation and verbal interactions that can enhance language development in young vulnerable children.^{10,11} Previous studies have found parent-child shared reading to be associated with improved language functioning and better school performance among children in low income families.¹²⁻¹⁴

Based on these observations, The Reach Out and Read (ROR) Program was established to promote parent-child shared reading activity among poor at-

From the ¹PolicyLab, Center to Bridge Research, Practice, and Policy, The Children's Hospital of Philadelphia, ²Leonard Davis Institute of Health Economics, ³Center for Clinical Epidemiology & Biostatistics, Perelman School of Medicine, ⁴National Clinicians Scholars Program, University of Pennsylvania, ⁵Reach Out and Read Philadelphia, The Children's Hospital of Philadelphia, Philadelphia, PA; ⁶Department of Pediatrics, Rutgers Robert Wood Johnson Medical School, Rutgers University, New Brunswick, NJ; and ⁷Departments of Pediatrics and Population Health, New York University School of Medicine, New York, NY

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ACE	Adverse childhood experiences
PLS-5	Preschool Language Scale, Fifth Edition
ROR	Reach Out and Read
SAHL	Short Assessment of Health Literacy
SQRS	StimQ Read Subscale

risk children at pediatric well-child visits.¹⁵ Evaluations of ROR have shown beneficial effects on reading activity and language outcomes.^{16–18} These effects translate into an increase of 1 day/week of parent-child reading activity and a 4- to 9-point increase in expressive and receptive language scores, respectively.¹⁷ For these reasons, the American Academy of Pediatrics has recommended that pediatric clinicians promote literacy development beginning in infancy.¹⁹

Despite the encouraging results that ROR has shown to date, poor children who participate in the program still demonstrate language scores that are 6-15 points lower than national averages, and 37%-45% are still at high risk for reading problems prior to kindergarten.^{17,20} This may in part be the result of delays in promoting parent-child verbal interactions until children are 6 months of age or older. There may be reason to suspect that children exposed to richer and more intensive parent-child verbal interactions prior to 6 months of age may achieve greater language functioning and better outcomes.^{9,21,22}

We sought to determine whether initiating literacy promotion as part of a ROR program beginning in the newborn period is more effective at the promotion of language development than initiating ROR at age 6 months of age as is currently the standard model. We hypothesized that literacy promotion beginning in the newborn period would be associated with a richer home reading environment and result in greater language development by 24 months of age than standard literacy promotion beginning at 6 months of age.

Methods

The study was conducted at a single large urban pediatric practice affiliated with the Children's Hospital of Philadelphia from March 10, 2016 to July 16, 2018. The practice serves a predominantly poor (72% Medicaid) African American population and has an active ROR program beginning at the 6-month well-child visit and concluding at the 5-year well-child visit. Children were eligible to participate in this study if they were born ≥ 35 weeks estimated gestational age, without neurodevelopmental disabilities or congenital malformations, with Medicaid insurance (proxy measure for poverty), English or Spanish-speaking, and < 30 days old at the time of study enrollment. The study was approved by the Institutional Review Board at the Children's Hospital of Philadelphia. Written informed consent was obtained from all parents or guardians of children who served as study participants. The trial was registered prior to the first participant enrollment at [Clinicaltrials.gov](https://clinicaltrials.gov), Identifier NCT02713659.

Study Design

The study design consisted of a hybrid type 1 randomized parallel controlled implementation trial in which intervention effects are tested while data on implementation are gathered. Informed consent was obtained from parents of eligible newborns, and participants were randomized 1:1 to early literacy promotion or standard literacy promotion.

Participants were not blinded to intervention arm, but study staff were unaware of study arm assignment when completing study measures with participants. Randomization was accomplished using computer-generated random numbers that were placed in sealed opaque envelopes prior to enrollment by research staff. Early literacy promotion consisted of the provision of an age-appropriate board book and the promotion of shared book reading by clinicians at the following well child visits: < 1 week, 1 month, 2 months, and 4 months.

We conducted brief trainings with clinicians (attending, residents, and nurse practitioners), posted study flyers, and provided plastic totes with the early literacy promotion books and book markers next to the ROR books to prepare clinicians for the early literacy promotion program. To reinforce book reading with parents, early literacy promotion participants received weekly text messages designed to reinforce shared book reading prior to 6 months of age. An example of a text message is "speaking with your baby is a great opportunity for your baby to become social." Standard literacy promotion participants received usual well-child care, which did not include board books or the promotion of shared book reading. To ensure equal attention for both study groups, standard literacy promotion participants received weekly text messages regarding child safety prior to 6 months of age. Text messages for both groups were developed by research staff and piloted with clinic parents. All participants in both groups received board books and literacy promotion beginning at the 6-month well-child visit as part of ROR.

We implemented an electronic alert at well visits < 6 months of age to remind clinicians to provide one of the selected age-appropriate board books to early literacy promotion participants (**Figure 1**). These books consisted of "Sock and Shoe" at the newborn visit, "Baby Says Peekaboo" at the 1-month visit, "Hello Baby Animals" at the 2-month visit, and "Itsy Bitsy Spider" at the 4-month visit. The alert asked clinicians to check a box once they had provided the appropriate board book and completed literacy promotion with an early literacy promotion participant. We standardized reading promotion by having clinicians review a script from a study book marker with parents when they distributed the board books at any of the well visits above (**Figure 1**). If a participant did not receive a book or missed a well visit, we provided the appropriate book and the book marker to parents by mail or in-person depending on their preference.

Measures

To assess implementation of early literacy promotion, we examined the proportion of early literacy promotion participants who received board books and reading promotion from pediatric clinicians at the newborn, 1-week, 1-month, 2-month, and 4-month well-child visits. The primary outcome was the Preschool Language Scale, Fifth Edition (PLS-5) measured at 6 and 24 months of age. The secondary outcome was the StimQ Read Subscale (SQRS) scores measured at 6, 12, 18, and 24 months. The PLS-5 is a

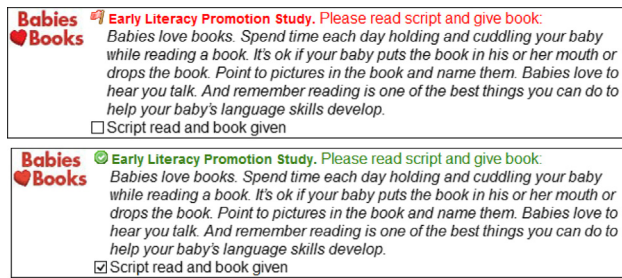


Figure 1. Electronic recruitment alert was activated at newborn, 1-week, 1-month, 2-month, and 4-month well-child visits for early literacy promotion participants. When clinicians clicked on box indicating that script was read and book provided to family, the color of the top line of the alert changed from red to green.

validated observational measure of expressive and auditory language function among children from birth through 7 years of age and is available in Spanish and English. The PLS-5 has been standardized in over 1400 children nationally with a sensitivity of 0.83 and a specificity of 0.80 for the detection of language delay.²³ The StimQ is a validated self-report measure of cognitive stimulation at home available in Spanish and English; the Read subscale of the StimQ contains questions on the frequency of parent-child reading activity and the number and variety of books at home.²⁴ Psychometric analysis of the StimQ shows high internal consistency (Cronbach alpha = 0.89) and test-retest reliability ($r = 0.84$) and moderate correlation with the Bayley Scales of Infant Development ($r = 0.52$, $P < .001$).

In addition, at the time of enrollment, parents completed surveys of demographic characteristics (child age, sex, race/ethnicity, maternal age, family structure, maternal education level, family income category), childhood adversity, maternal health literacy, and maternal depressive symptoms as potential confounding factors. The 9-item adverse childhood experiences (ACE) questionnaire queried parents as to their exposure to childhood adverse experiences (economic hardship, domestic violence, parent mental health, discrimination, parent substance abuse, divorce, parent death, parent incarceration, and neighborhood violence) and were obtained from the 2011-2012 National Survey of Children's Health, a nationally representative telephone survey.²⁵ The Short Assessment of Health Literacy (SAHL) is a validated measure of health literacy for English- and Spanish-speaking populations.²⁶ Values of the SAHL less than 14 represent low health literacy. The Edinburgh Postnatal Depression Scale is a validated 10-item scale for maternal depression symptoms with scores of >9 having a sensitivity of 97% and specificity of 43% for major or minor depression.²⁷

Statistical Analyses

To assess implementation of early literacy promotion, we examined the proportion of children in the early literacy pro-

motion arm who received board books and literacy promotion from clinicians at well-child visits under 6 months of age. To determine the effectiveness of early literacy promotion compared with standard literacy promotion, we examined differences in PLS-5 scores and subscale scores and SQRS scores between groups using independent sample t tests. We used intention-to-treat analysis in which participants were evaluated based on their initial randomization status. We examined for potential confounding by demographic characteristics, maternal adversity, health literacy, and/or maternal depression. Those variables that were associated with outcomes ($P < .20$) were included in a multiple regression model along with group status (early literacy promotion vs standard literacy promotion). A subgroup analysis was conducted among those with and without an older sibling to determine if prior exposure to ROR influenced the home reading environment and language development. The study had $>90\%$ power to identify a difference of 4 points in the PLS-5 total scores between groups, which is the minimum clinically significant difference. All analyses were conducted using Stata Statistical Software, v 15 (Stata-Corp, College Station, Texas).

Results

Of 148 potentially eligible patients approached for enrollment between March through September 2016, 120 consented and were randomized to early literacy promotion ($n = 60$) or standard literacy promotion ($n = 60$) study arms (Figure 2). Of these, 99 (83%) completed the 6-month study visit: 53 in the early literacy promotion arm and 46 in the standard literacy promotion arm. At subsequent study visits, 54 in the early literacy promotion arm and 50 in the standard literacy promotion arm completed the 12-month visit, 50 in the early literacy promotion arm and 50 in the standard literacy promotion arm completed the 18-month visit, and 49 in the early literacy promotion arm and 45 in the standard literacy promotion arm completed the 24-month visit (78%). Seven participants changed clinics and were withdrawn, 18 did not complete the final study visit, and 1 was deceased.

Participants in both arms had similar demographic characteristics with the exception that there was a greater percentage of African American participants (95% vs 77%, $P = .03$) in the early literacy promotion arm and a greater percentage of Other (Asian, more than 1 race, unknown/not reported) participants in the standard literacy promotion arm (Table I). Most participants resided in families with a single parent, less than \$25 000 in family income, or a maternal education level of high school or less. In addition, few participants in either arm had mothers who reported postpartum depressive symptoms (Edinburgh Postnatal Depression Scale >9), adverse childhood experiences (ACE ≥ 4), or inadequate health literacy (SAHL < 14). There were no statistically significant group differences in these latter clinical characteristics at baseline (Table II).

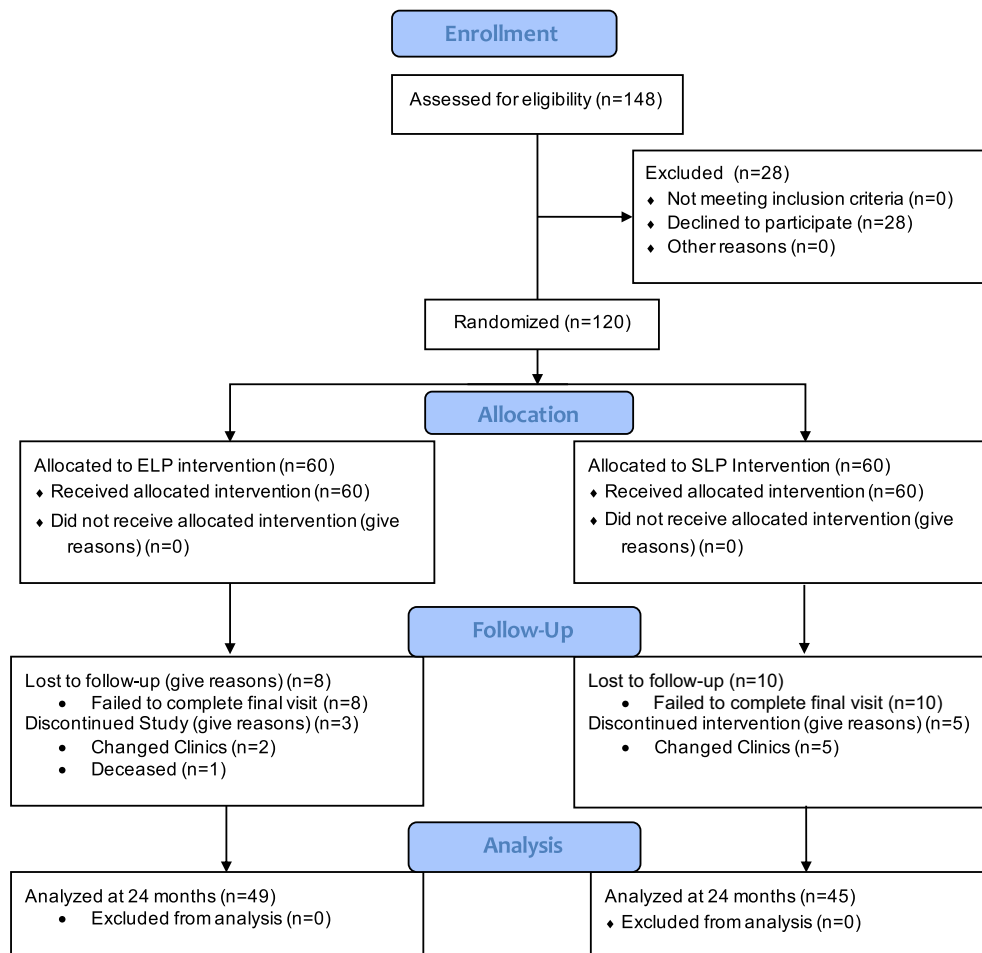


Figure 2. Flow of participants through the study. In total, 148 eligible participants were approached for enrollment; 120 consented to participate and were randomized; 99 completed the 6-month visit, 104 completed the 12-month visit, 100 completed the 18-month visit, and 94 completed the 24-month visit. *ELP*, Early literacy promotion; *SLP*, standard literacy promotion.

Of the initial 60 participants that were randomized to the early literacy promotion arm, 59 of 60 (98%) at <1 week, 42 of 58 (74%) at 1 month, 41 of 56 (73%) at 2 months, and 44 of 53 (83%) at 4 months received age-appropriate books and literacy promotion at well-child visits by pediatric clinicians. This resulted in an overall book distribution and literacy promotion rate of 82% across visits. Those participants who did not receive a book and counseling at a given well-child visit or who missed a well child visit were mailed the corresponding age-appropriate book and the book marker providing literacy promotion.

Early literacy promotion participants reported higher mean SQRS scores (11.0 vs 9.4, $P = .006$) than standard literacy promotion participants at 6 months of age (Table III). This was the result of early literacy promotion participants reporting a greater mean number of board books at home (5.4 vs 4.0) and greater mean frequency of past week reading (3.9 vs 3.1 days/week) than standard literacy promotion participants. Early literacy promotion participants also reported an earlier age at initiating parent-child reading (2.9 vs 4.3 months, $P = .007$) than

standard literacy promotion participants. After adjustment for race and total ACE score, early literacy promotion participants reported significantly higher SQRS scores ($B = 1.7$, 95% CI 0.5, 2.8) than standard literacy promotion participants. However, there were no differences in mean SQRS scores at 12, 18, and 24 months of age. When we examined changes in SQRS scores from 6 to 24 months of age there were no differences in change scores (2.4 early literacy promotion vs 2.8 standard literacy promotion, $P = .57$) between groups as both groups improved.

There were no differences in PLS-5 total and subscale scores between groups at 6 and 24 months of age (Table IV). Participants ($n = 99$) scored 4 points on average below national norms on the total PLS-5 at 6 months and 8 points below national average on the total PLS-5 at 24 months. These results were primarily a result of expressive communication subscale scores being substantially lower on average than auditory comprehension subscale scores. After adjustment for race and total ACE scores, PLS-5 total scores were not different

Table I. Demographic characteristics of participants

Characteristics	Standard literacy* n = 60	Early literacy* n = 60	P value
Mean parent age, y (SD)			
Mother	25.3 (5.2)	25.4 (5.2)	.888
Father	28.7 (7.0)	28.2 (6.4)	.680
Child sex (%)			.714
Female	34 (57)	32 (53)	
Male	26 (43)	28 (47)	
Race (%)			.026
Black or African American	46 (77)	57 (95)	
White	2 (3)	0 (0)	
Hispanic	4 (7)	2 (3)	
Other	8 (13)	1 (2)	
Marital status (%)			.324
Single, separated, divorced	39 (66)	42 (71)	
Married or living together	20 (34)	17 (29)	
Mean adults living with mother (SD)	1.2 (0.6)	1.3 (1.1)	.561
Mean other children (SD)	1.0 (1.2)	1.2 (1.2)	.599
Gross income (%)			.965
Less than \$25K	48 (81)	47 (81)	
\$25K or higher	11 (19)	11 (19)	
Maternal education (%)			.805
< High school	9 (15)	11 (19)	
High school or GED	24 (41)	27 (46)	
> High school or college	26 (39)	21 (31)	

*Participants were age <1 month old, Medicaid-eligible, and attended a participating primary care practice. Numbers in columns may not sum to column totals because of missing data.

between groups at 6 and 24 months (data not shown). When we examined changes in PLS-5 scores from 6 to 24 months, there were no statistically significant changes between groups in total scores (-5.9 early literacy promotion vs -3.3 standard literacy promotion, $P = .49$), expressive communication scores (-3.9 early literacy promotion vs -2.0 standard literacy promotion, $P = .53$), or auditory comprehension scores (-8.2 early literacy promotion vs -9.0 standard literacy promotion, $P = .85$).

In subgroup analysis, SQRS scores were higher at 6 months among early literacy promotion participants than standard literacy promotion participants if there were older children in the family ($n = 53$, 10.9 vs 9.0 , $P = .01$) but not if there were not ($n = 37$, 11.1 vs 9.8 , $P = .18$). SQRS scores at later

Table II. Baseline clinical characteristics of participants*

Measure	Standard arm n = 60	Early literacy arm n = 60	P value
Average EPDS score (SD) (out of possible 30)	3.4 (3.6)	3.8 (4.2)	.529
EPDS >9 (%)	4 (6.7)	5 (8.3)	.73
Average ACE score (SD) (out of possible 10)	1.4 (1.9)	1.0 (1.5)	.12
ACE score ≥ 4 (%)	2 (4.0)	7 (12.3)	.12
Average SAHL score (SD) (out of possible 18)	15.6 (3.2)	15.6 (2.6)	.97
SAHL <14 (%)	16 (26.7)	15 (25.0)	.84

EPDS, Edinburgh Postnatal Depression Scale.

*Participants were age <1 month old, Medicaid-eligible, and attended a participating primary care practice.

ages and PLS-5 total scores at 6 and 24 months of age were not different between groups regardless of whether there were older children or not. These subgroup analyses were limited by smaller sample sizes.

Discussion

In this hybrid type 1 randomized controlled implementation trial, we found that implementing a literacy promotion program in the newborn period using an established ROR program was feasible in a large urban pediatric practice, improved the home reading environment of participants, but did not result in improved language outcomes among participating children. Overall, early literacy promotion participants received an age-appropriate board book and literacy promotion from clinicians at 82% of well visits prior to 6 months of age. Electronic alerts at the point of care were utilized to remind clinicians to provide books and counseling, and this likely contributed to the high proportion of participants who received books at well visits. These results are consistent with those of Mendelsohn et al who found that introducing shared reading prior to 6 months as part of a randomized controlled trial of the Video Interaction Project was well received and associated with increased reading aloud.²⁸

We also found that initiating literacy promotion in the newborn period was associated with a richer home reading environment than standard literacy promotion by 6 months of age. This result was due to a reported greater number of board books at home, a greater frequency of reading among early literacy promotion participants and their families, and an earlier age of initiation of reading. This finding is novel among young infants and supports the American Academy of Pediatrics policy statement that endorses reading among young infants.¹⁹ The finding is consistent with previous studies involving older children showing that participation in ROR is associated with a greater number of books at home, a greater frequency of reading, and a preference for reading among children's activities.^{16,18,29-33} However, this early difference in the home reading environment disappeared by 12 months of age and beyond, corresponding to the initiation of ROR at the 6-month well visit.

We did not find that early literacy promotion was associated with differences in language development compared with standard literacy promotion using a ROR program. Children who participated in the early literacy promotion arm had similar expressive and auditory language development as children in the standard literacy promotion arm. Children in both arms, however, had substantially lower expressive communication than auditory comprehension subscale scores, which is consistent with previous studies.¹⁷ The ability of the PLS-5 and other validated language assessments to differentiate subtle differences in language development and identify language disorders in infancy and early childhood is limited. The PLS-5 is normed in 3-month bands under 12 months of age and in 6-month bands

Table III. Differences in the home reading environment at 6, 12, 18, and 24 months of age*

Outcomes	Standard arm n = 60	Early literacy arm n = 60	P value
6-mo StimQ Score [†] (SD)	n = 40	n = 50	
Total	9.4 (3.2)	11.0 (2.1)	.006
Number of board books	4.0 (5.0)	5.4 (4.1)	.12
Frequency d/wk	3.1 (2.3)	3.8 (2.1)	.10
12-mo StimQ Score [†] (SD)	n = 50	n = 54	
Total	13.1 (2.5)	13.5 (2.3)	.45
Number of board books	10.1 (11.0)	11.3 (11.4)	.58
Frequency d/wk	4.6 (1.7)	4.6 (1.6)	.99
18-mo StimQ Score [†] (SD)	n = 50	n = 50	
Total	12.8 (2.1)	12.9 (2.1)	.89
Number of board books	9.7 (9.8)	11.2 (15.5)	.58
Frequency d/wk	4.7 (1.5)	4.5 (1.7)	.49
24-mo StimQ Score [†] (SD)	n = 45	n = 49	
Total	12.6 (2.7)	13.0 (2.3)	.42
Number of board books	12.2 (14.2)	12.7 (14.0)	.87
Frequency d/wk	4.4 (1.7)	4.3 (1.8)	.80

*Participants were age <1 month old, Medicaid-eligible, and attended a participating primary care practice.

†StimQ Score refers to the SQRS, which is a validated measure of the home reading environment and contains questions on the frequency of parent-child reading activity and the number and variety of books at home.

over 12 months of age. It is primarily designed to identify young children with overt language delays and disorders.^{23,34} We speculate that any small differences in language development in infancy and early childhood because of the early introduction of literacy promotion may not have been evident on a standardized language assessment such as the PLS-5.

This study has limitations that should be mentioned. First, the study was conducted at a single large urban pediatric practice affiliated with a children’s hospital and provided care to a predominantly poor African American population. The results may not be generalizable to patients attending pediatric practices in other geographic areas or to children of other race/ethnicity groups. Second, families in the early literacy promotion group reported only modest increases in

Table IV. Differences in language development at 6 and 24 months of age*

Outcomes	Standard arm n = 60	Early literacy arm n = 60	P value
6-mo PLS-5 score [†] (SD)	n = 46	n = 53	
Standard total score (SD)	96.9 (7.1)	96.3 (6.7)	.64
Auditory comprehension score (SD)	103 (7.5)	101 (7.2)	.20
Expressive communication score (SD)	92 (9.6)	92 (9.3)	.75
24-mo PLS-5 score [†] (SD)	n = 44	n = 49	
Standard total score (SD)	93.9 (18.5)	91.1 (13.4)	.40
Auditory comprehension score (SD)	95.2 (14.0)	93.7 (16.5)	.64
Expressive communication score (SD)	89.3 (9.2)	89.8 (11.1)	.89

*Participants were age <1 month old, Medicaid-eligible, and attended a participating primary care practice.

†The PLS-5 is a validated measure of expressive and auditory language function among children from birth through 7 years of age.

reading frequency and board books at home in the first six months compared with the standard literacy promotion group. Many of the participating families had older children and were likely exposed to the ROR Program at the practice, which may have diluted the effects of early literacy promotion. For example, families in the standard literacy promotion group reported shared reading on average 3.1 days per week prior to the 6-month visit. Third, the comparator for early literacy promotion was standard literacy promotion using an established ROR program and not a no intervention control group. Readers should not interpret results to suggest that literacy promotion among infants is ineffective. Fourth, we did not exclude children with chronic health conditions like recurrent otitis media. Finally, we assessed the effects of early literacy promotion on the home reading environment and language development. Other potential benefits such as improved socioemotional development, parenting, and attachment were not measured.

However, our study has a number of strengths to point out. It was a randomized controlled trial that was designed to limit bias and confounding. Our study utilized a hybrid implementation design in which book distribution and literacy promotion were provided by practicing clinicians and not researchers, simulating a standard ROR program. Fidelity, as measured by an electronic reminder at the point of care, resulted in >80% adherence by clinicians. In addition, the reach of the project as measured by the percentage of eligible families who chose to participate in the study was high (81%).

In this study, we found that early literacy promotion using the ROR model beginning in the newborn period was feasible in a busy urban pediatric practice. We also found that it was associated with a richer home reading environment by 6 months of age. Policies aimed at expanding the ROR Program to newborn infants can be considered feasible and provide at-risk children with greater opportunities to expand their language development. However, we found that early literacy promotion was not associated with differential language development compared with standard literacy promotion beginning at 6 months of age. Given the competing priorities at well child visits, early literacy promotion may not merit inclusion in the ROR Program if language development is the primary objective. Future research efforts should assess whether other benefits to early literacy promotion exist including improvements in child socio-emotional development, infant attachment, and parenting stress and whether effects differ by prior exposure to a literacy promotion program. ■

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Reprint requests: James P. Guevara, MD, MPH, Roberts Center for Pediatric Research, The Children's Hospital of Philadelphia, 2716 South Street, Rm 11-172, Philadelphia, PA 19146. E-mail: Guevara@email.chop.edu

Data Statement

Data sharing statement available at www.jpeds.com.

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