Title: **Digital Literacy Promotion among Medicaid Children**

Short Title **Digital Literacy Promotion**

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ABBREVIATIONS AND DEFINITIONS OF TERMS

ROR	Reach Out and Read
ACE	Adverse Childhood Experiences
SAHL	Short Assessment of Health Literacy
EPDS	Edinburgh Postnatal Depression Scale
StimQ	Measure of Cognitive Stimulation Provided in the Home
ERPQ	Early Reading Practices Questionnaire
BSID-III	Bayley Scales of Infant and Toddler Development, Third Edition
DialogPR-I	Dialogic Reading Practices- Infant, parent-report pilot measure

ABSTRACT

Context:

Reach Out and Read (ROR) has become a standard evidence-based primary care practice to support early literacy development of young at-risk children. It utilizes board books which are distributed at pediatric well visits along with literacy promotion and reading modeling by pediatricians. However, digital reading utilizing e-books and apps for reading on electronic devices has become popularized. We would like to address the important question of whether digital reading with e-books is as effective as reading with standard board books on early development. For this 18-month investigation, we propose to recruit 100 parent-infant dyads from 3 CHOP primary care pediatric practices (Indian Valley, Cobbs Creek and Roxborough). Healthy infants at least five months of age who are Medicaid eligible and whose parents have access to smart phones and other mobile digital devices at those practices would be recruited and randomized 1:1 to early literacy promotion using either 1) standard early reader board books or 2) digital electronic early reader books (e-books). Books would be distributed at 3 time points to coincide with well visits up to 13 months of age. Outcomes corresponding to reading behaviors (quantity and quality of joint reading) would be measured approximately 1 month after the 6, 9, and 12 month well visits. Child development would be measured when the child is between 12 and 18 months, 30 days of age. A subset of up to 40 parent infant dyads will be recruited to participate in a videotaped interaction while reading both an e-book and standard board book. Parent and child behaviors during the reading task will be coded and analyzed for differences across book type.

Objectives:

1) To test the effects of digital versus standard literacy promotion on early development using a randomized controlled trial design.

2) To explore the reading practices and reading activities among children and their parents when comparing the use of e-books to traditional board books.

3) To identify themes regarding dialogical reading behaviors among parents participating in the Video Sub-study.

Study Design:

A randomized controlled trial will be conducted comparing digital versus standard literacy. Participants will be stratified by clinic site and randomized to receive literacy promotion using 1) standard early reader board books or 2) digital electronic early reader e-books. Randomization sequences will be developed by the project biostatistician using computer-generated random numbers prior to enrollment and will be placed in sealed opaque envelopes. Randomization will ensure equivalence between groups on measured and unmeasured characteristics and is

considered to be the strongest protection against bias in study design. A total of 40 participants will be recruited between 9 and 12 months of age for the videotaped interaction and interview.

Setting/Participants:

In the randomized control trial, we will recruit and consent one hundred eligible parent-infant dyads, with the infant being between 5 and 7 months of age at enrollment. Eligible participants must have Medicaid insurance coverage, access to one of the three CHOP Care Network practices (Cobbs Creek, Roxborough and Indian Valley) for this 18-month trial. The video sub-study will recruit up to 40 eligible parent-infant dyads. Eligible participants will be recruited from both the randomized control trial as well as external to the larger trial from a participating clinic. Eligible participants must have Medicaid insurance coverage, access to a digital device, and present to one of the three CHOP Care Network practices (Cobbs Creek, Roxborough and Indian Valley).

Study Interventions and Measures:

In this intervention, parent-infant dyads randomized to the digital arm will receive developmentally appropriate e-books. Those randomized to the standard arm will receive developmentally appropriate board books. Participants will receive either the e-book or board book for their 6, 9 and 12 month well visits. The developmentally appropriate books selected for each of the 3 well visits are as follows: Dr. Seuss' *Hop on Pop* for the 6 month well visit, Sandra Boynton's *Barnyard Dance* for the 9 month well visit, and Margaret Wise' *Goodnight Moon* for the 12 month well visit.

In addition to the books, parent-infant dyads in both arms will be provided information on the importance of early parent-child reading activity by pediatric clinicians using the Reach Out and Read framework.

We will collect standard measures of demographics (child age, sex, race/ethnicity, maternal age, family structure, maternal education level, and family income category), maternal adversity (9 ACE questions), maternal health literacy (SAHL), and maternal depressive symptoms (EPDS) at baseline. About 1 month after the infant has, or is age-eligible for, their 6 and 9 month well visits we will collect measures of reading activity (StimQ and ERPQ). Roughly 1 month after the infant has, or is age eligible for, their 12 month well visit, the infant will receive a developmental assessment (BSID-III), along with additional measures of reading activity (StimQ, ERPQ). They will additionally complete the paper-based DialogPR-I at this visit. A video recorded reading task will be obtained for up to 40 participants. These participants will be asked preliminary questions about their reading practices at home at the time of the video session.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Children who receive Medicaid are more likely to be at increased risk for language and cognitive delays. Such delays can lead to poor school readiness and disparities in educational outcomes when compared to children from middle and upper income strata. Reach Out and Read (ROR), a national program which promotes parent-child reading activities for children 6 months through 5 years of age at pediatric well child visits, has been shown to improve at-risk children's expressive and receptive language development. However, children who participate in ROR still demonstrate language outcomes that are below national averages. It is not clear whether digital literacy promotion, i.e. promotion of parent-child reading with the use of e-books, is as effective as standard literacy promotion and if it could improve poor urban children's language and cognitive outcomes.

The disparities that continue to exist among language development despite literacy promotion efforts suggest that other barriers and factors may exist that influences these disparities. While it has been demonstrated that reading to infants is imperative for appropriate language development, the differences between reading to children in an e-book format versus a standard board book format have not been explored. In a growing digital age access to e-books is ever present and investigating potential differences in early literacy outcomes is beneficial for families and pediatricians.

1.2 Name and Description of Investigational Product or Intervention

The intervention will be an adapted version of the Reach Out and Read (ROR) Program, a national program that promotes parent-child reading activities for children 6 months through 5 years of age at pediatric well child visits. It will be adapted for use with parents of children from 5 to 18 months, 30 days. Digital literacy promotion will consist of the provision of developmentally appropriate standard and digital books selected specifically for all well visits from 5 months of age onwards. In this instance we define standard as the use of age appropriate board books in literacy promotion initiatives and digital as the use of mobile app based e-book versions of the same board books. It will also include follow-up contact with the parent to ascertain whether or not they encountered issues with the apps functioning, reminders to schedule and/or attend upcoming well visits, and for some parents, an interview and video recorded reading task with their infant.

1.3 Relevant Literature and Data

Early childhood is a critical period in which young children attain developmental skills necessary for language function.[1] Early stimulation of brain centers involved in language development

promotes critical neuronal connections leading to growth in language functioning. Unfortunately, language delays are common among children under age 3 years, particularly for children residing in impoverished communities.[2] The cause of these language delays are multifactorial but in part result from deficits in parent-child verbal interactions.[3] Twelve to sixteen percent of young children are estimated to have delays that affect language development.[4,5] Differences between poor and advantaged children in language processing skills and vocabulary are evident by 18 months of age.[6] These delays contribute to social and emotional problems and result in poor educational and functional outcomes.[7] Lifetime costs for individuals with developmental disabilities including language deficits has been estimated to exceed $60 billion in 2003 U.S. dollars.[8]

Parent-child dialogic reading represents an important source of language stimulation and is rich in verbal interactions that can stimulate language development.[9] Studies have found parent-child reading to be associated with improved language functioning and better school performance.[10-12] Based on this observation, the ROR Program was established to promote parent-child reading activity. ROR is based in pediatric clinical settings and provides developmentally appropriate books to young children and encourages a discussion of the importance of reading by pediatric clinicians at well child visits from 6 months through 5 years.[13] Evaluations of ROR have shown beneficial effects on reading activity and language outcomes.[14-16] These effects translate into an increase of 1 day/week of parent-child reading activity, a 4-fold increased likelihood of reporting reading to their child, and a 4 to 9 point increase in expressive and receptive language scores respectively (a 3-6 month advance in language) [16] For this reason, the American Academy of Pediatrics has recommended that pediatric clinicians promote early literacy development beginning in infancy.[17]

Electronic or e-books for children have grown in popularity. They come in a number of formats including Nooks, Kindles, and iPads as well as a number of digital apps that are used on smart phones and tablets. They permit children to follow along with stories, activate games and sounds, and listen to music. Their popularity may be related to parental beliefs that e-books help promote child intellectual development.[18] However, a recent study examining reading behaviors and comprehension among children using e-books found that e-books were associated with fewer dialogic language behaviors and lower reading comprehension compared to traditional books.[19] However, the study was limited by only enrolling middle to upper income preschool-aged children, so it isn't clear that the findings are generalizable to younger children from low-income households.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective of the study is to discover the effects of language development of young, at-risk children in digital versus standard literacy promotion using a randomized controlled trial design. In this instance we define standard as the use of age appropriate board books in literacy promotion initiatives and digital as the use of mobile app based e-book versions of the same board books in a literacy promotion intervention.

Specific Aim 1: To determine the comparative effectiveness of digital literacy promotion to standard literacy promotion on early development among young Medicaid eligible children in the Philadelphia metropolitan area.

2.2 Secondary Objectives

Specific Aim 2: To explore the reading behaviors and reading activities among children and their parents when comparing the use of e-books to standard board books.

Specific Aim 3: To identify themes regarding dialogical reading behaviors among parents participating in the Video Sub-study.

Specific Aim 4: To explore the impact of digital literacy on healthcare utilization

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Randomized Control Trial

We propose to test the effects of digital versus standard literacy promotion using a randomized controlled trial design. One-hundred eligible parent-child dyads, with infants between 5 and 7 months of age, who present to one of the three CHOP Care Network practices (Cobbs Creek, Roxborough and Indian Valley) will be recruited and consented to participate in this 18-month long study. Participants will be stratified by clinic site and randomized to receive literacy promotion using 1) standard early reader board books or 2) digital electronic early reader e-books. Randomization sequences will be developed by the study team using computer-generated random numbers prior to study enrollment and will be placed in sealed opaque envelopes.

Randomization will ensure equivalence between groups on measured and unmeasured characteristics and is considered to be the strongest protection against bias in study design.

Participants randomized to the digital arm will receive the e-book version of Dr. Seuss' *Hop on Pop* for the 6 month well visit, Sandra Boynton's *Barnyard Dance* for the 9 month well visit, and Margaret Wise' *Goodnight Moon* for the 12 month well visit. Additionally they will receive information on the importance of early parent-child reading activity by pediatric clinicians using the Reach Out and Read framework. The appropriate e-books will be electronically gifted to the participants. Parents must have an appropriate mobile digital device such as a smart phone or tablet to download and open the digital e-books.

Participants randomized to the standard arm will receive the board book versions of Dr. Seuss' *Hop on Pop* for the 6 month well visit, Sandra Boynton's *Barnyard Dance* for the 9 month well visit, and Margaret Wise' *Goodnight Moon* for the 12 month well visit. Furthermore, participants will be provided information on the importance of parent-child reading activity by pediatric clinicians using the Reach Out and Read framework.

Participants in both study arms will be followed every 3 to 4 months until the infants are between the ages of 12 and 18 months, 30 days. Information on reading activities and developmental outcomes will be collected in concert with scheduled well child visits. Differences in reading activities and developmental outcomes will be assessed between groups using intention-to-treat analysis. Parents will complete measures of demographics, health literacy, and maternal depressive symptoms at baseline. Parents will also complete measures of reading activity with their infant about 1 month after the child has, or is age-eligible for, their 6, 9, and 12 month well visits. The infant will also receive a developmental assessment at the second study visit which will happen about 1 month after they have, or are age-eligible for, their 12 month well visit. At this time the infant should be between 12 and 18 months, 30 days old. Secondary data to address these study questions does not exist, which will necessitate the collection of new data as proposed here. We anticipate that this collection of rich new data will support a careful assessment of the effects of digital vs. standard literacy promotion. The HER will be reviewed for children in both arms to count the number of well child visits and examine their vaccination history.

We anticipate collecting this data in conjunction with well child visits. In our experience, low-income families can be difficult to reach for study visits, even with appropriate study incentives. By coordinating data collection with the 6, 9, and 12 month well child visits timeframes, we can increase the probability of families attending both the well visits (to receive the Reach Out and Read Program materials) and the study visits (to collect measures of reading activity and development). In a previous study of 2100 children enrolled in a study of developmental screening, we were able to achieve a >90% follow-up rate by coordinating data collection with well child visits. In addition, our research staff can check the clinic schedule to ensure families have made timely well child visit appointments and then make reminder calls to families prior to these visits to encourage parents to attend. Study visits will be held at a location that is preferred

and most convenient for the parent, including but not limited to: the clinic, a separate CHOP-based facility, the Temple Infant and Child Lab, or another location based on availability and parent preference.

3.1.2 Video Sub-study

Up to 40 participants will be additionally recruited to participate in an interview and video recorded reading task. Participants will be recruited both from the larger RCT as well as from external sources (see Section 8.4). Dyads enrolled in the randomized control trial who agreed to participate in the sub-study at the time of their initial consent, and who are in the control (Traditional board book) arm, will be approached by telephone call, or the method of communication that they prefer, immediately following the time that they become age-eligible for their 9-month well visit. Participants meeting eligibility criteria and recruited external to the randomized control trial will be approached for participation at clinic appointments at one of the study sites. Participants will be continuously recruited until either the enrollment goal (40 dyads) is reached or until saturation of themes is achieved for this qualitative sub-study. Sessions, lasting approximately 45 minutes, will be held at a location that is preferred and most convenient for the parent, including but not limited to: the clinic, a separate CHOP-based facility, the Temple Infant and Child Lab, or another location based on availability and parent preference. For participants recruited from the larger study, no additional demographic data will be collected, as it will be accessed from the previously reported data. Participants recruited externally for the sub-study will complete the demographic and screening questionnaires that were previously collected by the larger study participants upon enrollment. These externally recruited participants will not participate in or be consented for participation in the larger randomized control trial.

On the day of the video sub-study session, all parents (regardless of whether or not they were recruited from within or external to the main RCT) will first be instructed to read a book with their child. This reading task will be video recorded by a member of the study staff. Parents will be asked to read to their child in the same manner that they had learned from their provider during their well-child check as part of Reach Out and Read. Parents will be receiving this instruction on dialogic reading, regardless of study arm, as part of the larger study. The selected book will be Sandra Boynton's *Barnyard Dance*, which is the same book that the participants recruited from the main RCT study will have received for their 9-month well visit. All participants will read the same book with electronic books provided on a tablet device. Participants will be randomized on the order they read the types of books (print book, basic e-book and enhanced e-book).

Following the video-recorded reading tasks, all parents will participate in a 20-minute, semi-structured, audio-recorded interview with a member of the study staff. An interview guide will be developed and piloted with parents of infants prior to use within the study. In the interview,

parents will be asked their behaviors (frequency, duration, style) and perceptions on reading to their infant and whether this would vary based on using print books and electronic books. All participants will be asked the same questions.

3.1.3 Screening Phase

3.1.3.1 Randomized Control Trial

About 16% of the children seen at CHOP Primary Care Roxborough, 21% of those seen at CHOP Primary Care Indian Valley and 50% of those seen at CHOP Cobbs Creek have Medicaid. Children will be 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), and at least 4 months of age at the time of enrollment. Children who are born premature <35 weeks EGA, who have neurodevelopmental disabilities, or who have congenital malformations are at increased risk of language delays and will be excluded. In addition, we will exclude families who do not speak English or Spanish, as the main measures of reading activity (StimQ, Appendix 5) and language development (Bayley Scales of Infant Development-III, Appendix 7) are only available in English and Spanish.

Potential subjects will be identified at the time of their four month well child visit using the electronic health record (EHR). The pediatrician or nurse overseeing the wellness visit will receive a notification to inquire whether the parent-child dyad would be interested in participating in the study. If the parent indicates interest, one of our research staff will be in contact to explain the study procedures, and arrange to meet with the parent-child dyad at a time before their 6 month wellness visit while the child is between 5 and 7 months of age. Research staff will obtain written informed consent from participants. Participants will be randomized to either the digital literacy arm or the standard literacy arm based on random assignment. Randomization sequences will be developed by the study team using computer-generated random numbers prior to study enrollment and will be placed in sealed opaque envelopes. Randomization will ensure equivalence between groups on measured and unmeasured characteristics and is considered to be the strongest protection against bias in study design.

Written informed consent will be obtained in person prior to any study related procedures being performed. The consenting process will include a discussion of study rationale, procedures, measures, benefits, risks, and alternatives to participation. After consent, subjects will either be assigned to the digital literacy arm or the standard literacy arm of the study. Regardless of their assignment, once they have consented to participate, they will complete a demographic questionnaire (Appendix 1), questionnaires about adverse childhood experiences (Appendix 2) and health literacy (Appendix 3), and the Edinburgh Postnatal Depression Scale (EPDS) (Appendix 4).

3.1.3.2 Video Sub-study

Children will be eligible to participate in this sub-study if they were born ≥35 weeks estimated gestational age, without neurodevelopmental disabilities or congenital malformations, with Medicaid insurance (proxy measure for poverty), and, for participants being recruited externally, at least 9 months and 0 days and no more than 12 months and 0 days at the time of enrollment. As in the randomized control trial, children who are born premature <35 weeks EGA, who have neurodevelopmental disabilities, or who have congenital malformations will be excluded, as they are at increased risk of language delays. In addition, we will exclude families who do not speak English for this sub-study, as resources are not available in this pilot to execute and code video data in additional languages.

Potential subjects will be identified from 1) participants in the randomized control trial that previously consented to participate in the sub-study, were randomized into the control group (traditional board book arm), and are age-eligible for their 9 month well visit, and 2) eligible patients recruited from the Cobbs Creek clinic who are 9 to 12 months old. For participants recruited external to the randomized control trial, study staff will identify eligible participants and, when on-site at the time of the appointment, approach participants in person at the clinic before or after their appointment with the clinician. At that time, a member of our study staff will explain the study procedures and consent the parent and infant for participation. The consenting process will include a discussion of study rationale, procedures, measures, benefits, risks, and alternatives to participation. Once they have consented to participate, they will complete a demographic questionnaire (Appendix 1), questionnaires about adverse childhood experiences (Appendix 2) and health literacy (Appendix 3), and the Edinburgh Postnatal Depression Scale (EPDS) (Appendix 4). They will also schedule the parent and child for a study visit at that time if the parent is able. Parents who are unable to be scheduled for participation at that time will be contacted by study staff via telephone to schedule the study visit.

3.1.4 Randomized Controlled Trial Treatment Phase (start of the study intervention)

Once recruited and enrolled, the parent-child dyads will be randomized into either the digital or standard literacy arm. Parent-infant dyads randomized to the digital literacy arm will receive the digital e-book version of Dr. Seuss' *Hop on Pop* for the 6 month well visit, Sandra Boynton's *Barnyard Dance* for the 9 month well visit, and Margaret Wise' *Goodnight Moon* for the 12 month well visit. Moreover, they will receive information on the importance of early parent-child reading activity by pediatric clinicians. Information on early literacy will be standardized and age-based and will be provided to parents by pediatric clinicians at the well visits.

Parent-infant dyads randomized to the standard literacy arm will receive Dr. Seuss' *Hop on Pop* for the 6 month well visit, Sandra Boynton's *Barnyard Dance* for the 9 month well visit, and Margaret Wise' *Goodnight Moon* for the 12 month well visit. In addition, they will be provided information on the importance of parent-child reading activity by pediatric clinicians.

Information on early literacy will be standardized and age-based and will be provided to parents by pediatric clinicians at the well visits. This conforms to the ROR National Program recommendations and is considered standard of care at these 3 clinics.

To prevent contamination in which pediatric clinicians inadvertently provide books and instruction on reading activity to the different arms of the study, an automated alert will appear on the screen of the eligible child's EHR at each well visit with a reminder to the health professional. This will ensure that books and reading instructions are consistent with their assigned study arm. Phone call or text message reminders will be used throughout the course of the study. The initial reminder will be made within the first week to participants in the digital literacy arm to verify that the participant was able to download the e-book if this was not already confirmed during the initial visit. Another reminder will be sent out about 1 month after the infant has, or is age-eligible for, their 6, 9 and 12 month well visit, either to remind the participant to complete the emailed REDCap survey, or for other study-related reminders.

Children in both study arms will be followed every 3 to 4 months until they are between 12 and 18 months, 30 days. Parents will complete study measures consisting of demographic characteristics, postpartum depression symptoms, health literacy, and adverse childhood experiences at the initial study visit. Parents will complete measures of reading activity at baseline, and via the REDCap survey sent by email, or completed in person, about 1 month after the infant has, or is age-eligible for, their 6, 9 and 12 month well visits. Differences in reading activities and language outcomes will be assessed between groups using intention-to-treat analysis.

Parents of children who are participating in the study will be informed of the results of their BSID-III testing in writing and/or by phone. Those whose child scores less than 1.5 standard deviations below the mean will be informed that their child's development is within the average range. Parents whose child scores 1.5 standard deviations or greater below the mean will be informed that their child is exhibiting delays in an area of their development. In addition, we will recommend that the parent inform their child's clinician of the results.

3.1.5 Video Sub-Study Treatment Phase (start of the study intervention)

Parents and their infant who are enrolled to participate in the video recorded task will be observed during an unstructured reading task, using both an e-book and a standard book, in a pre-scheduled visit, outside of their primary care visits. They will not receive any additional instruction at this visit. Parents will also participate in a brief, semi-structured interview following the reading task.

3.2 Allocation to Treatment Groups and Blinding

Participants will be stratified by clinic site and randomized to receive literacy promotion using 1) standard early reader board books or 2) digital electronic early reader e-books. Randomization sequences will be developed by the study team using computer-generated random numbers prior

to study enrollment and will be placed in sealed opaque envelopes, assigning participants to one of the two treatment arms.

Participants in the video sub-study will also be randomized to determine the order in which they are asked to read the three versions of the selected book (print, basic e-book, enhanced e-book). As with the larger trial, randomization sequences will be developed by the study team using computer-generated random numbers prior to study enrollment and will be placed in sealed opaque envelopes, assigning participants to receive one of the six possible orders of the three book types.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration for the randomized control trial per subject will be approximately 7 months following enrollment. The study duration for the video sub-study will be one day of participation.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The randomized control trial will be conducted at three CHOP Care Network Practices: 1) Roxborough, located in Philadelphia, Pennsylvania, 2) Indian Valley located in Souderton, Pennsylvania and 3) Cobbs Creek, located in Philadelphia, Pennsylvania. These sites have been individually recruited to participate (see PeRC letter of support) and have agreed to participate.

Recruitment for the randomized control trial will stop when approximately 100 subjects (100 dyads of parent and infant) are enrolled. Recruitment for the video-taped component will stop when approximately 40 participants have completed the video and interview task.

3.4 Study Population

3.4.1 Randomized Control Trial

3.4.1.1 Inclusion Criteria

1) English or Spanish speaking
2) Child who is between 5 months 0 days and 7 months 0 days at time of enrollment and born ≥ 35 weeks estimated gestational age.
3) Parent (if mother) must be 15 years or older at the start of the study. Parent (if father) must be 18 years or older at the start of the study.
4) Parental permission for the child's participation and consent of the parent for their participation
5) Child with Medicaid Insurance

6) Parent has access to a smartphone and/or tablet

3.4.1.2 Exclusion Criteria

1) Children with neurodevelopmental disabilities or congenital malformation at increased risk of language delays

3.4.2 Video Sub-study

3.4.2.1 Inclusion Criteria

1) EITHER enrolled in the randomized control trial and age-eligible for their 9 month well visit OR (for patients recruited externally) >9 months 0days, but <12 months 0 days old and born ≥ 35 weeks estimated gestational age
2) Parent (if mother) must be 15 years or older at the start of the study. Parent (if father) must be 18 years or older at the start of the study
3) Parental permission for the child's participation and consent of the parent for their participation
4) Child with Medicaid Insurance
5) Parent has access to a smartphone and/or tablet

3.4.2.2 Exclusion Criteria

1) Parent does not speak English
2) Children with neurodevelopmental disabilities or congenital malformation at increased risk of language delays

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening/Consenting Visit and Study Visit 1

- Identify eligible 4-month old infants at the time of their well child visit using the electronic health record (EHR)
- Recruit and consent eligible parent-child dyads at or before child's 6 month well visit.
- Randomize parent-child dyads into intervention and control groups.
- Collect baseline demographic, parent adversity, and parent mental health information.

4.2 Study Treatment Phase

- Implement an EHR alert to remind clinicians which arm (digital or standard) the patients are in at time of well visits at 6, 9 and 12 months.

- Provide developmentally appropriate standard books or e-books and a bookmark to clinicians to give to participants at 6, 9, and 12 month well visits.

- Parents will complete measures of reading activity (StimQ and ERPQ) via REDCap survey sent to their email about 1 month subsequent to the time the child has, or is age-eligible for, their 6 and 9 month well visits.

- Phone calls and/or text messages will be made to all participants throughout the study to remind them to schedule and/or attend well visit, and for other study-related reminders.

- Selected parents will complete a videotaped reading task at a scheduled time convenient to the participant and after the participant becomes age-eligible for their 9 month well visit. For parents enrolled external to the larger randomized control trial, this will be the only study visit completed by these participants. These participants will complete the study related questionnaires, including the demographic questionnaire, the ACE, SAHL, EPDS, StimQ and ERPQ, at the time of this study visit. Participants enrolled in the sub-study (either within the RCT or externally) will additionally complete the paper-based DialogPR-I at the time of their video sub-study visit.

- Contact participant after the child has, or is age-eligible for, the 12 month well visit to schedule the second study visit.

- At the second study visit, about 1 month after the child has, or is age-eligible for, the 12 month well visit, parents will complete measures of reading activity (StimQ,ERPQ and DialogPR-I) in addition to a measure concerning depressive symptoms (EPDS), and their child will receive a developmental assessment (BSID-III) administered by the study's Early Childhood Assessor.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Parental Adversity (ACE)

The 9 ACE questions query adults as to their exposure to 9 different adverse childhood experiences (economic hardship, domestic violence, parent mental health, discrimination, parent substance abuse, divorce, parent death, parent incarceration, and neighborhood violence) and are contained in the 2011-12 National Survey of Children's Health, a nationally representative telephone survey.

5.1.2 Parental Health Literacy (SAHL)

The Short Assessment of Health Literacy (SAHL) is a validated measure of health literacy for English- and Spanish-speaking populations.

5.1.3 Parental Depressive Symptoms (EPDS)

The Edinburgh Postnatal Depression Scale (EPDS) is a validated 10-item scale for postpartum depression symptoms with scores ≥9 having a sensitivity of 97% and specificity of 43% for major or minor depression.

5.1.4 Reading Activity (StimQ)

The StimQ is an office measure of cognitive stimulation at home available in Spanish and English, and 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's Alpha=0.89) and test-retest reliability (r=0.84) and moderate correlation with the Bayley Scales of Infant Development (r=0.52, $p<0.001$).

5.1.5 Reading Practices (ERPQ)

A series of questions designed by the study team to get a better understanding of the reading practices between parents and their babies.

5.1.6 Language Development (BSID-III)

The Bayley Scales of Infant Development, Third Edition (BSID-III) is a validated, examiner-administered assessment of cognitive, language, and motor development. It is designed for children 1 to 42 months of age.

5.1.7 Dialogic Reading Practices (DialogPR-Infant)

The DialogPR-I is a pilot measure, expanding upon the DialogPR, previously validated in children 3-4 years old. This series of parent self-report questions assesses parent self-reported dialogic reading practices. This Infant subscale is modified from the main, validated scale to

incorporate non-verbal parent/child dialogic reading interactions, and will be piloted with all enrolled participants, either at the second study visit, or at their video sub-study visit, whichever comes first.

5.1.8 Demographic Questionnaire

A brief set of questions used to collect demographic information about the participants.

5.1.9 Standard Text Messages

Standard text messages will be sent out to participants throughout the study. These text messages include an initial text message to welcome participants to the study, as well as text message reminders of upcoming well-child visits, to complete the emailed surveys, to download the e-book (digital arm participants only), and to schedule the final study visit. Additionally, text messages will be sent out to subjects who consented to participate in the videotape sub-study, reminding them of their study visit.

5.1.10 Audio-recording and Videotaping of Interviews

Parent-infant dyads recruited into the videotape sub-study will participate in a video recorded reading exercise and a brief, audio-recorded semi-structured interview. Parents will be videotaped while reading a print book and two versions (basic and enhanced) of an electronic book with their infant. As part of this exercise, parents will also be audio recorded while participating in a semi-structured one-on-one interview with a study team member. Videotaped book readings will be analyzed without transcription. Interview audio recordings will be transcribed by ADA Transcription (http://www.adatranscription.com/). Audio recordings will be de-identified and sent via their secure server, and subsequent transcripts will be saved on a secure server accessed only by members of the study team.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint for the randomized control trial will be the BSID-III scores at the second study visit when the child is between 12 and 18 months, 30 days of age.

6.2 Secondary Endpoints

Secondary endpoints will be the difference in StimQ scores, and the information about reading practices and activities from the ERPQ, collected approximately 1 month after the infant has, or is age-eligible for, their 6, 9, and 12 month well visits for the randomized control trial, the DialogPR-I collected between 9 and 18 months, 30 days, as well as themes derived from the transcripts of the video and audio-recordings in the Video Sub-study. The Video Sub-study is contributing to the main study's exploration of dialogic reading behaviors when comparing e-

books to standard board books, and determining the comparative effectiveness of digital literacy promotion to standard literacy promotion on parent-child language interaction and parent reading behaviors.

6.3 Statistical Methods

Summary statistics will be obtained, and differences between digital and standard arms will be assessed using intention-to-treat analysis. Cross-sectional differences in StimQ scores between digital and standard groups at the 6, 9 and 12 month well visits will be assessed using t-tests. To determine how the effects of digital versus standard literacy is associated with language development, we will develop regression models using longitudinal data methods that adjust for correlation in BSID-III scores over time and for potential confounding by demographic characteristics. To explore the impact of digital literacy on healthcare utilization, the EHR will be reviewed to identify a subjects' number of well visits and their vaccination history.

To determine whether parent adversity, health literacy, and/or parent mental health modify the effects of digital versus standard literacy on language development, we will develop similar regression models using longitudinal data methods, but we will also fit interaction terms between study group and ACE score (≥4), SAHL (high or low) and EPDS score (>10). To determine if parent-child reading activity mediates the association of intervention group assignment and language development, we will use mediation analysis with separate models regressing group assignment on language development, parent-child reading activity on group assignment, and group assignment on language development adjusted for parent-child reading activity.

Assuming a mean cognitive subscale on the BSID-III of 96, a power of 0.70, an alpha of 0.05, and a clinically significant difference of 7.5 points on the BSID-III between groups, we estimate that we will need to recruit a total sample size of 100 eligible children (50 in each group) to participate in the main RCT study (Figure 1). To attain thematic saturation in the Video Sub-study, we will recruit up to 40 participants 9-12 months of age. These 40 participants may be recruited external to the main study if we are unable to recruit up to 40 from the 100 enrolled in the main study in a timely fashion. All analyses will be conducted using Stata Statistical Software, version 13 (College Station, TX).

Figure 1

Power	n
0.60	80
0.65	90
0.70	100

Assuming a mean cognitive subscale of the BSID-III, an alpha of 0.05, and an SD of 15.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study. The main risks are disclosure of private health information (PHI) and study responses and discomfort with answering sensitive questions concerning childhood trauma or depressive symptoms.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review. We will query participants concerning any disclosures of PHI at each study visit. We will only query participants once concerning childhood trauma at the baseline visit and twice concerning depressive symptoms at the baseline and second (final) study visit.

8 STUDY ADMINISTRATION

8.1 Data Collection and Management

All records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

Unique identifiers will be created for each subject in the study. REDCap will be used to store the data. A master list containing PHI and subject ID number will be kept separate from data forms (electronic and paper). The master list will be kept using password-protected files. These files will be encrypted and maintained on the CHOP secure server to ensure security. Participants' information will be stored in the REDCap database and configured to export data without PHI. All de-identified records will be retained forever. De-identified data will be shared with the study sponsor. Stored data and patient identifiers will be kept for 6 years subsequent to the study completion, and possibly longer if required by the sponsor.

Any paper copies of research instruments will be stored using the patient's ID code and will be kept in the department of General Pediatrics at The Children's Hospital of Philadelphia.

All audio and video recordings will be destroyed within three years of data analysis completion.

8.2 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study with the exception of mandatory reporting requirements for child maltreatment.

No identifiable data will be used for future study without first obtaining IRB approval. The research staff will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

8.3 Regulatory and Ethical Considerations

8.3.1 Data and Safety Monitoring Plan

Monitoring of adverse events, mainly disclosure of PHI from medical records and study assessment responses, will be ongoing during the intervention period until all data have been de-identified. Participants will be asked whether they know of any breaches of confidentiality at all contacts with subjects. All non-serious adverse events including disclosure of information will be reported to the CHOP IRB at the time of continuing review and to the funding agency annually. The PI will be responsible for overseeing the monitoring plan. Trained research assistants under the supervision of the Principal Investigator will conduct monitoring of data and safety twice annually.

8.3.2 Risk Assessment

There is minimal risk for harm to the participants in this study. Some information collected from the study participants on the study assessments is sensitive information and may cause the subjects discomfort, e.g. questions concerning childhood trauma or depressive symptoms. This could include assessment of caregiver's suicidal ideations and a screening of caregiver's suicide risk in primary care flow. The results of the screener will be reviewed soon after completion (See Appendix 4). Dr. Marsha Gerdes, PhD, is a co-investigator and child-psychologist who has expertise in early child development and measurement. She will serve as the licensed psychologist to contact if screener is positive or suicide risk is high. This risk is considered minimal and no more than what is normally associated with being in a physician's or mental health practitioner's office. Furthermore, families incur a risk of disclosure of private health information to individuals not connected with this study. This could occur through inadvertent disclosure of PHI by research staff. This risk will be minimized by using the study identifier on all study instruments and the research database as well as storing identifying information in a separate place than study information.

Unique identifiers will be created for each subject in the study. Any paper forms used will be stored in a locked file cabinet. REDCap will be used to store the data. A master list containing

PHI and subject ID number will be kept separate from data forms (electronic and paper). The master list will be kept using password-protected files. These files will be encrypted and maintained on the CHOP secure server to ensure security. Participants' information will be stored in the REDCap database and configured to export data without PHI. All de-identified records will be retained forever. De-identified data will be shared with the study sponsor.

8.3.3 Potential Benefits of Trial Participation

Parents or guardians of the participants in either arm may not benefit from the digital literacy promotion intervention. Parents and their children may benefit from initiating parent-child reading activity earlier with the potential for improved language development. Information from this study could be used to generate generalizable knowledge to reshape the views on digital literacy initiatives, the ROR program and provide information for other early literacy campaigns such as Philadelphia's Read! By 4th and the Great Start Collaborative's Early to Read Campaign. If results from this study favor the digital book arm, then administrators of the ROR program and other local and national literacy campaigns can encourage the distribution of developmentally appropriate e-books in conjunction with standard books. Nationally, pediatric clinicians may benefit by knowing evidence of whether there is a difference in effectiveness of language development in children who are read to by their parents via digital or standard book. This may have an impact in environments where access to books may be limited by financial, geographical, or time constraints on parents. Locally, pediatric clinicians could benefit by having CHOP's ROR program expanded to additional areas in the Philadelphia metropolitan area. Information from this study can be used by policymakers and grant funders to increase funding support to expand the ROR program and other local and national literacy campaigns to infants.

8.3.4 Risk-Benefit Assessment

The risks to participants are minimal and further minimized through protections. The benefits of parents receiving advice and materials through the support of the digital literacy promotion program outweigh the risks of participation. Therefore, the risk-benefit ratio is considered favorable.

8.4 Recruitment Strategy

8.4.1 Randomized Control Trial

We will have an EHR recruitment prompt sent only to potentially eligible children with Medicaid at their 4 month well visit at the CHOP Primary Care Roxborough, PA, CHOP Primary Care Cobbs Creek and CHOP Primary Care Indian Valley. Parents who are conceivably interested in participating will be contacted by research staff. Research staff will briefly explain the study procedures, guided by the information set forth in the approved consent form. This includes reading the inclusion criteria to the potential participant, and asking whether or not this individual is interested in participating. Research staff will then schedule a time to meet with the parent in person. This will happen at a time before their infant's 6 month well visit in order to obtain informed consent, confirm that all of the inclusion criteria are met, and randomize the

participant into either the digital or standard book group. In the event that the research staff is unable to confirm that all inclusion criteria are met after the participant has been enrolled, the participant will no longer be able to participate. Additionally, potentially eligible 5 to 7 month olds that have been identified by study staff on EPIC as potentially eligible by screening via review of the medical record, may be approached in person before or at the time of their 6 month well visit. These potentially eligible participants will be screened, consented and enrolled into the study prior to the child's time with the provider.

We may also hang recruitment flyers in the hallways at both clinics giving information about the study and contact information for the study coordinator in case they are interested and we miss their names in the screening process.

8.4.2 Video Sub-study

Participants previously screened for the randomized control trial will be made aware of the video sub-study at the time of consent and can elect at that time to include the video sub-study in their consent procedure. These participants will be contacted once they have become age-eligible for their 9-month well child visit to schedule the video sub-study visit.

Additionally, infants and parents not previously enrolled in the randomized control trial presenting to the Cobbs Creek site will be approached to participate in the video sub-study. These participants will be identified by study staff on EPIC as potentially eligible by screening via review of the medical record. Study staff will screen and consent these participants in person prior to the child's time with the provider.

8.5 Informed Consent/Assent and HIPAA Authorization

Following the screening via review of the medical record, eligibility for study participation will be explained, either in person or via phone. During the research staff visit subsequent to the screening process, written informed consent will be completed. Research staff will discuss the study aims, procedures, risks and benefits, alternatives to participation, and confidentiality protocols with the parent. Research staff will speak to the parent about the voluntary nature of participation and provide the potential subject with the opportunity to ask questions about the study and its risks and benefits. Parents who consent to participate and who give parental permission for the child's participation, will sign two copies of the informed consent form: one will be kept for study purposes and the other will be provided to the consenting parent. In order to give parental permission for the child to participate, the consenting mother must be at least 15 years old, or the consenting father must be at least 18 years old. Parents will be provided with plenty of time to ask questions and to decide whether they want to participate. Parents will be explicitly instructed that they are free to choose to participate and that their decision to participate will not affect the health care they or their children receive at participating practices.

Similarly, Spanish-speaking participants will be contacted and recruited to participate in the main RCT only (Parent who does not speak English is part of the Exclusion criteria for eligibility

to participate in the Video Sub-study;see section 3.4.2.2) either in person or via phone by a Bilingual member of the study team. When it is time to consent the participant, an interpreter will be present and will carry out the Spanish Short Form Consent process with the Spanish-speaking subject.

Participants in the randomized control trial who agree to participate in the video sub-study will provide their consent by indicating whether or not they would be willing to participate in this additional study visit in a section of the consent form for the randomized control trial. Participants recruited for the video sub-study who are enrolled external to the larger trial will complete a consent form at the time of enrollment. This consent will be for participation limited to the video sub-study. Study staff will follow the procedures outlined above to consent participants into this sub-study. Of note, non-English speaking participants will not be enrolled in the sub-study (see exclusion criteria), as it is infeasible at this time to conduct and analyze these qualitative data in languages other than English.

8.6 Payment to Subjects/Families

8.6.1 Payments to parent for time and inconvenience (i.e. compensation)

All participants will be paid up to $70 total for their participation. They will receive $20 upon completion of the initial study visit. They will then receive $5 upon completion of each of the two surveys emailed to them. At the second (final) study visit, they will receive $40. All payments will be made in the form of pre-paid, CHOP-issued debit cards.

Participants recruited to participate in the video-taped reading task will receive an additional $50 pre-paid card at the completion of the visit.

8.6.2 Gifts

Participants will receive three books over the course of the study, one for each well visit (6 months, 9 months and 12 months). All parents will receive a small non-monetary gift of a Reach Out and Read tote bag filled with 3 additional books to thank them for participating at the end of the final study visit. Participants in the video sub-study will receive an additional book at the time of their participation.

9 PUBLICATION

We propose a multipronged dissemination strategy for this study that will have the goal of distributing study results to scientific audiences, lay audiences, policy audiences, and parents. If funded, we will work with the Strategy Team at Policylab at CHOP to implement this

dissemination strategy. We will present findings from this study at the Pediatric Academic Societies annual meeting, where pediatric clinicians, early literacy experts, and Reach Out and Read advocates attend. We will also develop as many as 3 peer-reviewed manuscripts for publication and target them to pediatric and child health journals in order to reach a clinical and scientific audience. One manuscript will report the overall results of the randomized controlled trial of digital literacy promotion vs. standard literacy promotion. A second paper will detail the analyses of the video recorded data, while a potential third will cover the methodology of validating parent reported data to the observed video-taped behaviors.

To reach lay and policy audiences with findings from this study, we will place a summary of the results of the study on the Policylab website (http://policylab.chop.edu/) and tweet the results to our Policylab twitter followers. This latter group is a diverse group of individuals from policy, advocacy, government, and clinical fields. We will also prepare an Evidence-to-Action (ETA) policy brief, which attempts to capture the policy implications of the study findings. ETA briefs, which are developed at Policylab, are mailed and/or emailed to policymakers and child health advocates on our distribution list.

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APPENDIX

See attached.