

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD – Protocol
and
Community Health Center, Inc IRB
Protocol Template (HRP-212)

1) Protocol Title

Rx for Success: A Randomized Controlled Trial of Technology-Based Dialogic Reading Training Incorporated Into Reach Out and Read

2) Principal Investigators

Overall: John S. Hutton, MS MD FAAP
Cincinnati Children's Hospital Medical Center
Division of General and Community Pediatrics
Reading and Literacy Discovery Center

On-site at CHC: Dr. Catherine Wiley, MD
Community Health Center at Connecticut Children's Hospital

Other staff: Amy Kerr (coordinator, CCHMC), Dr. Tom DeWitt MD (co-I, CCHMC), Dr. Nikki Shearman, PhD (consultant, Reach Out and Read National Office (MA)), Tom Hatton (consultant, Children, Inc.). A primary research coordinator will be hired to conduct this study at the primary care clinical site in CT.

3) Funding Source

The Carol Ann and Ralph V. Haile, Jr./U.S. Bank Foundation
The Grossman Family Foundation

4) Objectives*

Specific Aim 1 (Rx for Success; RS): To explore the efficacy of incorporating dialogic reading training via the RS application into ROR during well-child visits for infants (6-12 months old) and toddlers (18-24 months old), compared to standard ROR practice.

Hypothesis 1a (language): Language scores (LENA Snapshot) will be higher in children whose caregivers are provided with the RS app.

Hypothesis 1b (social-emotional): Social-emotional development scores (DECA-I/T items) will be higher in children whose caregivers are provided with the RS app.

Hypothesis 1c (dialogic quality): Dialogic reading quality scores (DialogPR-I/T) will be higher in caregivers presented with the RS app.

Hypothesis 1d (attitudes): Attitudes towards shared reading at home (items from StimQ-P READ and PVR) will be higher in families provided with the RS app.

Specific Aim 2 (exploratory):

Hypothesis 2a: Reported screen-based media use (ScreenQ) will be lower in families provided with the RS app, reflecting greater emphasis on interactive shared reading.

Hypothesis 2b: Language (LENA Snapshot) and social-emotional (DECA-I/T items) scores will be higher for children with less reported screen-based media use (ScreenQ).

5) Background*

Literacy is a major public health issue, the cost of low attainment estimated at over \$300 billion in the United States and over \$1.2 trillion worldwide, disproportionately affecting low-socioeconomic status (SES) populations.²⁹ While an estimated 5-12% of reading difficulty has an organic cause (e.g. dyslexia),³⁰ the majority is attributable to inadequate resources, motivation and/or stimulation required to learn to read.²⁹ As of 2015, 64% of US 4th graders scored below proficient in reading, largely unchanged from prior reports,²⁸ and scores skewed lower for low-SES and minority children.^{28, 31} The seeds of environmental reading difficulty are planted early; many children arriving at school at a substantial disadvantage in readiness and increasingly unlikely to catch up with peers as academic demands accelerate.^{31, 32} Environmental illiteracy is considered “heritable,” fueling cycles of poverty and poor academic, vocational and health outcomes.³³ Prevention and early intervention offer tremendous cost savings in terms of health and productivity.³⁴⁻³⁶

The American Academy of Pediatrics (AAP) recommends literacy promotion in primary care settings beginning at birth, and increased funding for reading promotion programs such as ROR, provider training, and research.⁴ The bases for these recommendations are enduring cognitive, social-emotional and neurobiological^{20, 37} benefits of nurturing shared reading environments during the critical developmental span of early childhood.⁴ Children’s books serve as catalysts for verbal and social-emotional engagement^{26, 38, 39} and foster positive attitudes towards reading.^{4, 40} However, the *quality* of shared reading tends to moderate - or negate, if deficient - these important benefits.^{13, 21} Dialogic reading is a method of shared reading developed to promote reciprocal dialogue between a caregiver and child,⁸ particularly in low-SES households where such dialogue is often lacking.⁶ Behavioral evidence suggests that dialogic reading may confer substantial cognitive benefits beginning in infancy,^{10, 11} including oral language,^{12, 13} narrative comprehension,¹⁴ print concepts,¹² and attention¹⁵ - foundational emergent literacy skills.¹⁶ Social-emotional benefits have also been shown, including increased parent-child bonding, pro-social behavior¹¹ and enjoyment of reading.^{17, 18}

The major objective of ROR is to improve emergent literacy and social-emotional health during the span of rapid brain growth and development between birth and age 5, particularly in low-SES families at risk for adverse outcomes. Thus, in addition to providing children’s books and literacy-related developmental screening, ROR encourages pediatric providers to model dialogic reading during well-child visits. However, this critical aspect of shared reading quality deserves greater reinforcement than is generally feasible in a standard office visit, given time and reimbursement constraints.^{41, 42} Furthermore, there is currently a gap in knowledge as to optimal, effective means to improve shared reading quality and developmental outcomes involving families of very young children. This study is

highly significant in that it for the first time explores the efficacy of amplifying dialogic reading training delivered via the established ROR program using a novel, inexpensive, scalable smartphone-based application (**Rx for Success**) during this critical span of development.

The **Rx for Success** (RS) application integrates professionally produced instructional videos and interactive content tailored to age and developmental level into a smartphone-based application, to clearly and consistently reinforce dialogic reading. The RS app features ethnic, gender and economic diversity, is free and simple to download onto a variety of mobile platforms, and fun and intuitive to use. To increase the “dosage” of the message, and encourage ongoing learning and practice, the app sends text reminders with tips about reading aloud, and an embedded gamification component provides enjoyable feedback. If shown effective, RS would be an impactful enhancement to the ROR program, allowing pediatric providers a convenient, inexpensive means to provide dialogic reading instruction to families in busy clinical settings, in addition to books, developmental guidance, and other aspects of the program. The RS app could be integrated into ROR via its existing infrastructure involving over 5,900 sites and 29,000 providers across the US. No similar study has been conducted, to our knowledge.

Overview/Rationale: Our strategy is to conduct an innovative experiment that is achievable within 15 months, providing data for a larger, longer-term longitudinal study exploring the impact of “enhanced” ROR on home reading environment and cognitive and social-emotional development. This study involves a low-SES population of infants and toddlers at-risk for adverse cognitive and social-emotional outcomes, during a foundational period of early brain development, who stand to benefit from effective early intervention to improve the quality of cognitive stimulation and nurturing in the home. Such innovation is needed, given challenges to providing consistent, effective dialogic reading training in busy clinical settings, where such at-risk families are uniquely accessible. The resources and infrastructure are in place via ROR for this work to commence expeditiously with high probability of success.

Preliminary data: A pilot process evaluation field test of 26 predominantly African-American and Urban Appalachian low-income families enrolled in ROR, demonstrated an overwhelmingly positive response to the RS app with 100% of participants rating the video as motivational and 95% rating the reminders as helpful. Quotes from participants included:

“The video talked about singing and when I did that she seemed to really like it and become engaged.”

“My grandson loves it. He’s really interested and we are happy to get the reminders.”

“We all know that it’s important to read to your child, but we don’t always remember every day....having the reminders helped me to actually do the reading more.”

A separate pilot study involving ROR families found that those who already knew about the importance of reading aloud considered videos incorporated into the RS app to be valuable in explaining how to read more interactively with their young children. By contrast, a recent MRI-based study involving video observations of 22 low-SES mothers

reading with their preschool-age children found low verbal interactivity and engagement despite prior access to home visiting and ROR, suggesting a need for improved dialogic training.²⁰

Other recent work that will support this proposed project includes initial validation of brief measures assessing shared/dialogic reading quality (DialogPR) and screen-based media use in the home (ScreenQ).⁴⁶

6) Setting of the Human Research

This study, including will be conducted at Community Health Center, Inc. at Connecticut Children's (CHC@CCMC), a high volume, primary care clinic affiliated with Connecticut Children's Medical Center, a major academic teaching hospital. Dr. Catherine Wiley will be the primary on-site supervisor for the CRC, and clinical contact at CHC@CCMC, including oversight of patient-related issues such as distress during evaluation. Recruitment, behavioral testing, surveys and intervention, will take place in exam rooms during regularly scheduled clinic visits, mindful to place minimal burden on participating families and clinic staff. Data analysis will be conducted in Cincinnati, OH via Children, Inc, under the supervision of the principal investigator. This study will be submitted to and adhere to guidelines specified by the CCMC Institutional Review Board (IRB), as well as those of Cincinnati Children's Hospital Medical Center IRB.

7) Resources available to conduct the Human Research

Team Experience: The proposed project combines the skills and resources of the RS developer, principal investigator, and team of co-investigators and collaborators at the ROR host site at CHC@CCMC. Since 1972, Community Health Center, Inc. has been one of the leading healthcare providers in the state of Connecticut, building a world-class primary care system committed to caring for uninsured and underserved populations. CHC@CCMC is a patient-centered medical home providing a full suite of pediatric services, is a well-established ROR site, and employs an electronic medical record system.

The RS developer (Tom Lottman) has considerable experience developing developmentally robust, multimedia content for young children.⁴³ The recently published report from the Harvard Graduate School of Education and the Wallace Foundation named Children, Inc.'s *Before the Bullying AFTER* program⁴⁴ as one of the top 25 research-based social and emotional learning programs (Jones, *et al.*, 2017).

Dr. Nikki Shearman, Chief of Network Strategy and Evaluation with the ROR national office based in Massachusetts, will serve as a consultant for this study regarding the logistical implementation of the RS intervention within the ROR program.

The principal investigator (Hutton) is a primary care pediatrician who has conducted innovative, reading-related research involving young children with a high degree of success, including randomized trials of home reading environment⁴⁵, development of clinic-based screening tools,⁴⁶ video observations of parent-child reading quality,^{19, 20} and the application of functional MRI to explore the effects of home reading environment,

including shared reading quality, on the developing brain.^{19, 20, 37} Addressing younger infants and toddlers in this study during critical stages of early brain development is a natural extension of this work, and would build on a cohesive eco-bio-developmental model⁴⁷ of the influence of home reading environment on emergent literacy. Prior to the launch of this study, the principal investigator will travel to the CHC@CCMC host site to discuss and train the study team in this protocol, specifically the research coordinator, including practice “role play” sessions.

A full-time clinical research coordinator (CRC) will be recruited for this study in cooperation with the Weitzman Institute, a community-based research center affiliated with CHC@CCMC dedicated to quality improvement and research in primary care for the underserved. The CRC will be trained in this study protocol via the principal investigator (Dr. Hutton), the on-site medical director and co-principal investigator (Dr. Wiley), and a co-investigator from the national ROR program (Dr. Shearman). The CRC will then recruit the 248 children in our desired age ranges (124/category) via convenience sampling during regularly scheduled well-child visits. Full enrollment within 6 months is feasible given historical well-visit volumes for these ages (40/month meeting enrollment criteria) at the participating clinic at CHC@CCMC. The CRC will optimize enrollment efficiency factoring scheduled well-visit volumes and demographic needs (age), via advance communication with clinic managers. Biostatisticians affiliated with Children, Inc., will perform all required statistical analyses, accessing data via a secure REDCap database housed at CCHMC Division of Biomedical Informatics. Application developers aligned with Children, Inc., will be available to perform any required technical modification or “troubleshooting” of the RS application.

Rx for Success Application (RS): The RS mobile application (app) was developed by Children, Inc. The app is designed to be informational and motivational with both video and cueing content. The app uses a, “View It, Cue It, Do It” model that allows parents to quickly download the free smartphone app, view brief videos of the age-indexed, research-based language enrichment practices; and regulate a text message cueing program. The app uses three motivational strategies in the cueing program: 1) Personalization; 2) Gamefication; and 3) Social media. Videos embedded in the RS app provide a summary of DR tailored for the child’s age, and suggestions for encouraging verbal interactivity and social-emotional engagement through dialogic reading. Key behaviors reinforced by the app include discussing the story before reading to build interest and enthusiasm, followed by interactive reading modeled by the acronym PEER:⁹ 1) **P**rompt the child to say something about the story, 2) **E**valuate what the child says or does, 3) **C**onnect on what the child says or does, and 4) **R**epeat and reinforce associations or responses. The acronym CROWD reflects simple types of prompts that can encourage the child’s involvement in the story, which gradually apply with age and development: 1) **C**ompletion (of a sentence), 2) **R**ecall earlier aspects of the story, 3) **O**pen-ended questions, 4) **W**h- questions, and 5) **D**istancing (relate the story to the child’s life). Finally, the RS app encourages the caregiver to review the story with the child after it is finished to reinforce the book sharing experience.

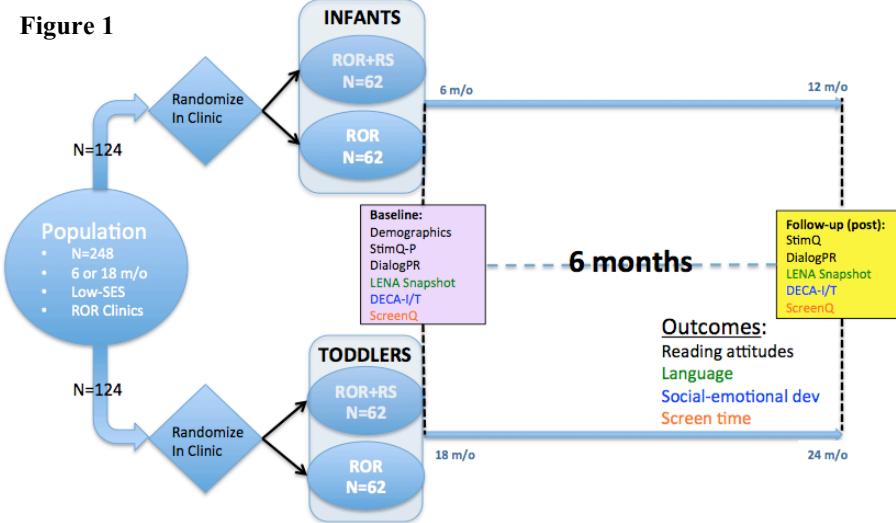
While highly impactful independently, this research will also provide valuable pilot data for a larger, longitudinal study exploring means to improve home

reading environment during early childhood via the ROR model incorporating traditional and novel technologies, especially in underserved populations.

8) Study Design

Study Design: This is a prospective, randomized controlled trial involving 2 age categories of low-SES caregiver-child dyads served by the ROR program, each followed for 6 months. For each category, a baseline assessment (pre-) and an outcomes assessment (post-) will be conducted, to explore effects of “enhanced” ROR using the RS app. Category 1 will involve 6 month-old infants, followed until they are 12 months old. Category 2 will involve 18 month-old toddlers, followed until they are 24 months old. Recruitment, informed consent, behavioral testing and intervention will take place at a high-volume primary care clinic based in a major, urban academic medical center in Connecticut (Community Health Center, Inc. at Connecticut Children’s Medical Center; CHC@CCMC). Providers in the clinical sites are trained in child development and the administration of ROR during well-child visits between birth and age 5, including those involved with our study at 6, 12, 18, and 24 months old.

A graphic of our study design is provided in **Figure 1** below. Families assigned to the control arm in each age category will receive customary ROR, including the provision of an age-appropriate children’s book, and reading-related developmental surveillance and anticipatory guidance. In addition, control families will receive a new children’s book reinforcing AAP screen-based media recommendations.⁴⁸ Families in the intervention arm in both age categories will receive “enhanced” ROR involving the provision of the **Rx for Success** (RS) application at the baseline visit (6 months old and 18 months old, respectively). No additional intervention will take place, other than text messages and other content built into the RS application.



a) Recruitment Methods

Sample Size/Power Analysis: Via our CRC, we will recruit 248 children in 2 age categories: approximately 6 months old (infants, n=124), and approximately 18 months old (toddlers, n=124) via convenience sampling in the CHC@CCMC clinic waiting room

during regularly scheduled well-child visits. This study will be powered based on the primary language outcome measure (LENA Snapshot). For a two-group (intervention/control), pre-post repeated-measure analysis with two age categories (6-12 months, 18-24 months), an ANCOVA model will be applied for both age categories and their interaction, to assess the difference in language scores between intervention and control groups. For this study, at least 180 subjects will be needed to have 80% statistical power to detect slightly greater than medium effect size (Cohen $f=0.30$), controlling for the baseline pre-measurement with a two-sided significance level of 0.05. This effect size was determined considering the 2008 National Early Literacy Panel Report, which examined 16 studies and reported an effect size of 0.6 for dialogic reading on language outcomes ($d=0.6$; Shanahan, et al).⁴⁹ A separate meta-analysis of 18 studies that tested dialogic reading intervention found average effect size for language outcomes and vocabulary of 0.29 and 1.02, respectively.⁸ However, these reports largely involved preschool- and school-age children, and no studies to our knowledge have reported effect sizes of dialogic reading for language in infants and toddlers.

We anticipate that full enrollment for this study within 6 months is feasible given historical well-visit volumes for these ages (40/month meeting enrollment criteria) at the participating clinic at CHC@CCMC. The CRC will optimize enrollment efficiency factoring scheduled well-visit volumes and demographic needs (age), via weekly communication regarding clinic schedules with clinic managers. The CRC will identify the arrival and registration of potential participants by monitoring the daily schedule (in Centricity) to identify well child visits for children of the appropriate age groups, and will greet them in the waiting room. For enrolled patients only, the CRC will also monitor scheduled encounters (in e-Clinical Works) to identify upcoming appointments for the follow-up (post-intervention) visit, and will monitor arrival in Centricity. The CRC will approach families in the waiting area, confirm that the child meets inclusion criteria by age, and present the major aims of the study in plain language:

“We are conducting a research study looking at how different ways of providing tips about reading with young children affects attitudes towards reading and early child development. This will involve a little extra time at today’s checkup to ask some questions, and at another checkup in 6 months. You will be compensated for your time. Would you be interested in learning more?”

For those expressing interest, written informed consent will then be administered via the CRC in a quiet area of the clinic waiting room, or private room if available, during the same visit where baseline data collection and intervention will take place. The CRC will review the form in plain language, including details about inclusion/exclusion, aims, incentives, and that participation is voluntary.

Participants will receive a gift card valued at approximately \$25 as compensation for time and travel, with \$10 provided at enrollment (pre-) and \$15 provided at follow-up testing (post-), each taking place during normally scheduled well-child visits. All children will receive a new children’s book per standard ROR practice. Participants in the control arm will receive an additional, new, age-appropriate children’s book reinforcing screen-based media reduction (*Baby Unplugged: Play*), retail value \$7.99.

Study Advertisement: To optimize enrollment and reduce the burden of surprise for families being approached in the waiting room, a brief postcard developed by Reach Out

and Read will be distributed to eligible families at well-child visits immediately preceding those for our study (i.e. at 4 month visit and 15 month visit, respectively). This will advise them that at their next visit, they may be eligible to participate in this study, describe the study in very general terms, and also note the financial incentive.

Inclusion and Exclusion Criteria: Accounting for a potential 10% attrition rate, at least 200 subjects with 100 in each age category is recommended for this study. We anticipate that 248 should be ample, given variation in effect sizes reported, uncertainty for those in younger children, and higher than usual attrition for this high-risk population.

Inclusion criteria for this study are:

- Gestation of at least 34 weeks,
- Age at initial screening 6 months (5.75 months-7.5 months) or 18 months old (17-21 months).
- No documented history of major neurological insult such as intracranial hemorrhage or V-P shunt.
- Comfortable speaking English during their WCC and reviewing/comprehending study materials without a translator, including informed consent.
- Functional literacy in at least one primary caregiver, defined as the ability to navigate the RS application, read prompts provided by the RS application (targeted 6th grade reading level as estimated via the Readable.io website), and understand/provide informed consent, administered in English.
- Possession of a smartphone or tablet device capable of downloading, installing and utilizing the RS application.

Twins will be excluded from the study, to minimize confounding.

In the case of 2 eligible siblings presenting at the same visit (i.e. 6 month old and 18 month old), both may be enrolled, though will be randomized to the same group to minimize confusion and confounding.

In the case of an eligible sibling presenting after another sibling has been enrolled, this second child (and any other siblings) will be ineligible, to minimize confounding via a training effect.

b) Study Endpoints*

Outcomes of interest for this study (6 months post-intervention) are as follows:

a) **Descriptive Statistics:** Descriptive statistics will be used to summarize parent-child demographics, language and social-emotional testing scores (LENA Snapshot, DECA-I/T excerpted items), home reading environment/dialogic reading/cognitive-language attitudes (StimQ-P READ and PVR excerpted items, DialogPR-I/T), and screen time (ScreenQ). Group-wise comparisons will be performed to determine any differences

between randomization groups. Spearman's rank correlation will then be used to assess correlation between variables of interest at baseline and 6-month follow-up visits, applying age and gender as covariates.

b) **Pre-post intervention cognitive-behavioral outcomes:** Outcomes of interest will involve group-wise statistical comparisons pre-post intervention of language, social-emotional development, and home reading practices/attitudes measures. All repeated measures (LENA, DECA-I/T excerpted items, StimQ READ and PVR excerpted items, DialogPR, ScreenQ, reading attitudes) will be examined via paired t-test, Wilcoxon signed-rank test, and McNemar's tests. Association between home reading environment and screen time and language and social-emotional testing scores will be assessed by correlation coefficient and applied in general linear regression models, applying age and gender as covariates.

c) **Satisfaction with RS and frequency of use:** responses on surveys administered to caregivers at the 6-month follow up visit (12 or 24 months old) will be analyzed, including frequency and ease of use (e.g number of “push” notifications).

d) **Feasibility:** Caregiver satisfaction with RS will be conducted via closed and open-ended survey items administered via the CRC, including barriers to use (e.g. cell phone minutes, clinical flow, data plan), time of administration, and suggested means of improvement.

There are no safety endpoints involved with this study.

c) Procedures involved in the Human Research*

Randomization: Following agreeing to participate and providing informed consent, families in both age groups (infant and toddler) will be assigned to either the intervention or control cohort (62 in each cohort for each group) by research coordinators using a spreadsheet with assignment codes determined by computer-generated random numbers provided by a biostatistician (Group A and Group B). Participants will be blinded as to group assignment and not advised as to differences in intervention between groups, for the purposes of the research. The CRC will not be blinded, as this is infeasible. Statisticians will be blinded as to the definition of Group A or B (i.e. which is the intervention), to ensure objectivity in analyses.

Testing and Surveys: Testing and survey administration will be performed in a private part of the waiting area or clinic exam room, *in the following order of preference*, mindful of patient/clinic flow:

- 1) Before seeing the provider for the scheduled WCC.
- 2) After the provider has completed their exam, but before lab tests or shots.
- 3) After lab tests and shots, if needed.

Of note, all surveys and measures are administered to the parent (i.e. parent report), none directly administered to or involving the child.

At all times, deference will be given to clinic staff and the family to maintain the flow of the visit. The CRC will approach the clinic manager, supervising nurse, or clinical provider in charge of clinic flow on the morning of each clinic session, to discuss preferred strategies, including designated exam room for consent and survey administration. If unable to complete all data collection, the family will be free to go at their discretion and data collected will be utilized to the extent possible. The order of administration will prioritize items that are most important to achieve our study aims,

particularly demographics, home reading/language environment (StimQ READ/PVR items), language (LENA), and social-emotional development (DECA excerpted items).

Estimated testing/survey administration time is approximately 17 minutes.

Administered at baseline (pre-intervention; approximately 6 and 18 months old):

1) Demographic Surveys (3 minutes): During the first visit only, demographic information will be obtained from custodial parents including contact information, type of smartphone or tablet to be utilized including data plan (e.g. unlimited vs limited data), household income, parental education, history of reading difficulty including dyslexia or functional illiteracy, who usually reads to the child at home, primary language spoken at home, daycare attendance, and number of occupants in the home. Estimated administration time for this survey is 3 minutes.

2) LENA Snapshot (6 minutes) is a validated, 52-item, evaluation of language skills for infants and toddlers by parental report focusing on well-established milestones associated with expressive and receptive language skills, with a standardized score under 77 suggesting risk for delay. It provides developmental age and percentile ranking information compared to age-matched peers. Correlations with standard measures such as PLS-4 and test-retest correlations average 0.93. Estimated administration time is 3 minutes. Of note, this measure is not directly administered to the child.

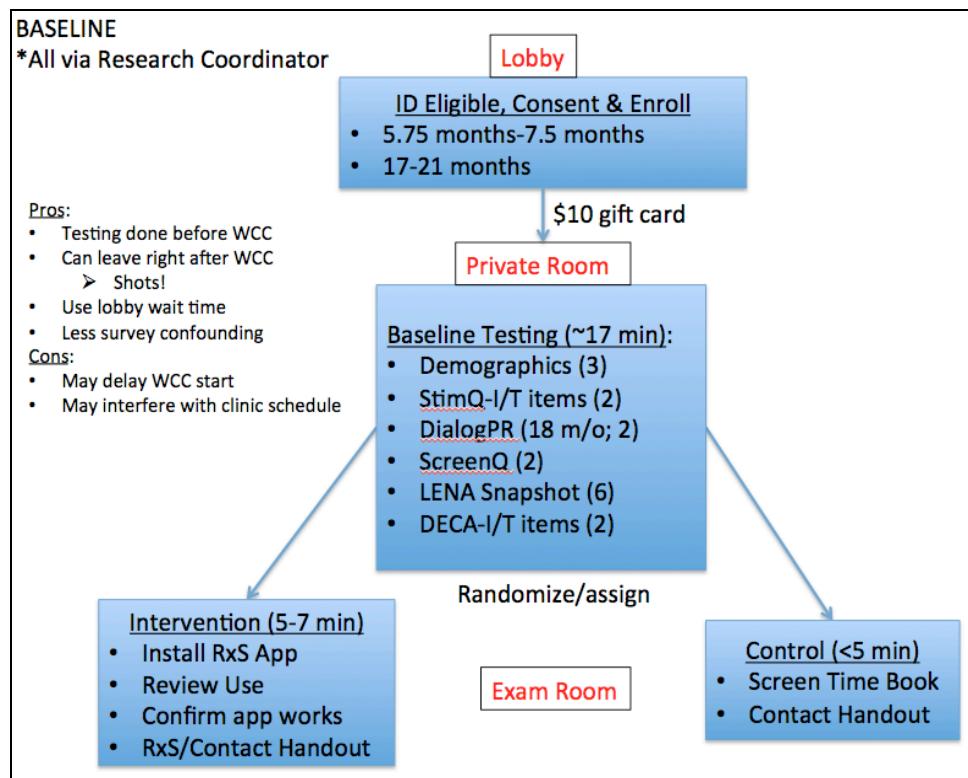
3) Devereux Infant/Toddler Early Childhood Assessment (DECA-I/T items; 2 minutes) is a measure of social and emotional health validated for use in children between 1 month through 36 months, which are strength-based, nationally standardized, and easy to use. The DECA has 4 scales: Attachment/Relationships (18 items), Initiative (11 items), Self-Regulation (7 items), and Total Protective Factors composite. The infant form (1-18 months old) has 33 items, and the toddler form (18-36 months old) has 36 items. *To keep our administration time as brief as possible, we will excerpt 5 items from the attachment subscale* (those most likely to be influenced by shared reading) for this study, and add these item scores to determine a total score. Estimated administration time for these items is 2 minutes.

4) StimQ-Infant/Toddler (excerpts, 2 minutes) is a validated assessment of cognitive stimulation in the home. *For this study, to keep administration time brief, 5 items excerpted from the READ and Parental Verbal Responsivity subscales will be administered,* assessing access to books, frequency of shared reading, and verbal interactivity in the home. In addition, caregivers will be asked to list their 3 favorite activities to do with their child at home (open ended, coordinators noting whether reading is included), as in Needlman, et al (2005). Estimated administration time is 2 minutes.

5) DialogPR-I/T (2 minutes) is an 8-item parental report assessment of shared reading quality created by the principal investigator for caregivers of children age 18 months and up, and a related version for younger infants (DialogPR-I/T) based on a dialogic reading conceptual model. Initial validation involving a low-SES population⁴⁶ showed strong psychometric properties. Estimated administration time is less than 2 minutes.

6) ScreenQ (2 minutes) is a novel assessment of screen-based media use in the home developed by the principal investigator, consisting of 10 evidence-based⁵⁰⁻⁵² items reflecting access to screens, frequency of use, content, and interactivity. This measure was recently pilot tested and psychometrically refined in a diverse sample of preschool-age children, and is applicable for ages 0-9 years. Estimated administration time is 2 minutes.

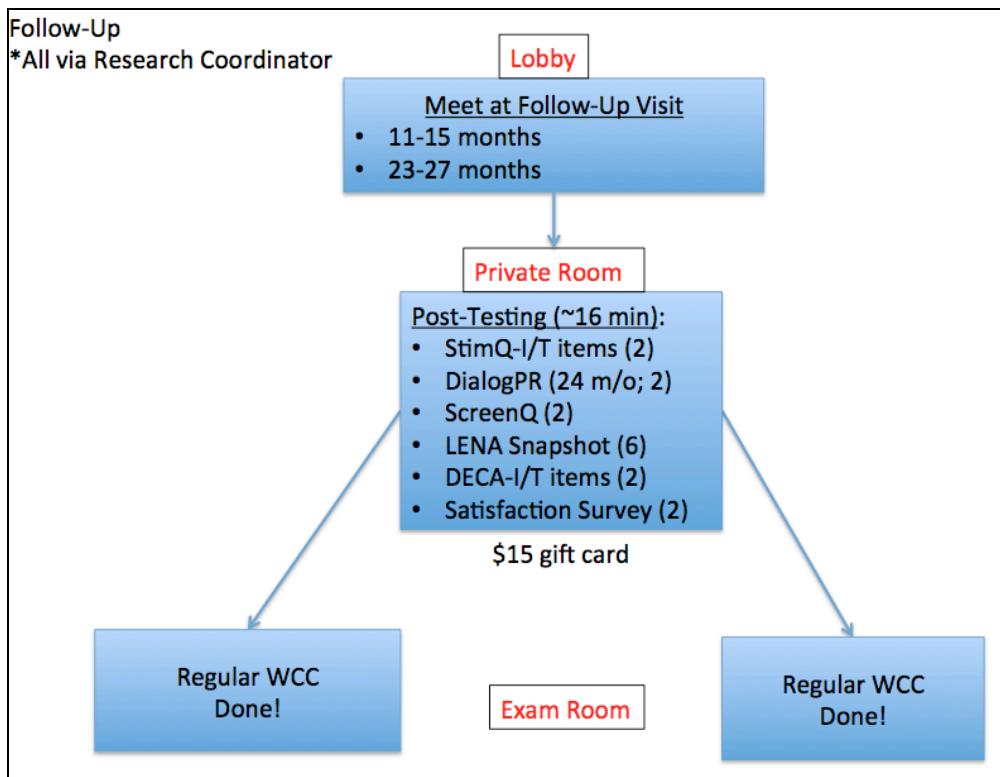
A flow diagram summary of enrollment, consent, and baseline testing is provided below:



Administered at the follow-up visit (post-intervention; approximately 12 and 24 months):

At the 12-month (11 to 15 month) or 24-month (23-27 month) well-child visit, the LENA, DECA-I/T items, StimQ-I/T items, DialogPR, and ScreenQ will be repeated. Caregiver surveys of frequency and ease of use of the RS app will also be administered. The CRC will contact families by phone and text message approximately 1 month in advance of the follow-up visit to remind them of the date and time, and importance to attend this visit. Estimated administration time is ~16 minutes.

A flow diagram summary of follow-up testing is provided below:



Dialogic Reading Intervention (DRI): For families assigned to the DRI group, in addition to customary ROR procedure in the clinic, the DRI will involve:

a) Training in DRI: At the baseline well-child visit (approximately 6 or 18 months), the CRC will assist participating families in downloading and installing the RS app onto their mobile device, and briefly review its use. This is anticipated to take approximately 5-7 minutes. After downloading RS, the CRC will confirm that caregivers were able to open it, activate the videos, and address any questions. A postcard with simple, picture-based instructions (target 6th grade reading level) will also be provided, created by ROR. This handout/card will also convey contact information for the CRC in the event of a change in participant phone number or other contact information. Care will be taken to make the instruction process as brief as possible, to simulate how a pediatric provider or support staff would function in a busy, real-world clinical setting. The CRC will record administration time, qualitative feedback from families, and any major logistical concerns.

b) Rx for Success Application (RS): The RS mobile application (app) was developed by Children, Inc., available for free download via the iTunes or Android App stores (search term: Rx for Success). The app is designed to be informational and motivational with both video and cueing content. The app uses a “View It, Cue It, Do It” model that allows parents to quickly download the smartphone app (no iTunes or other account is needed, and installs on a variety of platforms), view brief videos of the age-indexed, research-based language enrichment practices; and regulate a text message cueing program. The app uses three motivational strategies in the cueing program: 1) Personalization; 2) Gamefication; and 3) Social media. Videos embedded in the RS app provide a summary of DR tailored for the child’s age, and suggestions for encouraging verbal interactivity and social-emotional engagement through dialogic reading. To achieve this, approximately 2 “push” notifications will be generated by the app per day

(not via cellular text message so will not count against participant's data plan). Key behaviors reinforced by the app include discussing the story before reading to build interest and enthusiasm, followed by interactive reading modeled by the acronym PEER:⁹ 1) Prompt the child to say something about the story, 2) Evaluate what the child says or does, 3) Expand on what the child says or does, and 4) Repeat and reinforce associations or responses. The acronym CROWD reflects simple types of prompts that can encourage the child's involvement in the story, which gradually apply with age and development: 1) Completion (of a sentence), 2) Recall earlier aspects of the story, 3) Open-ended questions, 4) Wh- questions, and 5) Distancing (relate the story to the child's life). Finally, the RS app encourages the caregiver to review the story with the child after it is finished to reinforce the book sharing experience.

c) Monitoring adherence and “dose” of DRI: At the 12 or 24-month follow-up visit, a survey of frequency and ease of use of the RS app, developed by the principal investigator, will be administered to the child's primary caregiver.

Families assigned to the Control group will receive a new children's book regarding limiting screen-based media use (*Baby Unplugged: Play*, Hutton/Jones, blue manatee press), which lists AAP screen time recommendations on the back cover.⁴⁸ This will be briefly reviewed by the CRC, in addition to customary ROR procedure in the clinic. A postcard will be provided conveying contact information for the CRC in the event of a change in participant phone number or other contact information. Care will be taken to make the instruction process as brief as possible, to simulate how a pediatric provider or support staff would function in a busy, real-world clinical setting.

d) Data management*

Power Analysis: We will recruit 248 children in 2 age categories: approximately 6 months old (infants, n=124), and approximately 18 months old (toddlers, n=124) via convenience sampling in the CCMC clinic waiting room during regularly scheduled well-child visits. This study will be powered based on the primary language outcome measure (LENA Snapshot). For a two-group (intervention/control), pre-post repeated-measure analysis with two age categories (6-12 months, 18-24 months), an ANCOVA model will be applied for both age categories and their interaction, to assess the difference in language scores between intervention and control groups. For this study, at least 180 subjects will be needed to have 80% statistical power to detect slightly greater than medium effect size (Cohen $f=0.30$), controlling for the baseline pre-measurement with a two-sided significance level of 0.05. This effect size was determined considering the 2008 National Early Literacy Panel Report, which examined 16 studies and reported an effect size of 0.6 for dialogic reading on language outcomes ($d=0.6$; Shanahan, et al).⁴⁹ A separate meta-analysis of 18 studies that tested dialogic reading intervention found average effect size for language outcomes and vocabulary of 0.29 and 1.02, respectively.⁸ However, these reports largely involved preschool- and school-age children, and no studies to our knowledge have reported effect sizes of dialogic reading for language in infants and toddlers.

Confidentiality will be maintained by storing all data on secure, password-protected servers hosted by the Cincinnati Children's Division of Biomedical Informatics. The CRC at CHC@CCMC will log in to this database via a password to enter study data, as is

customary for off-site studies. REDCap software will be used for data capture and is a secure, HIPAA-capable web-based data management tool, and is provided at no cost by Cincinnati Children's via a grant to its Center for Clinical and Translational Science (CCTST). Access to REDCap data and the servers is limited to personnel directly involved in the study. All hard copy records including consent forms will be securely stored by the CRC at CHC@CCMC, access restricted to study related personnel. All potentially identifying data will be destroyed within 3 years of study completion.

e) Provisions to monitor the data for the safety of subjects*

This study involves minimal risk, and such provisions are not required.

f) Withdrawal of subjects*

Subjects may advise the CRC or investigators of their desire to withdraw from this research at any time, prior to their second (final) study visit. Following the second visit, their data will be deidentified, and will not be able to be removed. The investigators may remove subjects who do not complete the second visit (i.e. missing data), do not present for their scheduled well-child visit, or are lost to follow up.

9) Risks to subjects*

As reading with children is considered to be helpful for their development, this study involves minimal to no risk to subjects. However, the following risks/inconveniences are possible:

- *Financial risks* may involve the use of cell phone data minutes, though these are expected to be small.
- The well-child visit (checkup) may take longer than usual, due to *time* spent completing surveys. We will try to finish these during normal waiting time before the doctor is ready to see participating families, so that inconvenience is minimal, and the visit goes smoothly. We will be working with clinic staff to help make sure this happens.
- Increased screen-based media use is possible via encouraging use of a smartphone-based application (RS app), and this possibility is explored via one of our study aims. By contrast, families in the control group will receive a specially designed children's book discussing alternatives to screen time.

10) Potential benefits to subjects*

Potential benefits to subjects include:

- Increased knowledge of healthy reading practices to try at home (very likely).
- Increased knowledge about the child's emotional and language development (likely).
- Improved emotional and language *development* through more healthy reading practices to try at home (possible, the purpose of the study). The mechanism of reading instruction (RS app) is unproven at this time.

11) Provisions to protect the privacy interests of subjects

Subjects will be approached as discretely as possible via a trained CRC in the clinic waiting area, and invited to discuss the study in an area that is as quiet and private as possible. For those expressing interest, written informed consent will be obtained in either a private area of the waiting room or in a private exam room, and all data will be collected in a private exam room. As this study involves minimal risk, initial discussion of the aims of the study or eligibility requirements in the waiting area does not represent a major risk to subject privacy, though the CRC will be advised to be as discreet as possible.

12) Provisions to maintain the confidentiality of data

Screening and survey data will be directly entered by the CRC into REDCap (www.REDCap.org), a secure, HIPAA-capable web-based data management tool, to the greatest degree possible (demographics and select parental surveys). All paper-based data will be transcribed into REDCap as expeditiously as possible. All subjects will be assigned a unique Study ID in REDCap, and at the conclusion of data collection for all subjects, all identifying information such as names and phone numbers will be deleted. Biostatisticians at Children Inc. and the principal investigator will only download deidentified data via REDCap for analysis, and then store this data on password-protected servers at their respective institutions (Children Inc. and CCHMC). REDCap data will be stored on secure, password-protected servers hosted by Cincinnati Children's Division of Biomedical Informatics, with state of the art security features. Hard copy records will be restricted to IRB-approved study personnel in locked cabinets at CHC@CCMC. Hardcopy data will be destroyed within 3 years of conclusion of the study.

13) Medical care and compensation for injury

This study involves minimal risk, and such provisions are not required.

14) Cost to subjects

There are no costs involved with participation in this research, other than use of smartphone data minutes using the RS application (if applicable; would not result in any cost in the case of increasingly common unlimited data plans), expected to be minimal. The RS application is completely free, with no special accounts needed.

15) Consent process

- Written informed consent will be administered via a trained CRC in a private section of the waiting area or private exam room at CHC@CCMC.
- A single CRC to be hired via the Weitzman Institute will be solely responsible for informed consent.
- Informed consent will cover all aspects of the study included on the consent form, in plain English, anticipated to take less than 5 minutes. The ability to comprehend the informed consent documents in plain English without a translator is a requirement for inclusion in this study.

- Non-English speaking families are excluded from this pilot study due to restrictions on time, budget, and the need to minimize covariates such as language spoken at home in our analyses, especially as bilingual children are known to have short-term language delays likely to influence our findings. The RS app is also not currently available in Spanish. In the future, we plan to expand our research to non-English speaking households.
- As this study involves convenience sampling in the waiting area, there is no lag expected between approach for consent, administration of consent, and enrollment in the study for those interested.
- The CRC administering informed consent will emphasize that participation in this study is optional and voluntary, and that their child will receive the same well-child care regardless of participation, including via the Reach Out and Read program.
- Consent from one custodial parent is all that will be required for this research. “Custodial” parent will be defined as with necessary permission to accompany the child to the doctor at the current visit, and who lives with the child at home and would have the opportunity to consistently read to them. As reading with children is generally considered to be beneficial, we feel that permission from one parent is adequate for our study design. If, by small chance, the second parent or custodial caregiver protests this enrollment and requests removal, the child will be removed from the study.
- If the child is accompanied by another family member such as an aunt or grandparent, they will not be enrolled in this study, unless this family member has full-time legal custody of the child, authorized by a court order.
- This study clearly involves children (age 6-12 months and 18-24 months old), by any definition. Children of this age can not reasonably be expected to provide consent or assent, and will not be asked to do so.

16) Process to document consent in writing

Written informed consent will be documented on the IRB-approved consent form accompanying this application, written in plain English per specifications and summarized in person via the CRC. One copy of this form will be given to the consenting family member, and the other securely stored in a locked cabinet dedicated to this study at CCMC.

17) Vulnerable populations

This research involves young children under the care of their parent(s) or custodial caregiver, who will be delegated responsibility to make an informed consent on their behalf. As this study involves minimal risk, and shared reading is generally considered beneficial, the child’s vulnerability to harm is negligible.

18) Drugs or Devices

This study does not involve drugs or devices.

19) Multi-site Human Research*

All data collection and intervention for this study will take place at a single site at CHC@CCMC. Data will be securely stored in a REDCap database hosted at Cincinnati Children's Division of Biomedical Informatics, accessed via the CRC using a unique password, and other access restricted to IRB-approved study personnel. All data downloaded for analysis by biostatisticians at Children Inc. or the principal investigator will be in deidentified form, and then stored in password-protected servers at the respective institutions (Children Inc. and CCHMC).

20) Sharing of results with subjects

Results from this study will not be directly shared with subjects. For children identified as being at risk for language delay via LENA Snapshot scores at their second study visit (standard scores <77), their primary pediatric provider will be notified by Dr. Wiley from CHC@CCMC, to discuss with families as soon as possible.

21) In the Event of Distress

In the unlikely event that a participant in this study becomes distressed, such as vomiting, the CRC will notify clinic staff at CHC@CCMC immediately to address the issues. No further evaluation or testing will be attempted unless specifically requested by the family and poses no discomfort to the child. Dr. Wiley will be notified via the most efficient means possible to advise of such an event, to follow up with the family and clinical providers as appropriate.