



# Randomized Trial of a Mobile App Introduced During Well-Visits to Enhance Guidance for Reading With Young Children

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## ABSTRACT

**OBJECTIVE:** To estimate feasibility, usability and efficacy of a mobile parenting app (*Rx for Success*; RxS) to enhance reading guidance provided to parents of young children during well-visits.

**METHODS:** This trial was conducted at a clinic serving primarily families of Hispanic ethnicity and low-socioeconomic status (SES) where Reach Out and Read (ROR) is standard practice. It involved 252 parent-child dyads in 2 age groups (~6-months old, ~18-months old) randomized during well-visits to receive RxS or a children's book modeling alternatives to screen time (Control) by research coordinators. RxS involves videos, activities and "push" messages. Follow-up assessments were conducted approximately 6 months later, including impression and use, shared reading behaviors, child language and screen time.

**RESULTS:** A total of 217 dyads completed both visits (110 RxS, 107 Control). Time to introduce RxS was under 3 minutes and 32% of parents experienced largely minor performance issues. Parent impression of RxS was favorable for

both age groups at baseline and follow-up, though use was infrequent, attributable to a desire for more relevant and updated content. Significant findings favoring RxS included shared reading as a favorite activity, more frequent shared reading reported at 12 months and higher language scores at 24 months. Screen time was equivalent between cohorts, exceeding American Academy of Pediatrics guidelines.

**CONCLUSIONS:** A mobile app introduced to parents of young children from low-SES backgrounds was feasible during well-visits, rated as helpful, and effective to enhance shared reading at younger and language at older ages. While a potentially impactful enhancement to ROR, features needing improvement were identified.

**KEYWORDS:** emergent literacy; home literacy environment; language development; mHealth; mobile app; parenting; Reach Out and Read; screen time; shared reading

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## WHAT'S NEW?

This pilot trial of a mobile app providing reading guidance complementing Reach Out and Read established feasibility during well-visits, acceptance by parents and higher reading at 12 months and child language at 24-months old versus controls. Features needing improvement were identified.

THE AMERICAN ACADEMY of Pediatrics (AAP) recommends literacy promotion during primary care beginning in infancy, citing cognitive, social-emotional and neurobiological benefits.<sup>1</sup> With trusted access to families when well-visits are frequent, brain growth is dynamic and

reading routines are shaped,<sup>1,2</sup> pediatric providers are poised to administer such guidance. This is the rationale behind the Reach Out and Read (ROR) program, where clinicians provide a children's book and encouragement to read at well-visits through age 5, which serves over 25% of US families in poverty.<sup>3</sup> However, guidance on how to read most effectively with young children ("shared reading") can be challenging to administer consistently, given constraints on time and availability of educational materials.<sup>4</sup> Reinforcement between visits is also a concern, where reading knowledge and/or motivation have potential to erode. This is especially concerning for families of low-socioeconomic status (SES), who tend to express more apprehension about reading particularly

during infancy,<sup>5,6</sup> read less frequently and interactively,<sup>7,8</sup> and are more likely to use screen media as an “educational” alternative.<sup>9</sup> While some families may feel empowered by encouragement to read, others may feel ill-equipped to do so,<sup>10,11</sup> suggesting a need for extra support.

Mobile (mHealth) apps are an increasingly utilized and appealing means to provide health information for families. Topics include perinatal health,<sup>12</sup> breastfeeding,<sup>13</sup> parenting in the neonatal intensive care unit,<sup>14</sup> and immunizations.<sup>15</sup> However, despite the appeal of such parenting-related apps, few have been rigorously studied in pediatrics.<sup>12,16</sup> Qualitative research suggests interest in health and parenting apps, yet raises concerns about usability/literacy, cultural sensitivity, cost, accuracy and privacy.<sup>16,17</sup> As health information can be complex and anxiety-provoking,<sup>18</sup> attractive options involve apps as an adjunct to guidance from clinicians.<sup>17</sup> To our knowledge, no app providing reading guidance to parents of young children has previously been studied in pediatric settings.

The primary aim of this trial was to explore feasibility, usability and efficacy of a mobile app (*Rx for Success*; RxS) provided during 6-month (infant) and 18-month (toddler) well-visits in terms of shared reading and child language outcomes. RxS includes videos and activities encouraging parent-child interaction, particularly shared reading. The control cohort received a children’s book modeling alternatives to screen time (*Baby Unplugged: Play*),<sup>19</sup> with no extra reading guidance. The study was conducted in a primary care clinic serving largely families of low-SES where ROR is well-established. The primary hypothesis was that RxS would be feasible to introduce, well-received by parents and would enhance shared reading attitudes, behaviors (frequency, interactivity) and child language skills, relative to controls. Characterizing screen-based media use in this population to inform future work served as an exploratory aim.

## METHODS

### PARTICIPANTS/SETTING

This pilot trial involved parent-child dyads in 2 age groups, each followed for approximately 6 months. All aspects were administered by clinical research coordinators (CRC) between Spring, 2018 and Summer, 2019. Families were recruited during well-visits at a pediatric primary care clinic affiliated with a children’s hospital in the Northeastern United States, serving largely families of low-SES and minority race and/or ethnicity (90% Medicaid insurance, 71% Hispanic). This clinic administers ROR at well-visits between newborn and 5-years old and conducts regular provider training to encourage fidelity with the ROR model. Potentially eligible families were identified via review of the electronic medical record, and parents were approached in the lobby or exam room by a CRC to gauge interest. Eligibility criteria were: 1)

gestation at least 34 weeks; 2) age at baseline well-visit ~6 months (5.75–9.75 months) or ~18 months (17–21 months); 3) no history of a medical condition likely to confer language delay; 4) fluency reading and writing English without need of an interpreter; 5) no acute infectious illness; and 6) a smartphone capable of installing RxS (iOS/Apple, Android). Twins and siblings presenting at subsequent visits were excluded (ie, maximum one child enrolled per family). Families received a gift card incentive at baseline and follow-up visits. Written informed consent was obtained and the study was approved by Institutional Review Boards at principal and host institutions.

### RANDOMIZATION

Following consent, families were randomly assigned to an intervention (RxS) or control cohort by the CRC using a spreadsheet with assignment codes determined by computer-generated random numbers provided in advance by a biostatistician (Group A or Group B). Participants were blinded as to group assignment, not advised as to differences in intervention between groups and also to the study intent other than general terms. The CRC was not blinded, as this was infeasible given the distinct nature of the materials. Statisticians were blinded as to the definition of Group A or B, to ensure objectivity in the analyses. Sample size was determined a priori based on a moderate effect size (Cohen’s  $d = 0.55$ ) within the range cited in reading interventions involving young children,<sup>20</sup> 80% power,  $\alpha_{2\text{-tailed}} = .05$ , and estimated 20% attrition. Families in both cohorts received ROR via their pediatric provider per usual practice (one age-appropriate book, encouragement and reading guidance).

### ASSESSMENTS

At the baseline visit and before intervention or seeing the provider, measures were administered to parents with data directly entered into a REDCap<sup>21</sup> database. Measures were: 1) a *demographic* survey including parental smartphone characteristics; 2) parental *attitudes* toward shared reading and *family history* of reading difficulties using items from published research<sup>6,22</sup>; 3) 6 items from the Reading and Parental Verbal Responsivity subscales of the StimQ<sub>2</sub> home cognitive environment survey (Infant and Toddler versions),<sup>23</sup> including *shared reading frequency* (ie, minutes/day); 4) the SharePR, a 10-item measure of *shared reading quality* with young children (eg, lap sitting, child-directed speech);<sup>24</sup> 5) ScreenQ-I/T, a 10-item survey reflecting AAP screen time guidelines,<sup>25</sup> involving access, frequency, content and co-viewing; and 6) the LENA Snapshot (Language ENvironment Analysis, Boulder, Colo), a report-based measure of expressive and receptive *language* validated for age 6 months and older, generating a standard score.<sup>26</sup> LENA Snapshot has 52 possible items, and parents are instructed to respond “Yes” if the child consistently demonstrates the behavior,

else “Not yet,” and proceeds until the parent responds “Not yet” for 5 items in a row. Examples are:

“Does your child imitate sounds you or others make?”

“Does your child say at least 10 meaningful words that you consistently recognize?”

### INTERVENTION: RX FOR SUCCESS

RxS is a free mobile application reinforcing constructive parenting practices that was developed by the nonprofit Children, Inc. (Covington, KY). This study used a beta version with sparse content emphasizing shared reading, to determine feasibility/usability in a pediatric setting. RxS features 2 videos: “Words Matter” for age 0–2 (talking, singing, reading; time 2:12), and “Dialogic Reading” for age 2–4 (time 1:35), the latter involving question prompts and ways to respond to a child to encourage verbal interaction.<sup>27</sup> Parenting tips (Activities) are organized into 5 categories: At Home, Reading, Crafts, On the Go, and Music. Parents receive “push” messages encouraging these at a desired frequency (daily, every other day, weekly). As of mid-2020, the RxS app is no longer available.

The intervention involved the CRC helping the parent install RxS on their phone and review its features. If installation failed such that review was not possible (eg, dead battery), the CRC described these features and the parent was given printed instructions on installation, which was confirmed at the follow-up visit. In all cases, the CRC then watched the RxS videos with the parent, either on the parent’s phone or on the CRC’s iPad without further guidance or discussion beyond encouragement to use the app, to ensure consistency with the intervention while deferring guidance to app content/use.

Administration time for RxS (download, review) and performance issues were documented, noting those prohibiting installation during the visit. Parents were finally administered a brief survey regarding *anticipated* usefulness of RxS.

### CONTROL: CHILDREN’S BOOK

*Baby Unplugged: Play* (Control) is a 14-page, board-format children’s book that is commercially available. It has a rhyming narrative and illustrated content modeling alternatives to screen time such as playing with blocks, featuring children of diverse ethnicity and gender. AAP screen time guidelines<sup>28</sup> are summarized on the back cover (Flesch-Kincaid 3rd grade reading level). The principal investigator has experience developing books for infant health promotion.<sup>19,29,30</sup> Following baseline assessment, the CRC presented the book to the parent noting tips on the back cover, and encouraged them to read the book at home. Rationale for this control condition was to provide age-appropriate parenting guidance (equipoise) using nontechnological media that was minimally confounding, as the RxS app does not mention screen time while the book mentions reading as one among several alternatives.

Sample images are shown in [Figure 1](#).

### FOLLOW-UP ASSESSMENT

At a well-visit approximately 6 months later (~12-months, ~24-months old), the CRC repeated the StimQ-I/T items, SharePR, LENA Snapshot and ScreenQ-I/T. Those in the intervention cohort were surveyed regarding impression of *actual* use of RxS. It was not possible to blind the CRC to cohort assignment given the distinct nature of this impression/usage survey.

### STATISTICAL ANALYSES

Descriptive statistics were computed for the whole sample, by each age group and by cohort, with a particular emphasis on family characteristics and reading-related behaviors. Screen-based media use (ScreenQ-I/T total and item scores) was analyzed for descriptive purposes. Parametric and nonparametric measures of central tendency, variability, and association were all computed. Analyses included a comparison of demographics to confirm cohorts were equivalent at baseline using both chi-square and Fisher exact tests.

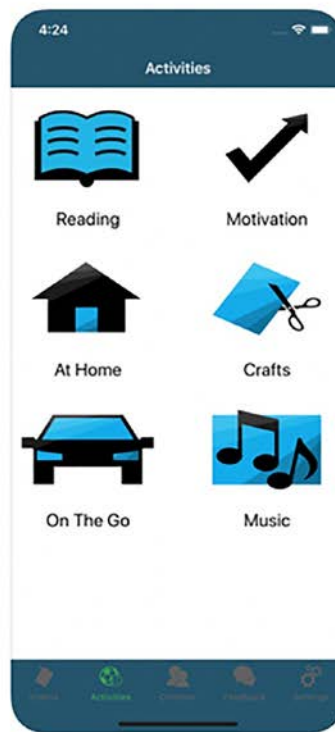
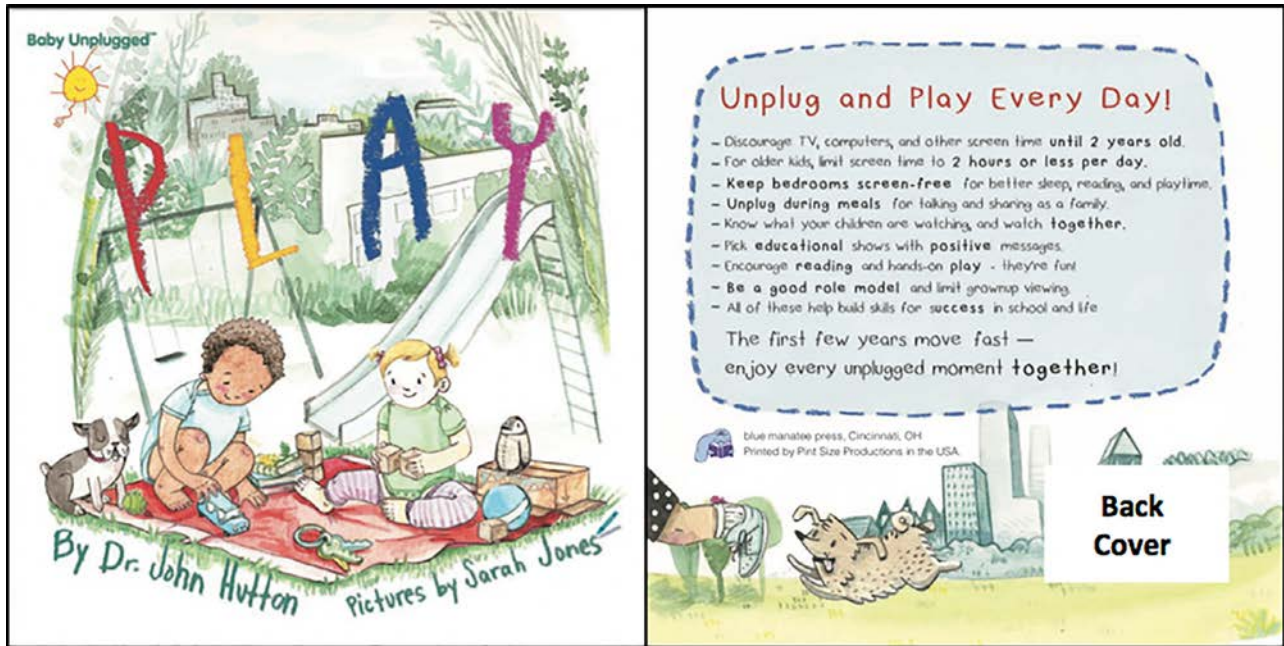
In the feasibility/usability component of the study, estimates of both were computed along with 95% confidence levels (CL). Baseline usability estimates included changes in parenting behaviors *anticipated* from use of the RxS app, particularly regarding reading with the child. Usability estimates determined at the follow-up visit included *actual* reported use, helpfulness, and enjoyment, and also changes in parenting behavior attributed to RxS.

In the efficacy component, planned comparisons were defined a priori and tested for each group at the baseline and follow-up visits, in accordance with a statistical analysis plan. For each of the 3 primary outcomes (shared reading minutes/day, SharePR score, LENA Snapshot), significantly higher scores were hypothesized for the RxS cohort (Intervention) relative to the Control cohort for the 6-month group as well as the 18-month group, after adjusting for respective baseline scores. Multiple logistic regression was used to compare reading minutes/day and SharePR scores due to the dichotomous nature of these outcomes, and multiple linear regression was used to compare LENA Snapshot standard scores due to the continuous and well-behaved nature of the distribution. In the case of the logistic models, scores were dichotomized at 15 minutes/day to correspond to a level recommended by major literacy groups (eg, Read Aloud 15 Minutes national campaign) and at a SharePR score of 15, to distinguish those who scored above the midpoint from those who scored below the midpoint. Data were analyzed using SAS v9.4.

## RESULTS

### RANDOMIZATION AND DEMOGRAPHIC CHARACTERISTICS

A total of 252 parent-child dyads in 2 equally sized age groups (n = 126 at 6-months and 18-months old) were consented for this study ([Fig. 1](#); online). Each dyad was randomized at enrollment into 1 of 2 groups: Intervention (RxS, n = 129) or Control (n = 126). The sample was



**Figure 1.** Materials provided to families at the baseline visit. Sample images from materials provided to Intervention (Rx for Success app, lower) and Control (Baby Unplugged: Play book, upper) families. App content includes 6 categories of suggested activities, “push” messages and 2 videos (talking to young children and dialogic reading).

evenly divided by sex, with a majority of Black race (33%) and 70% with at least one Hispanic/Latinx parent. The sample was largely of low-SES, with 50% meeting 2020 US poverty criteria,<sup>31</sup> and 14% reporting a family history of reading difficulties. Most parents had unlimited data plans (77%). These characteristics were statistically equivalent between cohorts at each age and are summarized in Table 1.

**FEASIBILITY**

A total of 129 parent-child dyads received the RxS intervention across the 2 age groups (n = 62 at 6 months, n = 67 at 18 months). Mean administration time was 6 minutes and 51 seconds (±0:31 minutes; range 5–8) or <3 minutes excluding viewing time for the 2 videos (~4 minutes). Difficulties were reported for 41 parents (32%; n = 20 at 6 months, n = 21 at 18

**Table 1.** Sample Demographics

Variable*	Age 6 Months		Age 18 Months	
	Control	Intervention (RxS)	Control	Intervention (RxS)
	n = 64 f(%)	n = 62 f(%)	n = 59 f(%)	n = 67 f(%)
Gender				
Male	30 (47)	33 (53)	26 (44)	36 (54)
Female	34 (53)	29 (47)	33 (56)	31 (46)
Child race**				
Black or African American	23 (36)	22 (35)	15 (25)	24 (36)
White or Caucasian	3 (5)	5 (8)	4 (7)	4 (6)
Other	5 (8)	6 (10)	3 (5)	5 (7)
Missing	33 (51)	29 (47)	37 (63)	34 (51)
Child ethnicity				
Hispanic/Latinx	46 (72)	42 (68)	46 (78)	42 (63)
Other	0 (0)	1 (2)	2 (3)	1 (1)
Missing	18 (28)	19 (30)	11 (19)	24 (36)
Annual household income level				
\$0–\$15,000	16 (25)	24 (39)	21 (36)	20 (30)
\$15,001–\$30,000	15 (23)	16 (26)	21 (35)	27 (40)
\$30,001–\$50,000	22 (34)	10 (16)	7 (12)	9 (13)
\$50,001–\$75,000	6 (9)	7 (11)	4 (7)	7 (10)
Over \$75,000	2 (3)	4 (6)	3 (5)	2 (3)
Missing	3 (5)	1 (2)	3 (5)	2 (3)
Income to needs***				
At/under poverty threshold	26 (40)	33 (53)	33 (56)	33 (49)
Above poverty threshold	35 (55)	28 (45)	23 (39)	32 (48)
Missing	3 (5)	1 (2)	3 (5)	2 (3)
Mother education level				
Less than high school	10 (16)	8 (13)	10 (17)	6 (9)
High school graduate/GED	24 (37)	29 (47)	30 (51)	31 (46)
Some college****	20 (31)	16 (26)	14 (24)	24 (36)
College graduate	10 (16)	9 (14)	5 (8)	6 (9)
Father education level				
Less than high school	17 (26)	9 (14)	12 (20)	7 (11)
High school graduate/GED	26 (41)	33 (53)	30 (51)	29 (43)
Some college****	12 (19)	9 (14)	10 (17)	20 (30)
College graduate	8 (12)	8 (12)	4 (7)	7 (10)
Missing	1 (2)	3 (5)	3 (5)	4 (6)
Primary reader at home?				
Both parents	8 (12)	2 (3)	7 (12)	9 (14)
Father	0 (0)	3 (5)	5 (9)	3 (4)
Mother	46 (72)	44 (71)	35 (59)	46 (69)
Other family member	7 (11)	7 (11)	10 (17)	8 (12)
None yet	3 (5)	5 (8)	2 (3)	0 (0)
Missing	0 (0)	1 (2)	0 (0)	1 (1)
Family history of reading difficulty				
No	55 (86)	53 (85)	49 (83)	57 (85)
Yes	8 (12)	8 (13)	10 (17)	9 (13)
Not sure	1 (2)	1 (2)	0 (0)	1 (2)
Smartphone type				
Android	28 (44)	32 (52)	25 (42)	24 (36)
iPhone	36 (56)	30 (48)	34 (58)	43 (64)
Data plan				
Limited	10 (15)	16 (26)	15 (25)	11 (16)
Unlimited	53 (83)	44 (71)	44 (75)	53 (79)
Missing	1 (2)	2 (3)	0 (0)	3 (5)

RxS indicates Rx for Success; GED, General Educational Development.

\*There are no statistically significant differences between groups at baseline.

\*\*Parent could report more than one race including Hispanic, which in this table is reported as ethnicity.

\*\*\*Derived using the 2020 US Department of Health and Human Services Poverty Table.

\*\*\*\*Includes Associates Degree.

months). Twenty-one of these difficulties were parent-related (51%, eg, dead batteries, forgotten passwords), 11 were clinic-related (27%, eg, WiFi problem) and 9

were RxS performance-related (22%, eg, no audio). For 10 parents (8% of the cohort) difficulties prohibited RxS installation during the well-visit.

**Table 2.** Parental Impression and Use of the Rx for Success App (RxS) Assessed at the Follow-Up Visit

	Combined f (%)	6 months f (%)	18 months f (%)
Around how often did you use the RxS app?			
Never	18 (17)	8 (15)	10 (18)
A few times	51 (48)	26 (49)	25 (45)
Once a month	8 (7)	3 (6)	5 (9)
Once a week	7 (7)	2 (4)	5 (9)
More than once a week	16 (15)	9 (17)	7 (13)
Every day	7 (7)	5 (9)	2 (4)
Did any of these get in the way of your using the RxS app? (choose as many as apply)			
Not enough phone minutes/worry about using minutes	7 (7)	4 (8)	3 (6)
Didn't work well on my phone	7 (7)	3 (6)	4 (7)
Too busy	32 (30)	16 (30)	16 (30)
Not fun	2 (2)	1 (2)	1 (2)
Confusing/hard to understand	4 (4)	3 (6)	1 (2)
Didn't seem to relate to my child	9 (8)	8 (15)	1 (2)
None of these	56 (52)	26 (49)	30 (56)
Was the RxS app helpful for improving how to read with your child?			
Not helpful	19 (18)	9 (17)	10 (19)
Somewhat helpful	22 (21)	8 (15)	14 (27)
Helpful	36 (34)	22 (43)	14 (26)
Very helpful	28 (27)	13 (25)	15 (28)
What was the most helpful part of the RxS app for you?			
The videos	54 (51)	29 (55)	25 (47)
The "push" notifications	9 (8)	5 (9)	4 (8)
The written tips in the app	35 (33)	14 (27)	21 (40)
Not helpful	8 (8)	5 (9)	3 (5)
Which activities, if any, in the RxS app did you find most helpful?			
Reading	32 (30)	16 (30)	16 (31)
Motivation	7 (7)	6 (11)	1 (2)
At home	11 (10)	4 (8)	7 (13)
Crafts	6 (6)	2 (4)	4 (8)
On the go	2 (2)	0 (0)	2 (4)
Music	23 (22)	16 (30)	7 (13)
Not helpful	24 (23)	9 (17)	15 (29)
Was the RxS app fun for you to use?			
Not fun	11 (12)	7 (15)	4 (9)
Somewhat fun	25 (27)	12 (25)	13 (29)
Fun	36 (39)	18 (37)	18 (40)
Very fun	21 (22)	11 (23)	10 (22)
Over the past 6 months, did you do anything differently when spending time with your child because of tips from the RxS app?			
Yes, definitely	73 (69)	38 (72)	35 (66)
Maybe/Not sure	7 (7)	3 (6)	4 (8)
Probably not/no	26 (24)	12 (22)	14 (26)
If yes/maybe, Anything in particular?			
Reading (together, more, differently) is mentioned	47 (59)	25 (61)	22 (56)

### USABILITY—ANTICIPATED

In terms of parenting behaviors, 73% (CL<sub>0.95</sub>, 62–85) of parents in the 6-month group anticipated change attributable to RxS, while 79% (CL<sub>0.95</sub>, 69–89) in the 18-month group anticipated change. Of these, 42% at 6 months (CL<sub>0.95</sub>, 29–54) and 49% at 18 months (CL<sub>0.95</sub>, 37–61) specifically mentioned anticipating reading to the child more often.

### USABILITY—ACTUAL

A total of 217 dyads presented for follow-up visits at approximately 12- and 24-months old (86%; 110 RxS, 107 Control; Fig. 1s). A majority of parents in both age groups reported using RxS (49%/45% “A few

times,” 15%/18% “Never”), that it was helpful and fun to use, and that it inspired actual changes in parenting behavior, most often reading. Most parents in both age groups reported no barriers to use of RxS (most frequent “Too busy”), and videos were rated its most helpful feature and reading the most helpful activity. The most frequent usability comments involved a desire for more engaging, relevant (eg, for child's age), actionable and/or updated content.

Usability statistics are summarized in Table 2.

### EFFICACY

Primary outcomes assessed at the follow-up visit are summarized in Table 3 and were:

**Table 3.** Summary Statistics for Primary Outcomes at Baseline and Follow-Up Visits

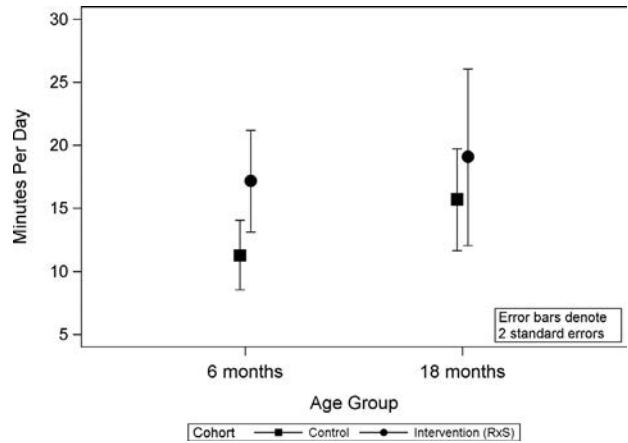
Primary Outcome Variables	Age 6-Months Group				Age 18-Months Group			
	Control		Intervention (RxS)		Control		Intervention (RxS)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Reading minutes per day	13.2 ± 12.1	<b>11.3 ± 10.1*</b>	12.4 ± 11.0	<b>17.2 ± 14.8*</b>	13.6 ± 9.6	15.7 ± 14.4	14.2 ± 10.5	19.1 ± 25.7
SharePR total score	18.3 ± 6.3	19.6 ± 4.6	17.7 ± 5.5	19.4 ± 4.8	19.0 ± 5.3	18.7 ± 4.5	17.8 ± 4.7	18.2 ± 4.6
LENA Snapshot standard score	112.6 ± 15.9	106.1 ± 16.2	109.9 ± 14.5	107.3 ± 14.6	99.0 ± 20.8	<b>92.4 ± 17.2**</b>	98.0 ± 16.4	<b>96.7 ± 16.6**</b>

RxS indicates Rx for Success; LENA, Language Environment Analysis.

Note. All values here are presented as mean ± SD.

\*Borderline—significantly higher for the RxS cohort in the 6-month group (model: likelihood ≥ 15), controlling for baseline level ( $P = 0.05$ ).

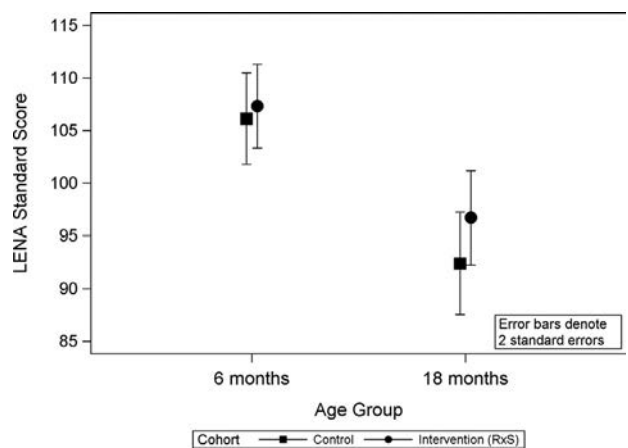
\*\*Significantly higher for the RxS cohort in the 18-month group, controlling for baseline level ( $P = 0.01$ ).



**Figure 2.** Shared reading frequency for each age group reported at the follow-up visit. Shared reading frequency (minutes per day) for each age group and between cohorts reported by parents at the follow-up visit. Relative to Controls, frequency was borderline-significantly higher for the RxS cohort for the 6-month group ( $P = .05$ ) and nonsignificantly higher for the 18-month group, controlling for baseline levels. RxS indicates Rx for Success.

1) Reading frequency (Fig. 2). Nine percent of parents in the younger group reported not yet reading with the child (14% baseline) and 7% in the older group (9% baseline). Mean reading frequency was 14 minutes/day (standard deviation [SD] ± 13; median 10; range 0–60) for the 6-month group and 17 minutes/day (SD ± 21; median 12; range 0–180) for the 18-month group. For the 6-month group, likelihood of reading ≥ 15 minutes/day was borderline-significantly higher for the RxS cohort ( $P = .05$ ), controlling for baseline level. There was no statistically significant difference for the 18-month group ( $P = .69$ ).

A secondary analysis found that shared reading was named as a favorite activity at the follow-up visit in the RxS cohort significantly more often in the 6-month group



**Figure 3.** Language scores for each age group at the follow-up visit. LENA Snapshot Standard scores for each age group and between cohorts assessed at the follow-up visit. Relative to Controls, scores were significantly higher for the RxS cohort in the 18-month group ( $P = .01$ ) and nonsignificantly higher for the 6-month group, controlling for baseline scores. RxS indicates Rx for Success.

(59% vs 35%;  $P = .01$ ) and nonsignificantly in the 18-month group (61% vs 47%;  $P = .15$ ).

2) *Reading Interactivity*. Mean SharePR score for parents who reported reading with their child was 20 (SD  $\pm 5$ ; median 20; range 7–27) for the younger and 18 (SD  $\pm 5$ ; median 19; range 6–27) for the older group. No statistically significant difference in likelihood of SharePR score  $\geq 15$  was observed between cohorts in either the 6-month ( $P = .13$ ) or the 18-month group ( $P = .98$ ).

3) *Language* (Fig. 3). Mean LENA Snapshot Standard Score at follow-up was 107 (SD  $\pm 15$ ; median 105; range 71–136) for the younger and 95 (SD  $\pm 17$ ; median 97; range 64–130) for the older groups. There was no statistically significant difference in scores between cohorts for the 6-month group ( $P = .61$ ). However, these were significantly higher for the RxS cohort in the 18-month group ( $P = .01$ ), controlling for baseline scores.

### SCREEN TIME

Mean ScreenQ-I/T score at the follow-up visit in the 6-month group was 8 for the RxS cohort (SD  $\pm 3$ , range 2–15) and 7 for the Control cohort (SD  $\pm 3$ , range 0–13). For the 18-month group, mean score was 10 for the RxS cohort (SD  $\pm 3$ , range 2–15) and 9 for Controls (SD  $\pm 3$ , range 2–16). These scores were not significantly different between cohorts at either age ( $P = .11$ ,  $P = .97$ , respectively), yet were significantly higher combined for the older group ( $P < .001$ ).

Mean reported age of initiating screen use was  $4 \pm 2$  months old for the 6 months and  $9 \pm 4$  months for the 18-month group. Mean use was 1.5 hours/day (SD  $\pm 1.5$ ; median 1; range 0–6) for the 6-month group and 2 hours/day (SD  $\pm 1.3$ ; median 2; range 0.2–6) for the 18-month group. A screen was reported in the child's bedroom for 46% in the 6-month group and 42% in the 18-month group, with 21% and 54% having her/his own device, respectively. Contexts of use reported included at meals (33% 6-month group, 50% 18-month group), to help the child fall asleep (23%, 42%) and to help the child calm down (100%, 100%).

### DISCUSSION

Existing programs excel at providing books to families, yet consistent guidance regarding how to read most effectively can be challenging, especially involving young children. The ROR program combines book distribution with encouragement from pediatric providers during well-visits,<sup>1,3</sup> where discussion of parenting and development is customary. However, the level of guidance is limited by time constraints and competing priorities such as vaccines and nutrition.<sup>4</sup> Thus, while in ideal circumstances reading and literacy would be discussed in detail tailored to child age family needs at each visit in accordance with AAP recommendations, in practice this does not typically occur. Erosion in caregiver knowledge and/or motivation between visits are also concerns (ie, “fadeout”<sup>32</sup>), especially in families from disadvantaged backgrounds facing stressors at home. Printed educational materials can be

helpful, yet are variable in quality and often pose literacy challenges.<sup>18</sup> Mobile health (mHealth) and parenting apps are advocated<sup>16,17</sup> given the ubiquity of smartphones,<sup>9</sup> yet few have been studied and none to our knowledge involve shared reading.<sup>12,33</sup> The purpose of this trial was to gauge feasibility, usability and efficacy of such an app installed during well-visits, as an enhancement to ROR.

An important consideration for any intervention is the burden on clinic resources. While administration times for RxS here appear long, the majority of the time was accounted for by the CRC watching 2 videos with the family to document fidelity with the intervention, and the intent is for these to be viewed at the parent/caregiver's discretion (eg, while waiting for the provider, at home). Installation could be guided by staff during registration or intake with instructions for later use. While a sizable minority of families experienced performance issues, most are readily addressed and likely to enhance family satisfaction with clinic visits (eg, stable WiFi connection, smartphone chargers). Consideration of a “data-lite” approach in subsequent app refinements to enhance performance is also important. Surprisingly, data use was not a substantial barrier, as most families had unlimited data plans. Altogether, the time and resources required seem reasonable during a well-visit at this age, freeing clinicians to frame guidance in the context of developmental milestones and AAP recommendations, as through the established ROR model,<sup>3</sup> to provide examples of complex concepts (eg, dialogic reading) and to provide a platform to sustain guidance after each visit.

Despite modest use attributable to limited content, most families reported RxS as fun and helpful, particularly to improve shared reading routines. While possibly influenced by social desirability bias, this suggests appeal of the app approach, notably featured videos. By contrast, “push” messages were largely not considered helpful, attributable to functionality in RxS that was not responsive or actionable (eg, new resources). This is consistent with feedback from parents regarding a desire for more relevant and/or updated content as an incentive to sustain engagement. However, significant improvements in reading attitudes and behaviors (proximal) and child language (distal) were found relative to the control group, suggesting potential of an app for this purpose, even with modest use. This raises questions about existing parenting apps that present large amounts of information including abstract concepts that may be overwhelming, especially for families of low-SES with fewer resources. The most frequent barrier to use identified was “too busy,” highlighting the appeal of simplicity. It is reasonable to speculate that simple, empowering content focused on reading, tailored to needs and updated regularly to incentivize use may result in more substantial effects than found here.

Despite modest use of RxS, parental reading attitudes and frequency were significantly higher for the RxS cohort in the younger age group and language scores in the older age group. This finding is notable, as while small in magnitude, these differences also manifest in a



relatively short span of time (~6 months). As shared reading is a known, major catalyst for language exposure in young children fueling subsequent language development,<sup>34</sup> it is intriguing to speculate that enhanced home reading behaviors inspired by RxS (or an improved app) over a longer span of time have the potential to fuel even larger language benefits than found here. That significant differences in language were not found between cohorts at 12 months may reflect difficulty for parents to discern differences at this age, where variability is relatively low. It is surprising that while parents in the RxS cohort at both ages more often named shared reading as a favorite activity, differences in reading frequency were not significant for the older group. This may be attributable to the 15-minute threshold set in our logistic regression model, which was below the mean level reported in the older group, making differences difficult to detect. It may also reflect a resistance level or ceiling effect at this age noted in prior surveys (<20 minutes/day).<sup>9,35</sup> That no significant differences in shared reading quality/interactivity (SharePR) were identified is not surprising, as reading guidance provided by RxS is general and ideal for older children (dialogic reading). Overall, while benefits found favoring the RxS cohort are promising, modest use, magnitude of effects and nonimpact in terms of quality/interactivity suggest areas for improvement.

Screen-based media use exceeded AAP recommendations at all ages.<sup>28</sup> This is consistent with trends of increasing screen time for young children fueled by mobile devices,<sup>9,36</sup> with 54% of 2-year olds here reported as having their own device. Discouraged behaviors found include introduction in early infancy, screens in sleeping areas, use at meals, for sleep and for calming.<sup>28</sup> Excessive use is not surprising as RxS does not address screen time and the *Baby Unplugged* book was provided passively via a CRC rather than a clinician, evidenced by statistical equivalence in both total ScreenQ score and frequency (minutes/day) between cohorts at both assessments for both ages. These findings are useful to guide app development incorporating screen time guidance, which may be addressed concurrently with reading.

This study has limitations. RxS was administered by a CRC and results may not generalize to pediatric providers. The sample largely involved families from low-SES and Hispanic/Latinx backgrounds, which may also not be generalizable. Due to the distinct nature of Intervention/Control materials and usage/impression surveys, it was not possible to blind the CRC to cohort assignment, though participants and biostatisticians were blinded. RxS was a preliminary version involving limited content, which likely influenced performance, use and impression. However, these were largely favorable and provided insights for refinement. Encouraged nonreading behaviors (eg, talking/singing) may have impacted language outcomes, though reading was reported as most inspired by RxS use. Given privacy and time constraints, health literacy was not measured and may have impacted use. LENA Snapshot is a report measure prone to bias, yet is validated

across the study age range and feasible during clinic visits.<sup>26</sup> SharePR and ScreenQ-I/T are not formally validated measures, yet are based on versions validated for older children,<sup>24,25</sup> reflect AAP guidelines and are grounded in evidence-based conceptual models.<sup>1,28</sup> Findings involving reading frequency used a threshold of 15 minutes rather than a continuous variable, which is justified given the skewed nature of score distributions, reflects a widely recommended level that is familiar to families, and was determined a priori for logistic modeling. Control families were given a children's book providing parenting guidance related to screen time, introducing a potential confounder, though its content largely involves active/outdoor play with only one spread mentioning reading. Further, screen time was statistically equivalent between cohorts at both ages, suggesting a negligible effect, and differences in reading and language outcomes may have been larger favoring RxS if controls had been given a book without parenting guidance.

This study also has important strengths. It addresses a need to provide consistent reading guidance involving very young children to underserved, at-risk families that is sustained beyond a clinic visit. Intervention was conducted during well-visits using an approach that is low-cost and scalable within existing programs, notably ROR, which has potential to reach a majority of families in the US living in poverty.<sup>3</sup> More than 85% of families completed both visits, high retention for a low-SES population. While involving a beta version of an app with limited content, this trial provided evidence of feasibility, usability, efficacy and areas needing refinement, including addressing screen time. To our knowledge, no parenting apps have been similarly studied in pediatric settings. Importantly, the longitudinal design allows inferences into causation in each age group during critical stages of development and suggest proximal (reading) and distal (language) benefits of the intervention. Future studies involving an optimized app, which has been developed by the study team with testing underway, and longer-term outcomes will address questions including intensifying and sustaining parental engagement, enhancing reading quality, integration into clinic workflows and limiting screen time. At this stage, this trial suggests that a parenting app is feasible to introduce during well-visits, helpful for parents even with limited use, and may be an effective complement to ROR and other programs to improve shared reading practices and child language, reinforcing AAP recommendations.

## CONCLUSIONS

In this pilot trial involving parent-child dyads from low-SES backgrounds during well-visits, a mobile parenting app was feasible to introduce, rated helpful and effective to improve shared reading with infants and language for toddlers, compared to controls receiving a children's book. App use was modest, attributable to limited content and a minority of parents experienced performance issues.

Screen time was excessive at both ages. These findings provide insights guiding development of an optimized app for subsequent use.

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### SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at <https://doi.org/10.1016/j.acap.2021.05.005>.

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