Addressing Disparities in Language and Social-emotional Skill Acquisition through Literacy Promotion in Primary Care: Literacy Promotion for Latinos Study

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- **Title of Project:**
  Addressing Disparities in Language and Social-emotional Skill Acquisition through Literacy Promotion in Primary Care: Literacy Promotion for Latinos Study

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1.0 Research Design

1.1 Purpose/Specific Aims

To test the extent to which tailored outreach text messages that provide a cue to action and an intervention that enhances access to poverty-reducing resources, in combination with a primary care literacy promotion program, can improve parenting behaviors, child language development, and social-emotional skill acquisition among low-income Latino children.

A. Objectives

Aim 1: To test the relative efficacy of 3 literacy promotion interventions on parenting behaviors, child language and social emotional skill acquisition among low-income Latino children

Aim 2: To examine mechanisms underlying the effects of the interventions

Aim 3: To conduct a mixed methods process evaluation of the literacy promotion interventions
Research question (RQ) 1: How are the literacy promotion interventions implemented?
RQ 2: What are barriers, facilitators, and modifications made to the interventions?
RQ 3: What are parents' experiences with the interventions?

B. Hypotheses / Research Question(s)

Hypotheses (H) 1A: Children in the ROR + texts arm will have enhanced language and social-emotional skill acquisition, and parents will describe enhanced parenting behavior, as compared to those receiving ROR only

H1B: Children in the ROR + texts + Connecting NJ (formerly Central Intake) arm will have enhanced language and social-emotional skill acquisition, and parents will describe enhanced parenting behavior, as compared to those receiving ROR only or ROR + texts

H2A: Effects of the interventions on child language and social-emotional outcomes will be partially mediated by the home literacy environment.

H2B: The effect of ROR + texts + Connecting NJ child outcomes will be partially mediated by reduction in parent stress and aspects of positive parenting (responsive verbal interactions)

1.2 Research Significance

Parenting routines play an important role in promoting child language and social-emotional skill acquisition.[1] Shared reading is among the most studied positive parenting routines and increases both the quantity and complexity of language exposure.[2, 3] High quality meta-analyses demonstrate that shared reading enhances language and literacy skill acquisition, which are critical precursors for school readiness and health-related decision-making.[2] Recent work by our team using a population based, longitudinal urban birth cohort, documents how shared reading in infancy is also linked to less disruptive behaviors (e.g. hyperactivity) at age 3 years.[4] However, infants from low-income Latino backgrounds are less likely to be exposed to shared reading than higher-income White peers.[5, 6]

Pediatric primary care is a trusted setting that is increasingly recognized as an innovative platform for universal delivery of preventive parenting interventions.[7] Pediatric primary care offers population-level reach (e.g., ~84% children attended a well-child visit in the last year)[8] and an opportunity for multiple contacts with children (e.g.,12 recommended visits from birth to 3 years).[9] Relevant to this proposal, Latino parents are more likely to attend recommended well child visits compared to other groups.[10]

Literacy promotion serves as an exemplar primary care preventive intervention having evolved into a pediatric care standard over the last 30 years. Reach Out and Read (ROR), the most common approach, was founded by pediatricians in 1989 in one clinic. Currently, over 5,000 clinics implement ROR and 32,000 clinicians are trained in the ROR model and participate. ROR reaches 25% of children within twice the poverty level.[7] The American Academy of Pediatrics (AAP) has long endorsed literacy promotion by clinicians. Guidance on shared reading has been present since the earliest editions of the AAP Bright Futures guidelines, the AAP formally endorsed ROR in 1998, and in 2014 the AAP released a policy statement that established literacy promotion as a pediatric care standard.[11] ROR increases shared reading, enhances the home literacy environment, and improves language outcomes.[7] However, even with participation in ROR, the scores of participating children remain well below the overall population.[12] For example, 37-45% of low-income, Latino children who participated in ROR continued to be at risk for reading problems prior to Kindergarten entry.[13] These data reflect the severity of existing disparities in language development faced by low-income Latino children and highlight the need to enhance existing efforts to reduce disparities in developmental health.

Prior research documents the impact of shared reading from infancy on language and social-emotional skill acquisition among diverse children.[3,4] Prior work also demonstrates that primary care literacy promotion has achieved substantial scale and improves shared reading frequency and child language outcomes.[7] However, low-income Latino children remain at risk for language and reading problems despite literacy promotion, which has a positive but partial effect.[12,13] Prior work leaves important knowledge gaps on how to optimize literacy promotion for this vulnerable group. The current study seeks to address these gaps, which are critical barriers to equity promotion, by testing novel enhancements to the ROR model.

1.3 Research Design and Methods

The proposed research integrates a randomized clinical trial with a mixed methods process evaluation. The goal of this proposal is to test the relative efficacy of 3 approaches to literacy promotion in promoting language and social-emotional skill acquisition among low-income Latino children and enhanced parenting behaviors in their caregivers. Given that early childhood experiences are critical for school readiness and the importance of parent behaviors including shared reading for development and behavior beginning in infancy, this proposal includes both children and their parents as subjects. Beginning in year 1, for Aim 1, we will recruit 630 parent-child dyads to participate in a longitudinal 3 arm randomized clinical trial. All participants will receive Reach Out and Read, which is a standard of care, in which a pediatrician distributes a book to the family and provides guidance on shared reading.

In Aim 1, 630 parent child-dyads will be recruited. Participants will be randomly assigned to one of three study arms: (1) Reach Out and Read; (2) Reach Out and Read + outreach text messages; (3) Reach Out and Read + outreach text messages + Connecting NJ (which will facilitate access to poverty-reducing resources based on the families' needs). We anticipate 210 parent-child dyads in each of the 3 study arms. Children will be ages 6 to 12 months at the time of enrollment. All participants will be asked to participate in an enrollment visit and 2 follow-up visits at 9 months and 18 months; the study will end at 18 months. Each visit will last approximately 90 minutes each in order to complete outcome measures.

The process evaluation will be occurring as the study is being conducted to examine how the three study arms are implemented over time.

A. Research Procedures

All research activities will be conducted by Rutgers study staff. We will be recruiting participants from community health centers: Eric B. Chandler Health Center (Chandler), Jewish Renaissance Medical Center (JRMC), and St. Peter's Family Health Center (St. Peter's) will be the primary sites; Robert Wood Johnson Medical Group at Somerset (Somerset) and Bristol Myers Squibb (BMS) will be secondary/back-up sites due to their smaller patient panels.

Because of COVID-19, we will need to enroll participants, at least initially, by phone or video conference. Clinicians will refer participants who identify as Hispanic or Latino/a/x and whose child is between 6 and 12 months to Rutgers study staff after receiving authorization from the potential participant to do so. Chandler and Somerset are Rutgers Robert Wood Johnson Medical School (RWJMS) clinics with which the PI is affiliated; clinicians there will give participants the study flyer and ask if they may forward us their contact information and/or ask participants to fill out our Information Release Form to forward their information to us. Since JRMC, St. Peter's and BMS are outside the Rutgers RWJMS system, clinicians there will give potential participants our study flyer and ask them to sign our Information Release Form before sending us referrals. All clinicians will send us the referrals via secure, encrypted email or study staff will pick up referrals from the clinic. Referrals will include potential participant name, phone number and/or email address. Study staff will call or email participants over the course of 6 weeks for initial outreach. Staff will screen potential participants for eligibility, thoroughly explain the study, ask if the potential participant has any questions, and only after asking the potential participant if all of their questions have been adequately answered will the staff ask if the potential participant would like to consent to be enrolled in the study. Staff will read our consent form with potential participants and ask them for a verbal consent. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. Study staff will send them our study materials by mail or email for their records and will record that the participant has consented for our records. Staff will then ask the participant if they have time to enroll or would like to schedule an appointment to conduct the enrollment surveys. Participants will receive a list of community resources that may help the participant with social support needs.

As part of our COVID-19 plan, study staff will conduct the two follow-up visits and assessments virtually. Staff will send a link to a free, secure video-conferencing platform, such as Microsoft Teams. These visits will happen 9 months and 18 months into the study.

When and if COVID-19 guidelines are relaxed, we would like to continue recruitment in person in clinic waiting rooms. Clinicians may continue to refer potential participants to us, as well. We will continue with the same process outlined above to screen the potential participant, explain the study, and provide informed consent. When in person, we will use our written informed consent form. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. We will perform our enrollment surveys and give the participant a list of community resources that may help with social support needs.

Participants will be randomly assigned to one of three study arms: Arm 1 Reach Out and Read: The Reach Out and Read model consists of creating literacy rich environments (e.g., children's books present in waiting room), healthcare professionals distributing age and language appropriate children's books, providing anticipatory guidance on shared reading, and modeling dialogical reading which emphasizes responsive and language-rich parent-child interactions.

Arm 2 Reach Out and Read plus outreach text messages: In addition to Reach Out and Read, participants will receive three text messages a week and one follow-up message per month for the study period with scheduled breaks. Messages will be tailored. Tailoring strategies will include personalization and feedback. We will personalize messages based on language preference (English or Spanish), child sex, and optimal timing of messages (morning or evening). For feedback, we will use bidirectional messages once per month. For the once-a-month follow-up message, parents will be asked to respond to a question regarding shared reading in the past week; they will receive a supportive response based on their answer. We will also send a text for birthdays and other child milestones to help build rapport.

Arm 3 ROR + texts + Connecting NJ: In addition to Reach Out and Read and text messages, participants will be referred to Central Jersey Family Health Consortium for Connecting NJ. Our RA will explain Connecting NJ and will email or link the participant to Connecting NJ informational

materials. We will provide Connecting NJ with basic demographic information about the participant. A case manager from Connecting NJ will then call the participant to assess potential participant needs related to child development, housing insecurity, food insecurity, transportation, financial strain, and problems paying utilities, as is her usual process when she receives referrals from the community and/or clinics. Families in this arm will be referred to Connecting NJ via electronic referral at enrollment. Connecting NJ is based on the national Help Me Grow model and simplifies access to poverty-reducing resources by creating a centralized access point, maintaining an updated data base of resources with existing capacity to support families, and providing case management to ensure families are linked to community resources (e.g., Supplemental Nutrition Assistance Program). Central Jersey Family Health Consortium will share data with us about which resources participants were referred to via a secure platform. We will sign a Data Use Agreement with them (forthcoming).

All participants will receive the standard Reach Out and Read intervention in which healthcare professionals distribute books and model shared reading during well visits to encourage parents to read aloud with their children. Literacy promotion is the pediatric standard of care.

Research materials will consist of:
(1) Demographic Information and Language Use questionnaire we constructed by adapting questions from the U.S. Census and the Medical Expenditure Panel Survey (MEP) and from our prior experiences in the field. This questionnaire includes a question about English proficiency.
(2) The Short Assessment of Health Literacy (SAHL-E),[14] a brief assessment of adult health literacy that asks the participant to identify words associated with health-related terms.
(3) We include two questions in our Discrimination Questionnaire related to racial/ethnic discrimination.
(4) A survey to assess participant Receipt of Reach Out and Read interventions.
(5) Language acquisition will be assessed using the Expressive One-Word Picture Vocabulary Test - Fourth Edition (EOWPVT-4) Spanish-Bilingual - Complete.[15]and the MacArthur Bates Communicative Development Inventory (CDI),[16] direct assessments of child language development.
(6) The Devereux Early Childhood Assessment (DECA),[17] a parent-completed behavior rating scale.
(7) The StimQ-2[18] Infant and Toddler subscales of Parent Verbal Responsivity and Reading, Teaching, Verbal Responsivity, which assess child and parent cognitive home environment, book-reading activities, and parent attentiveness to child language acquisition/skill development. We added 8 questions to the Read Infant version. We also will implement the DialogPR[19], a parent report of shared reading quality, plus an observation of shared reading and free play activities. (8) Modified Parenting Your Infant and Parenting Your Toddler surveys, derived from the Parenting Your Child[20] measure, to assess the frequency of different parenting/caregiving behaviors and positive parenting/parental warmth. The Parent Discipline Questionnaire, to address negative parenting styles, which includes two questions from the 2000 National Survey of Early Childhood Health[21] that address disciplining techniques. Our measures for positive and negative parenting behaviors will be comprised from responses to these instruments.
(9) A modified Parent Reading Belief Inventory (PRBI),[22] which measures beliefs and attitudes about reading, reading to one's child, and one's own experiences of reading as a child.
(10) An adapted version of the Survey of Income and Program Participation,[23] to assess family resource use of community and federal support programs.
(11) We plan to use a Modified Physician-Parent Communication Survey[24] to assess parents' perceptions of clinician's behavior of caring, collaboration, and interest.
(12) The Parental Stress Scale,[25] an adapted version of the Local Inventory of Needs and Knowledge (LINK).[26]
(13) We are using a Modified ScreenQ Survey,[27] to assess home media environment and child use of cellphones and visual media.

A trained study team member will assist parents in completing all forms. All adapted surveys and questionnaires and ones designed by the team are attached. ("Adapted" surveys are ones to which we made changes or added additional questions; "modified" surveys are ones we limited to components or subscales or otherwise reduced.)

For aim 3, research materials will consist of fieldnotes of health center observations of ROR capacity and delivery, if possible due to COVID-19 guidelines; data from Connecting NJ about referrals made; and parent surveys about resources they have used. Only trained study team members will have access to potentially identifiable information under the supervision of the PI. All study team members will be trained in data collection and maintaining confidentiality. When possible parent-reported information will be entered directly onto Research Electronic Data Capture (REDCap), a secure research server, to minimize the risk of breach of confidentiality. If for some reason this is not possible, paper surveys will be stored in locked file cabinets and all data will be transferred onto REDCap. All electronic data will be stored on REDCap or a password protected computer.

We will conduct a brief pilot for Arm 3 of the study before beginning recruitment for the full study. The purpose for this short pilot is two-fold: 1) to ensure study processes are as smooth and unobtrusive as possible for clinicians and participants; 2) to understand the implications any COVID-19 adaptations to clinic processes or to patients' life experiences may have on our study; and 3) to be able to make adaptations to these processes where necessary to ensure that we are able to collect the data necessary for the study. We anticipate this pilot will last August through September; we anticipate ending the pilot and beginning the study in late September/early October 2020.

For this pilot, we will recruit up to 20 participants across the clinic sites; clinicians from each site will refer participants to us in the same manner described above: clinicians will identify participants who are Latino/a/x and have a child age 6-11months; they will inquire if participants are interested in the study, and, if participants authorize release of their name and contact information to us, the clinician will email that information to our research assistant (RA) using an encrypted email or platform using the process described above. Our RA will contact the participant and conduct an abbreviated version of our study enrollment process: this will consist of the screener, informed consent process (using a tailored information sheet for the pilot, attached), modified demographic survey, modified LINK survey, and modified ROR survey. Our RA will also ask if we can contact the participant again to ask them about their experiences with Connecting NJ, to which we will refer the participant. The RA will then refer the participant to Connecting NJ, and follow-up with the participant within 3-4 days. (See attached "Pilot Scripts and Surveys" document for the survey and open-ended questions we will ask participants. We may need to adjust questions to better address participant responses in real time.)

During the pilot, our study team will debrief with clinicians about their ROR experience with the pilot participants. The questions we intend to ask them during these informal meetings include:

- What do they usually do for the three core elements of ROR (i.e., literacy-rich waiting room, giving patients books, how they advise patient families about reading (by age of child)?
- How COVID has impacted these practices?
- How do patients respond to ROR?
- How is our study process working for them?

If we do need to make adjustments for the study based off on these sessions with families and clinicians, we will file a modification with the IRB before starting our recruitment for the formal study.

PROCESS EVALUATION

Clinician Interviews and Surveys

For our process evaluation, we will be conducting practice surveys, to be completed by an office manager; clinic champion surveys and interviews; and clinician interviews and surveys. The goal of these surveys and interviews is to collect data on the contexts in which ROR is happening and the individuals who are responsible for implementing it.

The Practice Survey will ask basic characteristics and features of the clinic: i.e., number of patients seen, length of well visits, number of exam rooms, number of staff and clinicians, and Spanish language proficiency of staff and clinicians. We will ask office managers or other administrators to fill out this survey, which will be conducted online through a secure software program, Qualtrics. We will include the consent language online, ahead of the survey. Upon downloading the survey data from Qualtrics, our analyst will save the data in a restricted folder on our restricted drive.

Clinic champions and clinicians will be asked to complete a quick survey and then an interview via Zoom. We will discuss consent with each champion and clinician via email and/or phone or Zoom. We will include a copy of the consent form with a link to their survey. We will ask if they have any questions about the consent before they proceed to the survey and we will review these questions with them in the mode they prefer. Once questions are resolved and they agree to participate in the survey and interviews, we will direct them to a Qualtrics survey via a link. When they arrive at the survey, they will be asked to digitally consent to participate in the survey and subsequent interview. They will not be able to proceed to the survey without digitally consenting. We will revisit the consent with them before we interview them via Zoom, and we will ask for their verbal consent to record the interview at that time, sending the addendum to the consent ahead of the scheduled interview for them to re-review. Once we turn on the recorder, we will ask for them to confirm their consent on the recording. After the interview, we will save the recordings to our secure server, restricted drive, for our study evaluation team to analyze. If clinicians decline to have their interviews visually and/or audio recorded, clinicians may still participate in the interview; researchers will take notes in these instances.

Both champions and clinicians will be asked to submit a short survey about their demographics, their clinical training, and their ROR implementation. After they conclude the survey, we will interview them about their process for implementing ROR in the clinic. Interviews will be conducted by experienced RAs. As part of our interview, we will draw a process map based on what they tell us, and we will ask them to verify this map.

Interviews with champions and clinicians will occur three times over the course of the study implementation period – once in the beginning of the study, once in the middle, and once toward the end. Interviews will occur at least 6 months apart. The survey portion should take 5-10 minutes to complete; the interview will last approximately 40 minutes. Champions and clinicians will not receive financial remuneration for participating; instead, we will present them with a report at the end of the interviews about what we've learned to help them in their ROR implementation.

After the interviews are completed, we will reach out to clinicians who are new to the clinics and to clinicians we previously reached out to for interviews who did not participate in interviews to ask them to complete the demographic survey (this survey has already been approved, "Champion and Clinician Survey, V1"). We will reach out by email. We will send them an email with a link to an online consent form/information sheet for the survey; if they consent, they will be directed to the online survey in Qualtrics. We will send around 5 outreach attempts. If they do not click on the email link to the consent and survey or indicate that they have declined participation, an RA will ask in person if the clinician would be willing to participate and complete the same materials on paper or on a password-protected tablet/laptop the RA has with them. (We have found busy clinicians may not click on surveys from emails and giving them an option to do this in person may save them time and energy, reducing survey burden). We will have a crosswalk linking their name to the survey identifier saved in a secure folder on Rutgers OneDrive; their name will not be recorded

on the survey with their responses and will be stored in a separate secure folder in OneDrive on Rutgers' server.

Parent interviews

To better understand parents' experiences of the intervention and the factors that influence implementation, we will conduct interviews with approximately 60 parents (20 from each arm) after they have completed the study. We will purposively sample based on study arm and quantitative data to leverage comparisons based on receipt of key components of ROR and receipt of referrals from Connecting NJ (formerly Central Intake). We will conduct interviews until reaching thematic saturation (when no new ideas are generated from the interviews).

We have developed a semi-structured interview guide with sections about parent experiences of different components of the intervention: ROR, receiving the text messages, and receiving referrals for community organizations from Connecting NJ. We will tailor the guide based on the participant's study arm (e.g., if the participant is in arm 2, we will not include the section on Connecting NJ). The interview guide is meant to be a semi-structured guide and to evolve as we learn more from the participants through the interviewing process; hence the interviewer will modify/add probes to reach full understanding of parents' experiences of the intervention, barriers/facilitators to full implementation of ROR and Connecting NJ, and mechanisms influencing effectiveness of the intervention components. [After the English version is IRB-approved, we will submit a modification for the Spanish translation of the interview guide.]

Our bilingual research assistants (RAs), trained in qualitative interviewing by our team's qualitative experts, will reach out to parents who indicated on their original consent that they would be interested in participating in future research. The RAs will explain the purpose of the interviews and ask if they would like to participate. Interviews will last approximately one hour and be conducted over Zoom. If participants are interested in participating in the interview, the RA will send the participant a copy of our information sheet/verbal consent form to review ahead of the interview. The RA will answer all participants questions before asking for informed consent for the interview and to record the interview. The RA will ask for consent again upon starting the recording, to have the participant's consent on the recording. Participants will be given a $50 e-giftcard upon completion of the interview. [After the English version is IRB-approved, we will submit a modification for the Spanish translation of the consent form.]

ROR Experts Interviews

As part of Aim 3, we will conduct pilot interviews of ROR experts (e.g., ROR North American leaders, ROR state chapter medical directors) about the ROR program and implementation. We will conclude the pilot interviews in March 2024 and transition these interviews to a new study protocol, Core Literacy Promotion Protocol (IRB protocol: PRO2023002474).

Our research questions are: what do experts in the field think are the core components of ROR? What do they think are the mechanisms by which these elements work? We will identify and recruit these experts from their positions in the ROR organization and snowball sample. We will also ask our advisory team to identify others for our initial sample. We intend to interview 25-30 people for these interviews. Interview participants must be able to provide informed consent. As participants are high-level experts in the field, we will not offer compensation for participation.

Interviews will be semi-structured and done over phone or Zoom and, if providing consent for recording, will be recorded (otherwise the researcher will take notes). Participants will be sent an information sheet about the study ahead of the interview to review, with the addendum to record the interview. The interviewer will review the consent form with the participant and answer questions before proceeding with the interview. The participant must consent to the interview and the recording verbally before the interview proceeds. The interviewer will ask the participant to confirm consent on the recording.

Interview questions will be focused on five domains: 1) general ROR mission and implementation; 2) ROR core and peripheral components; 3) mechanisms by which ROR components work; 4) variability and fidelity in implementation; and 5) Inequalities in literacy and language acquisition.

Basic questions may address, for example, What are the core ROR intervention components? What are the mechanisms by which these components work? Which components are most important in terms of improving child development outcomes? What other factors influence ROR implementation and efficacy in different settings? Interviews will be professionally transcribed and analyzed by our qualitative team for important themes and differences of opinion. Findings will inform Aim 3 in helping us understand the ROR model as it is intended to be implemented, as compared to adaptations individual clinicians or clinics make in implementation. We will also be able to understand which components ROR experts perceive as adaptable versus ones that should be implemented with fidelity to ensure the best outcomes.

All the above interviews will be *transcribed* by a member of our study team or a professional transcriptionist/transcription company. Transcriptionists not on our study team will receive only the audio recordings of the interviews. Audio will be shared via a secure/password protected platform. Audio will not contain the participant's name and will be labeled with an ID number. The ID number will be linked to the participant's name in a file contained by the interviewer for tracking purposes and will be stored in a protected folder on Rutgers' OneDrive on their secure server. We may employ student *translators* from Rutgers' University (for example, from the Lives in Translation program or The Language Bank) to translate already transcribed documents from Spanish into English. Student translators will not receive identifying information about our study participants; they will not receive the audio recordings, only deidentified transcripts to translate.

Clinic observations

As stated below, in the "**Ethnographic Studies, Interviews, Or Observation**" section, depending on COVID-19 restrictions, we will use qualitative methods to understand factors that influence implementation from multiple perspectives for aim 3. We plan to conduct observations in each clinic to gain insight into barriers, facilitators, and adaptations made to the ROR interventions. A trained RA will observe ROR infrastructure at clinics and ROR delivery during well-child visits. We plan to conduct site visits for 1 to 2 days at each clinic (~12 hours/site= 48 hours total). The RA will begin with descriptive unstructured observations that will gradually become more focused on ROR activities. Observations will attend to clinic workflow, who is involved in ROR, where ROR activities occur (e.g., where the books are stored, in well visits), and what ROR delivery entails. We also hope to make observations during study visits at the clinics. The RAs will maintain detailed field notes of these observations. Field notes will not include any identifying information about the clinic or individuals in the clinic. Nothing will be recorded by video or audio. Clinics will approve these visits and we will comply with their requirements.

B. Data Points

Data Points				
	Construct	Measure	Study visit	Approximate Response time
Baseline information	(1) Demographics (with English proficiency)	Demographic Information and Language Use	Enrollment Short form at 9 m, 18 m	12 minutes 2.5 minutes
	(2) Health literacy	Short Assessment of Health Literacy (SAHL)	Enrollment	4 minutes
	(3) Discrimination	Discrimination Questionnaire	Enrollment	< 1 minute

Process measure	(4) Reach Out and Read Receipt	ROR Receipt Questionnaire	Enrollment, 9 m, 18 m	4 minutes
Primary Outcomes	(5) Language skill acquisition	Expressive One-Word Picture Vocabulary Test - Fourth Edition (EOWPVT-4) Spanish-Bilingual - Complete	18 m	5-20 minutes
		MacArthur Bates CDI	Enrollment, 9 m, 18 m	20 minutes
	(6) Social-emotional skill acquisition	Devereux Early Childhood Assessment (DECA)	Enrollment, 9 m, 18 m	5 minutes
	(7) Shared reading (Parent investment) and parent responsiveness	Modified StimQ Read scale	Enrollment, 9 m, 18 m	5 minutes
		StimQ Parental Verbal Responsiveness	9 m, 18 m	6 minutes
		DialogPR Observation of parent-child interactions	9m, 18 m	4 minutes
	(8) Positive and negative parenting behaviors	Parenting Your Infant, Parenting Your Toddler	Enrollment, 9 m, 18 m	4 minutes
		Parent Discipline Questionnaire	Enrollment, 9 m, 18 m	< 1 minute
Secondary outcomes	(9) Reading attitudes and knowledge	Parent Reading Belief Inventory (PRBI)	9 m, 18 m	3 minutes
	(10) Access to community resources	Adapted Survey of Income and Program Participation (SIPP)	Enrollment, 9 m, 18 m	2 minutes
	(11) Parent-clinician relationship	Modified Physician-Parent Communication Survey	Enrollment, 9 m, 18 m	2 minutes
	(12) Parent stress and wellbeing	Adapted LINK survey	Enrollment, 9 m, 18 m	8 minutes
		Parental Stress Scale	Enrollment, 9 m, 18 m	3 minutes
	(13) Child media use	Modified ScreenQ-I/T 2.0 (Infant/Toddler)	Enrollment, 9 m, 18 m	6 minutes

C. Study Duration
Up to 5 years; participants will be involved up to 2 years.

D. Endpoints
Study participation will conclude upon completion of data collection

1.4 Preliminary Data

Using community based participatory research methods, we conducted interviews, focus groups, and user testing with 50 low-income, Latino parents and engaged other stakeholders including health professionals, early educators, and community leaders to understand shared reading in the broader context of parenting. The themes we identified aligned with the Health Belief Model, and uncovered targets to enhance ROR. During interviews, low-income, Latino parents identified benefits of shared reading; they viewed it as an important activity that could enhance their children's future. Parents viewed their children as susceptible to language delays and doing poorly in school, citing their own missed educational opportunities; they saw shared reading as an opportunity to avoid these difficulties. These themes align well with the constructs of perceived susceptibility and benefits from the Health Belief Model.

Despite these beliefs, we found a gap between intention and behavior – almost half of the parents we later surveyed (77% Spanish-speaking) reported no shared reading in the last week (79/160) and 85% read ≤3 times. Parents intended to engage in shared reading but did not. Once at home other responsibilities (e.g., caring for other children, chores) took their attention away from opportunities for shared reading. One potential reason is that ROR activities are limited to the office, and thus parents do not receive any cues to action in their home environment when needed. Therefore, we designed an

outreach strategy with our stakeholder partners that consisted of text messages to provide a cue to action when parents were at home with their children to overcome this intention to behavior gap. The message content directly addressed beliefs about child development and shared reading that parents reported during interviews and provided reminders and reinforcement. We sought extensive feedback from stakeholders and assessed the acceptability of the messages through focus groups and user testing. We then conducted a RCT comparing the standard ROR to ROR plus texts. We found that ROR plus text improved the home literacy environment compared to ROR only at the 6-month post-assessment. However, while positive; we found the effects of text messages beyond ROR on the home literacy environment and shared reading more specifically are only partial and the effects on child outcomes beyond ROR are not known.

Subsequently, we conducted 21 interviews with Latino parents who received ROR to identify potential mechanisms of action and additional barriers parents encounter. Drivers of ROR's impact included delivery of literacy promotion by a trusted professional and receipt of a children's book. However, parents identified stress associated with material hardship related to poverty as an important barrier to shared reading even when they believed it would be helpful and intended to do it.

1.5 Sample Size Justification

We will recruit 630 Latino parent-child dyads (210 per arm) over a 24-month time period (Months 3-27). This sample size will be sufficient to achieve 80% power to detect a 0.3 standard deviation (SD) difference in language scores between (1) ROR + texts and ROR only and (2) ROR + texts + Connecting NJ and ROR + texts, assuming 20% attrition based on our ongoing work at one of the CHCs. An effect size of 0.3 SD difference would be clinically meaningful since it would be associated with a detectable difference in later cognitive functioning, based on work from a prospective cohort. The proposed sample size will provide 99.9% power to detect a 0.6 SD difference between the community resource arm and ROR only, based on the expected additive effects of the text message and enhanced access to poverty-reducing resources. We will plan for a conservative 24-month recruitment time period to account for seasonal variation in patient volumes and holidays to recruit the target sample (~2-3 participants /site/week).

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Participants will be randomly assigned to one of three study arms:

Arm 1 Reach Out and Read: The Reach Out and Read model is a pediatric standard of care and consists of creating literacy rich environments (e.g., children's books present in waiting room), healthcare professionals distributing age and language appropriate children's books, providing anticipatory guidance on shared reading, and modeling dialogical reading which emphasizes responsive and language-rich parent-child interactions.

Arm 2 Reach Out and Read plus text messages: In addition to Reach Out and Read, participants will receive three text messages per week, plus one interactive follow-up message, for the study period with scheduled breaks. Messages will be tailored.

Arm 3 ROR + texts + Connecting NJ: In addition to Reach Out and Read and outreach text messages, and referral to Connecting NJ through electronic referral. Connecting NJ, a program of Central Jersey Family Health Consortium, is based on the national Help Me Grow model and simplifies access to poverty-reducing resources by creating a centralized access point, maintaining an updated data base of resources with existing capacity to support families, and providing case management to ensure families are linked to community resources (e.g., Supplemental Nutrition Assistance Program). They will provide us with data on which community resources participants were referred to.

We will also collect the following process measures:

Table: Quantitative measures of key intervention components and data sources					
Key Component	Arm 1*	Arm 2*	Arm 3*	Process measure	Data source
Literacy rich waiting room	✓	✓	✓	- Availability of children's books - Volunteers in waiting room	ROR parent survey Observation checklist (when and if able to enter clinics)
Children's book distributed	✓	✓	✓	- Family receipt of language appropriate book	ROR parent survey
Anticipatory guidance on shared reading	✓	✓	✓	- Professional discusses reading - Professional models reading	ROR parent survey
Enrollment in text messages		✓	✓	- # of parents requesting stop	Text message portal data
Bidirectional text messages		✓	✓	- # of responses from parents to bidirectional messages	Text message portal data
Parent linked to Connecting NJ			✓	- Electronic referral form	Connecting NJ data
Material support referrals made			✓	- Number & type of referrals	Connecting NJ data
Linkage to services			✓	- Completed referral	Connecting NJ data Parent-reported resources
Arm 1: Reach Out and Read (ROR) only; Arm 2: ROR + texts; Arm 3 ROR + texts + Connecting NJ					

B. Dependent Variables or Outcome Measures

• Language acquisition will be assessed using the Expressive One-Word Picture Vocabulary Test - Fourth Edition (EOWPVT-4) Spanish-Bilingual - Complete. This multiple-choice format test consists of 190 items presented in developmental sequence; age-related starting points and cut-off points ensure that only a subset of items is administered.

• MacArthur Bates Communicative Development Inventories (CDIs)[16] are standardized, parent-reported check-lists that assess language and communication in children ages 8-37 months. These checklists focus on children's' nonverbal gestures and early signs of language comprehension, and they are available in English and Spanish.
• Social-emotional skill acquisition will be measured with the Devereux Early Childhood Assessment (DECA),[17] a validated 33-item parent report of socio-emotional problems that is available in both English and Spanish.

• Shared reading and parent responsiveness will be assessed with the StimQ.[18] The StimQ is a parent-reported measure of the cognitive home environment for children that includes domains on shared reading (Reading scale) and responsiveness (Parental Verbal Responsiveness scale). We added 8 questions to supplement this survey. We also will implement the DialogPR[19], a parent report of shared reading quality. We will also conduct observations of parent-child interactions during a shared reading and a play activity to assess parenting strategies around reading. We plan to video- and audio-record these sessions using a video-conferencing software, after consenting the participant to this process. The Research Assistant will observe the parent-child interactions and assess responsiveness and other characteristics of the exchange.

The observations will be done virtually, over the computer or phone, and recorded using a video-conferencing software, so that our study team can: (1) code reading strategies and interactions and (2) have a supervising researcher code the same interactions to strengthen the reliability of the coding.

• Positive and negative parenting behaviors will be assessed through The Parenting Your Infant or Parenting Your Toddler surveys, derived from the Parenting Your Child[20] measure. The Parent

Discipline Questionnaire assesses negative parenting disciplining styles and includes two questions from the 2000 National Survey of Early Childhood Health.[21]

1.7 Drugs/Devices/Biologics

Not applicable

1.8 Specimen Collection

Not applicable

1.9 Data Collection

A. Primary Data Collection

- **Location**: Participants will be recruited from these community health centers: Eric B. Chandler Health Center and St. Peter's Family Health Center in New Brunswick, NJ; Jewish Renaissance Medical Center in Perth Amboy, NJ; Bristol Myer's Squibb in Plainsboro, NJ; and Robert Wood Johnson Medical Group at Somerset in Somerset, NJ; Participants of Arm 3 will be referred to Central Jersey Family Health Consortium's Connecting NJ for community resources.

- **Process of Data Collection**: All research activities will be conducted by Rutgers study staff. During COVID-19 restrictions, all activities will take place over the phone and via video-conference. If and when COVID-19 restrictions are eased, aim 1 research activities will take place at the community health centers. Clinicians at study sites will not be engaged in research activities as researchers. They will refer participants to Rutgers study staff. Aim 3 interviews will take place by phone or Zoom.

- **Timing and Frequency**: Data collection will occur at enrollment, after 9 months of the intervention, and after 18 months of the intervention (see activities and timeline table in section 1.10). Data on referrals will be sent to us at point of referral following enrollment and again at 9-months.

  Clinicians will be interviewed three times over the course of the intervention, at least 6 months apart, to represent the beginning, the middle, and the end of the intervention (which altogether is approximately 2 years).

  If clinicians do not respond to requests to be interviewed or decline to be interviewed, or are hired after interviewing has been completed, we will ask them if they would be willing to complete only the demographic/background survey.

  ROR experts and interested parties will be interviewed once for 30-60 minutes.

  Parents will be interviewed once for 60 minutes after their participation in surveys has concluded.

- **Procedures for Audio/Visual Recording**:
  At the 9- and 18-month visits, we will describe to the patient/participant that we would like to record a 6-10 minute session of this study visit using a video-conferencing software. The Research Assistant will provide the participant with our consent addendum, answer any questions the participant has, and ask the participant to verbally consent to the video- and audio-recording. If the participant consents, we will record the verbal consent in REDCap. If the participant does not consent to video-recording, we will ask if we may audio-record; if the participant does not consent to either video- or audio-recording, we will skip the assessment and move on to the next survey item.

We will save the video file in our restricted study folder on a secure server. The recording will only be accessed and viewed by other IRB-approved members of our study team. If the participant consents, we will ask the participant to angle the camera on their laptop or phone so that we can conduct and record the observation. Observations will be coded by study team members to describe the interactions between the parent-child pair. Once coded in REDCap by the team for these visual elements, the video will be deleted.

Office administrator and clinician surveys will be done in Qualtrics and downloaded onto a restricted folder on our restricted drive. Interviews that are recorded will also be saved in a restricted folder on our restricted drive.

ROR experts and interested parties will need to consent to be interviewed. The information sheet will include information pertaining to audio and/or visual recording.

Parents will need to consent to be interviewed. The information sheet includes information pertaining to audio- and/or visual recording.

- **Study Instruments**:

Baseline information: We will collect the following information at enrollment.

Demographic Information and Language Use will be collected using questions adapted from the Census, MEPs, and our previous work. This questionnaire includes a question about English proficiency, which will be assessed by asking parents "How well do you speak English?" with a 4 level ordinal response (very well, well, not well, not at all). We will consider a response of "very well" as proficient. This approach demonstrates good concurrent validity with comprehensive measures.[28]

Health literacy of parents will be assessed with the Short Assessment of Health Literacy[14] (SAHL), a validated health literacy assessment with good reliability in both English and Spanish speaking samples. The SAHL includes 18 items and takes approximately 3-4 minutes to complete.

We are including a Discrimination Questionnaire which asks a general question about whether the participant and child have ever been discriminated against because of race or ethnicity.

Process measure:

The Reach Out and Read (ROR) Receipt is a brief questionnaire on whether the primary caregiver and child were exposed to literacy promotion in the healthcare setting. Information of interest includes whether a healthcare professional (e.g. doctor, clinic/office staff) ever provided a children's book to take home, whether books were read to children in the waiting room, and whether a healthcare professional ever talked about reading to the child. If applicable, the survey asks for the frequency of any of these events occurring in the past. Questions are adapted from previous work.

Outcomes: We will use validated measures to assess child outcomes.

Language acquisition will be assessed using the Expressive One-Word Picture Vocabulary Test - Fourth Edition (EOWPVT-4) Spanish-Bilingual - Complete. The EOWPVT-4 (Spanish-Bilingual) is a norm-referenced assessment of how well children aged 2+ can name the objects, actions, or concepts presented in full-color pictures. RAs trained by Dr. Perez-Cortes and Jimenez will administer this instrument at the 18-month visit.

The MacArthur Bates Communicative Development Inventory (CDI)[16] is a measure developed by Fenson et al. to evaluate communicative skills in infants (between eight and eighteen months) and toddlers (between sixteen and thirty months). The short-form version of the measure consists of different forms for infants and toddlers that specifically assess words that the child only understands, only says, and both understands and says at the time of data collection.

Social-emotional skill acquisition will be measured with the Devereux Early Childhood Assessment (DECA),[17] a validated 33-item parent report of socio-emotional development. The DECA is a nationally standardized measure to assess social and emotional skill development in infants (one to eighteen months) and toddlers (eighteen to thirty-six months) Participants are asked to indicate on a 5-point Likert scale how often the child does certain behaviors. Different forms are used for infants and toddlers that ask for different behaviors.

Shared reading will be assessed with the StimQ.[18] The StimQ is a parent-reported measure of the cognitive home environment for children that includes domains on shared reading (Reading scale) and responsiveness (Parental Verbal Responsiveness scale). It is available in both English and Spanish and takes 10 minutes to administer. Internal consistency (α=0.88-0.93) and test-retest reliability (intraclass correlation coefficient=0.93) are excellent. We added 8 questions after this survey, which will not affect internal validity since we are not including these questions within the original. DialogPR[19] is a parent self-report survey to assess shared reading quality. This is an eight-item questionnaire that enables the parent to evaluate how often they discuss with their child what the book is about before reading it, how often they discuss the book's story while reading with their child, and how often they use prompts when reading with their child. We will also ask the participant if we can observe and video-record them reading and playing with their child for a 6-10 minute session.

Parenting Your Baby (PYB) – 6 Months & Parenting Your Toddler (PYT) – 18 Months are based on the Parenting Young Children (PARYC)[20] measure, which is designed to assess caregiving practices by measuring the frequency of different caregiving behaviors, the perception of such behaviors as an issue, and the degree to which the caregiver would like to change their practices. Each survey asks questions specific to 6-month old and 18-month old children.

The Parenting Discipline Questionnaire was modified from the 2000 National Survey of Early Childhood Health[21] and asks two questions about "negative parenting" technique, yelling/raising one's voice and spanking.

Media Use will be assessed using the ScreenQ-I/T 2.0,[27] to assess home media environment and child use of cellphones and visual media. We added one question to this to assess the language in which children view/hear media.

Mediators/moderators: We will collect information about different parenting styles and attitudes about reading and parenting. We will also collect information on different types of stress – parenting, economic hardship, and racial discrimination – that we have found in prior work affects the efficacy of reading interventions.

The Parent Reading Beliefs Inventory (PRBI)[22] was designed to understand the beliefs of parents on reading aloud to children. In the original survey with fifty-five items, participants are asked to indicate on a 4-point Likert scale how much they agree or disagree with statements concerning attitudes and beliefs with regards to reading. For this study, the PRBI was adapted to contain sixteen of the fifty-five items.

The Survey of Income and Program Participation (SIPP)[23] is conducted by the U.S. Census Bureau to gain insight into income and participation in government programs among

households in the U.S. For this study, the SIPP was adapted to only inquire about the use of different types of resources (e.g. food/nutrition support, income support, childcare assistance, etc.) used by the caregiver and the child in the past year. We adapted this for this study.

The Modified Physician-Parent Communication Survey[24] measures parent satisfaction with clinician services and their evaluations of physician-parent communication dimensions. This is a 15-item questionnaire measuring three dimensions of communication: interest, caring, and collaboration.

The Parental Stress Scale (PSS)[25] is an eighteen-item measure created to assess parental stress. For each item, participants are asked to indicate on a 5-point Likert scale how much they agree or disagree with statements on stresses related to parenting.

The Local Inventory of Needs and Knowledge (LINK)[26] survey was designed to enable participants to report their own health, their child's health, and their family's social needs and stressors. On different 5-point Likert scales, participants are asked to describe their and their child's health, how true certain statements concerning social needs were for their family, and how stressful meeting different social needs were for their family. The survey was modified and adapted for the purposes of the study.

- **Ethnographic Studies, Interviews, Or Observation**: We will use qualitative methods to understand factors that influence implementation from multiple perspectives for aim 3. Depending on COVID-19 restrictions, we hope to conduct observations in each clinic to gain insight into barriers, facilitators, and adaptations made to the ROR interventions. A trained RA will observe ROR infrastructure at clinics and ROR delivery during well-child visits for 1-2 day site visits at each clinic (~12 hours/site= 48 hours total). The RA will begin with descriptive unstructured observations that will gradually become more focused on ROR activities. Observations will attend to clinic workflow, who is involved in ROR, where ROR activities occur (e.g., where the books are stored, in well visits), and what ROR delivery entails. We also hope to make observations during study visits at the clinics. The RAs will maintain detailed field notes of these observations. Field notes will not include any identifying information about the clinic or individuals in the clinic. Nothing will be recorded by video or audio. Clinics will approve these visits and we will comply with their requirements.

  Research Assistants will also conduct observations of parents during shared reading and free play activities to assess if parents perform certain activities or common best practices for reading. Video recordings of the observations will be deleted once visual elements are coded in REDCap.

  Research assistants will also interview approximately 60 parents for one hour each over phone or Zoom. We have uploaded the interview guide for these interviews.

  ROR experts and interested parties will be interviewed once for 30-60 minutes over the phone or Zoom. The interview guide for these interviews has been uploaded.

- **Subject Identifiers**: The following identifying information may be collected to facilitate recruitment and retention and sharing of study materials/giftcard: parent name and phone number(s), parent email address, family mailing address, child name, child date of birth, and a back-up contact name and phone number. Including the other parent or legal guardian's name and phone number is optional. This identifying information will be stored separately from study data in a secure research drive or REDCap using a study ID number.

  Interview participants will be assigned a study ID as well, and one crosswalk between names and study IDs will exist for researchers to be able to contact clinician participants and track their longitudinal interviews. This one document will be stored in a restricted folder on the

restricted drive. Once the study is concluded, there will be no need for the crosswalk to exist, and thus it will be deleted.

B. Secondary Data Collection
Not applicable

1.10 Timetable/Schedule of Events

Table: Activities and timeline						
Activity	Mos. -3 to 0	Year 1	Year 2	Year 3	Year 4	Year 5
Project startup						
ClinicalTrials.gov registration	xxx					
Clinical expert committee meeting	x	x x x x	x x x x	x x x x	x x x x	x x x x
Short pilot version of the study	X					
Aims 1 and 2: Clinical trial and mediation analysis						
Participant recruitment		xxxxxxxxx	xxxxxxxxxxxx	xxx		
Outcome assessment (OA) #1*		xxx	xxxxxxxxxxxx	xxxxxxxxxxx		
OA #2^			xxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	
Data analysis			xxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	xxx
Aim 3: Process evaluation						
Quantitative data collection		xxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	
Observation		xxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	xxx
Data analysis		xxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	xxxxxx
Dissemination						
Abstracts & manuscripts			xxxxxxxxxxxx	xxxxxxxxxxx	xxxxxxxxxxxx	xxxxxxxxxxxx

* OA 1 will occur 9 months into the intervention.
^ OA 2 will occur 18 months into the intervention.

2.0 Project Management

2.1 Research Staff and Qualifications

Manuel Jimenez, MD, MS (Principal investigator). Dr. Jimenez is a developmental behavioral pediatrician and health policy researcher. Relevant to this proposal Dr. Jimenez has extensive experience collaborating with the Eric B. Chandler Health Center as well as in child development and intervention design and evaluation. He has been an investigator on multiple foundation and state grants.

Shawna Hudson, PhD. Dr. Hudson is the chief of the Research Division in the Department of Family Medicine and Community Health. She has extensive research experience in primary care settings.

Benjamin Crabtree, PhD. Dr. Crabtree is a Distinguished Professor in the Department of Family Medicine and Community Health. He has extensive research experience in primary care settings.

Usha Ramachandra, MD, is a pediatric clinician-researcher at RWJMS-RWJBH and practices at Eric B. Chandler Health Center. She has extensive experience in pediatric primary care, Reach Out and Read, and research.

Katie Devine, PhD. Dr. Devine is an assistant professor in the department of Pediatrics at Robert Wood Johnson Medical School and in the department of Medicine, section on Population Science, at Rutgers Cancer Institute of New Jersey. She designs and evaluates behavioral interventions and has advanced electronic health application use in interventions**.**

Silvia Perez-Cortes, PhD. Dr. Cortes is a professor of Spanish at Rutgers Camden College of Arts and Sciences, specializing in bilingualism and second language acquisition. Her research foci include language acquisition in early childhood.

Pam Ohman Strickland, PhD. – Dr. Ohman Strickland is an assistant professor and associate dean within the Rutgers University School of Public Health, Environmental Epidemiology and Statistics. She conducts research into statistical methods to evaluate environmental-health associations. She has collaborated extensively as a biostatistician with researchers in the Department of Family Medicine and Community Health.

Jennifer R. Hemler, PhD. – Dr. Hemler is a medical sociologist and research associate within the Department of Family Medicine and Community Health. She has experience conducting mixed-methods research in primary care.

Alicja Bator, MPH – Ms. Bator is a Research Teaching Specialist within the Department of Family Medicine and Community Health. She has extensive experience as a biostatistician and research coordinator.

Daniel Lima – Mr. Lima has experience working with the study population in a research context. He is bilingual in English and Spanish.

Kevin Guerrero – Mr. Guerrero is a medical student at Robert Wood Johnson Medical School. He identifies as first generation Mexican-American and is fluent in Spanish. His main interest is to pursue a career in medicine and be able to serve the low-income minority community. He will be assisting with delivering surveys.

Pablo Colon – Mr. Colon is a medical student at Robert Wood Johnson Medical School and is fluent in Spanish. His previous work focuses on health disparities in minority communities. He will be assisting with delivering surveys.

Naomy Azcona – is bilingual and will be helping with recruitment and assessments. She has experiences working with vulnerable populations.

Lilian Mekhail, MD, a pediatric fellow at RWJMS, will be helping recruit ROR experts and other interested parties for interviews for Aim 3.

Arianny Isabel – Ms. Isabel is a Rutgers University graduate who majored in Biological Sciences with a double minor in Psychology and Latino & Caribbean Studies. She will be acting as a research assistant. She is bilingual and will be helping conduct parent surveys and interviews.

Juline Hanna – Ms. Hanna is a medical student at RWJMS who will be working on the process evaluation conducting interviews of ROR experts, analyzing data, and performing basic research duties.

Nicolas Rodriguez – Mr. Rodriguez is a medical student at RWJMS who will be assisting in data analysis.

Jennifer Dillon, an NP at RWJMS Dept. of Pediatrics, will help with data analysis.

Karen Melendez Alas – an undergraduate at Rutgers University, is bilingual and will perform basic research activities.

Nimrat Kaur – an undergraduate at Rutgers University and part of the Child Health Institute Honors College Program, is bilingual and will perform basic research activities.

Ysabela Perez Colon, a Rutgers graduate, is joining the team as a research assistant. She is bilingual and will be helping perform basic research duties, including conducting consent and outcome assessments.

Debosree Datta – a Rutgers Undergraduate in the School of Arts and Sciences who has experience working in clinics, with healthcare organizations, and with preschool children, will be joining the team as a research assistant/intern and will be performing basic research duties.

Johan Ayala – a graduate from Brown University with a Bachelor of Science in Biology, is a bilingual pre-medical student who has experience in qualitative research. He will be performing research assistant duties.

Regina Fasano, PhD – Dr. Fasano's research includes early childhood linguistic, social, and cognitive development, with a particular focus on children with developmental delays and disabilities. She is joining us a research associate and will conduct general research responsibilities and be the IRB study coordinator

Geeta Kersellias, MPH, MBS, CPH – Ms. Kersellias is a DrPh student in the School of Public Health at Rutgers University and will be assisting with data analysis.

Travis Anane – Mr. Anane is an undergraduate student who has working proficiency in Spanish and a background in assisting another research study.

Keith Miller – Mr. Miller is currently an MPH student concentrating in epidemiology. He has experience working in outcomes research and statistical analyses.

2.2 Research Staff Training

All study team members have completed CITI training. Study team members have reviewed the protocol in its entirety, discussed the protocol with the principal investigator, and contributed to its development. Accountability with duties and procedures will be maintained through weekly team meetings.

2.3 Resources Available

The risks posed by this study are not greater than minimal. The principal investigator (a board certified developmental behavioral pediatrician) and investigative team have extensive experience conducting pediatric patient oriented research. The community health centers manage a high volume of pediatric patients

2.4 Research Sites

Rutgers study team members will be responsible for all research activities. No personnel at sites will be engaged in the research activities. The community health centers from which we will be recruiting participants are:

Rutgers Robert Wood Johnson Medical School Eric B Chandler Health Center (Chandler)
Jewish Renaissance Medical Center (JRMC)
Bristol Myers Squibb Community Health Center (BMS)
St. Peter's Family Health Center (St. Peter's)
Robert Wood Johnson Medical Group at Somerset (Somerset)

(Please see attached letters of cooperation for non-Rutgers community health centers.)

We will also be working with Central Jersey Family Health Consortium for their Connecting NJ referral services.

3.0 Multi-Center Research

Not applicable

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Due to COVID-19, clinicians will refer patients to us who have self-identified as Hispanic/Latino/a/x and who have a child aged 6-12 months. Once COVID-19 restrictions are lifted, we will utilize mostly in-person recruitment strategies including clinician referral and approaching participants in the waiting room.

Clinicians will be identified from participating clinics for surveys and interviews. Any clinician working at these clinics is eligible to participate in interviews. If clinicians from these clinics decline to be interviewed or do not respond to be interviewed or are new to the clinic after we conduct a round of interviews, we will ask by email if they would be willing to complete the 5-minute demographic/background survey.

ROR experts and other interested parties will be identified on ROR websites and by our advisory committee; we will ask each participant to recommend others for us to interview based on having knowledge and experience in or of ROR implementation.

B. Recruitment Details

Because Chandler and Somerset are Rutgers RWJMS clinics with which the PI is affiliated, clinicians will notify potential participants about this study by using our recruitment flyer and asking them if they would agree to have their information forwarded to us. If so, clinicians will send us their name and contact information via a HIPAA-compliant email platform. If clinicians prefer, they may use our Information Release Form to ask participants for their permission and send us participant contract information. The clinician will not answer questions about the study other than what is included on the flyer and will refer the potential participant to the study team for questions. A study team member will contact potential participants to screen them for eligibility, conduct the consent process, and enroll them in the study.

As the other clinics, JRMC and BMS, are outside the Rutgers RWJMS system, clinicians will briefly explain the study to potential participants using our recruitment information sheet, and will then ask the potential participant if they are interested in learning more about the study from the Study Team; if they are interested, the clinician will ask if they may send the potential participant's contact information to the Study Team and will ask the potential participant to fill out and sign our Information Release Form.

In the event we are able to visit clinics in person after COVID-19 restrictions have been lifted, trained bilingual research assistants will work closely with clinical staff to identify potential participants.

All study documents including recruitment flyers (see attached) will be written in accessible language with low literacy burden in consultation with our clinical expert advisory committee and parents. Study documents will be translated into Spanish using forward back translation and will be reviewed by bilingual members of the study team.

Interview participants will be recommended to us from the clinics or from our advisory committee. We will send them the information sheet about the study and ask if they would like to participate in the interview.

C. Subject Screening

Trained research assistants will screen participants for eligibility using a checklist (see attached)

- **Inclusion Criteria**

  The inclusion criteria for parent participants in all aims will be: (1) primary caregiver of a child age 6 months to 12 months, (2) identifies as Latino/a/x, (3) primary language English or Spanish, (4) cell phone ownership, (5) age 18 years or older (6) willing to receive text messages, and (7) willing to accept randomization. Inclusion criteria for children will be age 6-12 months.

  We will also be interviewing clinicians from our study sites as part of our process evaluation. All clinicians who administer ROR will be eligible to participate in interviews. We will also ask an office manager or administrator to complete a very short practice survey.

  ROR experts and others will be recommended based on experience and knowledge of ROR implementation.

- **Exclusion Criteria**

  Individuals unable to provide informed consent will be excluded. Individuals who plan on changing their pediatric clinic within the study (i.e., because they are moving out of the country) will be excluded. Children with multiple congenital anomalies or genetic disorders and previously identified developmental delays will be excluded.

  At the 9- and 18-month surveys, we will ask parents to participate in an audio- and/or video-recorded reading and free play exercise with their child. We will provide an additional consent process at this time. Participants may decline to participate in the audio- and/or video-recording of parent-child observations but still remain in the study. If participants decline to participate in the audio- and/or video-recording of the reading and free play exercises, we will skip these exercises and continue the rest of the assessment and complete the other survey items.

  Participants who agree to participate in surveys and interviews but decline to be video- and/or audio recorded may remain in the study; our researchers will take notes in these instances.

4.2 Secondary Subjects

Not applicable

4.3 Number of Subjects

A. Total Number of Subjects

We expect to enroll 630 parent-child dyads. To achieve this sample size, we anticipate screening 1,500 children for eligibility over a 2-year period. Interviews with parents will not increase this sample size as we are interviewing parents who have completed the intervention.

B. Total Number of Subjects If Multicenter Study

Not applicable

C. Feasibility

The CHCs each manage a large volume of children under the age of 1. For example, each year 500 unique children under age 1 are seen at Eric B Chandler Health Center.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  The informed consent process will take place verbally over the phone or via video-conference, and we will follow up by mailing or emailing study materials to the participant for their records. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. We will document that participants have consented. Once COVID-19 restrictions are lifted, the informed consent process will take place at the participating clinics.

  At the 9- and 18-month survey visits, we will ask participants to consent to having us video- and audio-record a 6-10 minute reading and free play session with their child. This is voluntary. We will provide them with an addendum to the original consent, review with them, ask if they have any questions, answer them thoroughly, and then ask them to verbally consent. If they do not consent to being video- and/or audio-recorded, we will not conduct the observation.

  For ROR experts, clinicians, and other interested parties participating in interviews, we will email them a copy of our study information sheet ahead of scheduling the interview and will review the information sheet with them. Interviewers will answer any and all questions before asking participants to provide inform consent for the interview and to be recorded.

  For online background/demographic surveys, clinicians will receive an online consent form before being directed to the online survey. Study personnel will email participants with recruitment request and a link to a consent form/information sheet; if they consent, they will be directed to the online survey. They will be able to download a copy of the consent form/information sheet for their records.

- **Ongoing Consent**
  The research team will ensure participants understand that participation is completely voluntary, pause on multiple occasions to elicit questions, and provide several opportunities during the process to ask questions and also provide contact information for the principal investigator and IRB should participants have questions at any time during the study.

- **Individual Roles for Researchers Involved in Consent**
  CITI-trained study team members, Mr. Lima, Mr. Guerrero, Mr. Colon, Ms. Minetti, Ms. Azcona, Dr. Mekhail, Ms. Isabel, Ms. Hanna, Ms. Alas, Ms. Colon, Ms. Datta, Mr. Ayala, Mr. Anane and Dr. Fasano will obtain informed consent.

- **Consent Discussion Duration**
  The time devoted to the informed consent process will vary based on the individual needs of each participant to ensure that all elements of the informed consent process are covered and all questions are answered. Based on past experience we anticipate this process will take approximately 10 minutes.

- **Coercion or Undue Influence**
  The study team will employ multiple strategies to minimize the possibility or perception of coercion or undue influence. The study team will ensure that potential participants are aware that participation is completely voluntary, provide multiple opportunities to decline participation, and remind potential participants that their services will not be affected in any form based on their participation or lack thereof.

- **Subject Understanding**

Mr. Lima, Mr. Guerrero, Mr. Colon, Ms. Minetti, Ms. Azcona, Ms. Isabel, Dr. Mekhail, Ms. Hanna, Ms. Alas, Ms. Colon, Ms. Datta, Mr. Ayala, Mr. Anane and Dr. Fasano will ask if the participant has questions on multiple occasions and provide answers to the satisfaction of the participant. As part of the consent process, the team member obtaining consent will ask questions to ensure the participant (1) understands the information provided (2) does not feel pressured by time or other factors to make a decision (3) understands that there is a voluntary choice to make (4) is capable of making and communicating an informed choice.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  We will not waive consent. We are asking for verbal consent for the pilot and for the study during COVID-19, over the phone/videoconference. Once COVID-19 restrictions are lifted and we can resume recruiting in health centers, we will return to using our signed consent form previously approved by this IRB. We are asking for verbal consent to be video-recorded at the 9- and 18-month visits during a 6-10 minute session of reading and play with their child. We are asking for digital consent for practice administrators to fill out surveys. We are asking for digital consent for clinicians to fill out surveys and participate in interviews. We will be asking for verbal consent to visually and/or audio record interviews and we will ask clinicians to repeat their consent on the recording.
- **Destruction of Identifiers**
  Not applicable
- **Use of Deception/Concealment**
  Not applicable

C. Documentation of Consent

- **Documenting Consent**
  We are requesting a waiver of written consent. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. Staff will document verbal consents and save the document in REDCap, a restricted and HIPAA compliant software program. We will save pilot data in REDCap and/or in a restricted folder that only the core study team members will have access to. When in person, participants will be asked to sign the attached informed consent document, which will then be stored in a secure, lockable filing cabinet.

- **Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)**
  During COVID-19, we will be conducting informed consent via phone or videoconference and will be asking for verbal consent, which we will document in REDCap. Study staff will read and when possible display the consent form on videoconference; we will send the consent form to the participant via email or mail, per their preference. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. When we are able to conduct informed consent in person, we will be using our approved written-consent form.

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  Parents will provide permission for participation of their children.
- **Non-Parental Permission**
  Not applicable.
- **Assent Process**
  Based on children's chronological age for this study (6 to 12 months old) assent is not developmentally appropriate. However, study staff will ensure children's comfort when participating in assessments.
- **Documentation of Assent**

Not applicable

- **Reaching Age of Majority During Study**
  Not applicable

B. Wards of the State

Not applicable

- **Research Outside of NJ Involving Minors**
  Not applicable

C. Non-English-Speaking Subjects

Participants who speak English or Spanish will be included in this study

- **Process for Non-English-Speaking Subjects**
  Participants who identify Spanish as their preferred language will be recruited. Research assistants speak Spanish fluently and will use translated informed consent documents.
- **Short Form Consent for Non-English Speakers**
  Not applicable

D. Adults Unable to Consent / Cognitively Impaired Adults (for interventional studies)

Not applicable

- **NJ Law-Assessment of Regaining the Capacity to Consent**
  Not applicable.
- **Capacity to Consent**
  Not applicable.
  a. **NJ Law-Selecting A Witness**
     Not applicable
  b. **Removing a Subject**
     Not applicable.

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

No additional expenses for participants are anticipated. However, for those receiving text messages, standard message rates apply with receiving and or sending text messages if participants do not have an unlimited text message plan.

B. Compensation/Incentives

Parent participants will be compensated for their time. Participants will receive a $50 retail gift card at the initial visit and an additional $50 gift card after completing 2 follow up visits occurring at 9 months and 18 months (Total=$150). Participants will be texted/emailed links to electronic gift cards and/or given the plastic gift card in person.

Clinicians and ROR experts will not be compensated for their time.

C. Compensation Documentation

Participant compensation will be managed using an Excel spreadsheet. A study team member will document the study ID and gift card number which will be reviewed by the PI.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  The potential risks to the participants will be minimal. All study personnel will receive appropriate training in human subjects research and patient confidentiality. During assessments there will be the potential for psychological discomfort due to the personal nature of questions asked and for the potential loss of confidentiality. This risk is minimized

by conducting assessments and interviews in private settings. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms. Participants will be reminded that participation is completely voluntary and they may withdraw from the study at any time.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  Not applicable.
- **Other Foreseeable Risks of Harm**
  There is a minor risk of loss of confidentially. This risk is minimized by measures taken by the PI and the study team to ensure confidentiality. Risks are reduced by using secure files; storing master list files on secure, password-protected research servers and computers; and storing data files on REDCap, a secure, web-based application used for human subjects research studies. Whenever possible data will be directly entered into REDCap to minimize the risk of breach of confidentiality.
- **Observation and Sensitive Information**
  For qualitative data field notes will not include identifiable data. Video recordings of parent-child interactions will be deleted once coded.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
Not applicable.

C. Risks of Harm to Non-Subjects
Not applicable.

D. Assessment of Social Behavior Considerations
Not applicable

E. Minimizing Risks of Harm
The study team will employ several measures to minimize potential risks. Only trained study team members supervised by the PI will have contact with participants and access to the study data. It is possible that participants may feel uncomfortable during assessments. Participants will be reminded that they may discontinue participation at any time. There is also a small risk of breach of confidentiality. Participants will receive a unique code number and names will not appear on data. The key list linking participant identification with numeric codes will be locked in a secure filing cabinet and the key will be destroyed when data analysis is complete. All data will be stored on password protected computers or REDCap a secure server. When possible, information will be directly entered into REDCap.

- **Certificate of Confidentiality**
- We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms.
- The NIH Certificate of Confidentiality does not supersede reporting that federal, state, or local laws require, such as laws that require reporting of child abuse. Participants will be advised during the consent process for audio- and/or video-recording that there are instances where a breach of confidentiality is required by law. These are instances where suspected harm is occurring to a child or other vulnerable person.
- **Provisions to Protect the Privacy Interests of Subjects**
  Only trained study team members will perform study procedures. Participation is completely voluntary and participants can discontinue their participation at any time.

F. Potential Benefits to Subjects
All participants will receive the standard Reach Out and Read intervention an evidence-based intervention and a pediatric care standard. Although not guaranteed participants may receive additional benefits from the other study arms.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

The following identifying information will be collected to facilitate recruitment and retention: child name, child date of birth, parent name, parent phone number, parent email address, family mailing

address. Identifying information will be stored separately from study data in a secure research drive or REDCap using a study ID number.

5.2 Family Educational Rights and Privacy Act (FERPA)

Not applicable

5.3 NJ Access to Medical Research Act (Surrogate Consent)

Not applicable

5.4 General Data Protection Regulation (GDPR)

Not applicable

5.5 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations

Given that early childhood experiences are critical for school readiness and the importance of parent behaviors including shared reading for development and behavior beginning in infancy, this proposal includes both children and their parents as subjects. No greater than minimal risk to participating children is presented in this study. Children will only participate with the permission of their parent or guardian as outlined above. Given that all children will be age 6 to 12 months of age at enrollment assent is not developmentally appropriate.

6.0 Data Management Plan

6.1 Data Analysis

1. Enrollment: We will recruit 630 parent-child dyads (210 per arm) over a 24-month time period. We expect that 80% of the 630 enrolled parent-child dyads will complete the study, leaving 525 parent-child dyads (175 in each arm).

2. Sample size and power:

630 parent-child dyads (210 per arm) will be sufficient to achieve 80% power to detect a 0.3 standard deviation (SD) difference in the primary endpoints language scores on the EOWPVT-4 and social-emotional skill scores on the DECA at 18 months between (1) ROR + texts and ROR only and (2) ROR + texts + Central Intake and ROR + texts, assuming approximately 20% attrition based on our past work[29] and using 0.05 significance level. An effect size of 0.3 SD difference would be clinically meaningful since it would be associated with a detectable difference in later cognitive functioning, based on work from a prospective cohort.[30] The proposed sample size will provide 99.9% power to detect a 0.6 SD difference between the community resource arm and ROR only, based on the expected additive effects of the text message and enhanced access to poverty-reducing resources.

3. Analysis:

Distributions of baseline characteristics will be summarized overall as well as by randomization group. We will assess the distribution of outcome data using descriptive statistics to check the assumption of normality for continuous variables. We will estimate mean outcomes for each treatment group as well as mean differences between groups (with confidence intervals). If any continuous outcomes are skewed, we attempt log-transformation or other to stabilize the variance and normalize distributions.

For aim 1, analysis will follow the intention to treat principle, in which participants are analyzed based on their group assignment, whether or not they receive the strategies for all outcomes. Because of the multiple, potentially highly correlated outcomes, the step-down minP method (a re-sampling approach), will be used to assess the effects of treatment[31] across outcomes and timepoints within each domain (language development, social-emotional development, and parenting). We will use ANOVAs to evaluate treatment effects on adjusted outcomes. Specifically, for outcomes with more than one post-treatment timepoint and a baseline assessment, we will calculate individual- and baseline-adjusted outcomes from linear models with random individual-specific intercepts (random effect) and treatment and baseline as fixed effects. Then, the adjusted outcome is estimated as the observed outcome minus the best linear unbiased predictor (BLUP) of individual-specific intercept and baseline contribution. For outcomes with one post-treatment timepoint and a baseline assessment, a baseline-adjusted outcome

will be estimated from ANCOVA results as the observed outcome minus the estimated intercept and baseline contribution. The differences in means from ANOVAs focused on these adjusted outcomes will estimate treatment effects. For secondary outcomes, statistical significance will be set at $p < 0.05$ without adjustment for multiple comparisons. For language outcomes, we will adjust for child age and sex in sensitivity analyses.

For the mediation analyses in Aim 2, we will examine the extent to which the home literacy environment mediates the effect of the interventions on language skill and social-emotional skill acquisition using the product of coefficients method with each outcome at each post-intervention timepoint individually.[32] We will calculate bootstrap bias-corrected confidence intervals (n=5,000) to estimate the proportion of treatment effect explained via the home literacy environment. While we expect the effect of the ROR + text messages (arm 2) intervention will mainly operate through the home literacy environment (parent investment) based on our conceptual framework, we expect that the ROR + text + Connecting NJ (arm 3) intervention will also have effects on parenting stress and other responsive parenting interactions (parental verbal responsiveness) through increased access to poverty-reducing community resources accounting for the greater hypothesized impact. We will test this more complex conceptual framework based on an adaptation of the Gershoff model using Structural Equation modeling without latent factors.

For aim 3, the mixed methods approach will allow us to systematically compare data on intervention implementation with the perspectives of parents and clinicians in an ongoing manner. Integration of quantitative and qualitative data will occur at the design, methods, and reporting levels. We will use a convergent design in which we collect quantitative data on key intervention components in the same time frame as we conduct observation (if possible) of study visits.

Parent-child observations will be analyzed by the study team, led by Dr. Silvia Perez-Cortes. The observations will be coded according to parent-child interactive behaviors (did expected behaviors occur or not).

Practice and clinician surveys and clinician interviews will be analyzed using qualitative methods to identify changes and adaptations to ROR implementation protocols over time. The evaluation aims to determine what was implemented, how it was implemented, and what changes occurred to implementation over time. We also seek to understand how clinic context affected implementation. These qualitative findings will help inform our quantitative patient-reported outcomes.

6.2 Data Security

The study team will employ several measures to secure data. Only trained study team members supervised by the PI will have contact with participants and access to the study data. ALL participants (parent-child pairs, practice administrators, and practice clinicians) will receive a unique code number and names will not appear on data. The key list linking participant identification with numeric codes will be locked in a secure filing cabinet or digital folder and the key will be destroyed when data analysis is complete. All data will be stored on password protected computers or REDCap or a secure server/restricted folder. When possible, parent survey information will be directly entered into REDCap. Practice administrator and clinician survey data will be entered into Qualtrics and downloaded into a document and saved in a restricted folder on a secure drive. Interview recordings and transcripts and other documents from the interviews (notes, process maps) will also be saved on this folder. The research study data will be stored for 6 years after the study completion. Video recordings of the parent-child interactions will be deleted after they are coded in REDCap.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

1. Overall framework for safety monitoring and information to be monitored: The principal investigator (PI) and study team will implement a data and safety monitoring plan. The proposed clinical trial presents minimal risk to participants. For the proposed study, we will utilize standard Rutgers procedures and infrastructure for data and safety monitoring. All study team members have completed

or will complete certification in the protection of research participants before the beginning of the study. We will monitor quality assurance and participant confidentiality throughout the study as well as adverse events. We will also convene a Data Safety and Monitoring Board (DSMB) to ensure the safety of our study participants. The specific elements of our plan are described below. We have an NIH Certificate of Confidentiality, which will be issued automatically, and we have included this language in our consent forms.

2. Frequency of monitoring: We will implement specific monitoring procedures at regular intervals concerning quality assurance and participant confidentiality. We describe procedures for monitoring and reporting of adverse events further below on this page.

a. Weekly team meetings: We will utilize weekly team meetings to monitor quality assurance and confidentiality procedures. All participants will be screened for eligibility using a checklist created for this study and the PI will audit accrual to ensure that participants meet eligibility criteria. In addition, the PI will regularly audit the study files to ensure that questionnaires and assessments completed by participants contain all study items. In order to protect confidentiality all data will be numerically coded and information linking the numeric codes to the participant's name will be kept in separate secured files (e.g., cabinet in a secured office or secure research drive). In addition, computer data files will be stored on password-protected computers and communication among study staff will use participant code numbers, not names or other identifiers.

b. Annual and interim IRB monitoring: After initial approval, the protocol will be subject to annual review by the RBHS IRB to ensure adherence to the scientific and ethical aspects of the proposal.

3. Adverse event monitoring and reporting: We will implement a specific set of procedures concerning the reporting of adverse events as outlined below.

a. Regular and repeated assessment of adverse events. While unlikely, any adverse events from the study's literacy promotion interventions will be closely monitored and assessed throughout the duration of the project. Opportunities to do so include the ongoing process evaluation and participant follow-up visits. These contacts will be made in-person or by telephone by trained study team members.

b. Regular and repeated reporting of adverse events: All adverse events and unanticipated problems will be reported to the PI upon discovery. All reported adverse events will be reported to the IRB and DSMB (see below) within 48 hours of discovery; all such events will be reported to study co-investigators and staff and to NIH within 72 hours of discovery. Adverse events will also be discussed at weekly meetings between the PI and study team.

B. Data/Safety Monitoring Board Details

A data and safety monitoring board (DSMB) will be used for this study. The specific aspects of the DSMB for this study are as follows:

a. The DSMB will consist of 3 members: a physician-scientist from Rutgers Robert Wood Johnson Medical School who will serve as DSMB Chair; a biostatistician from the Rutgers School of Public Health; and a behavioral scientist from Rutgers Robert Wood Johnson Medical School. All members will have expertise in guidelines and policies concerning the protection of research participants.

b. The DSMB will meet twice per year to review study data concerning recruitment, randomization, retention, compliance, form completion, inclusion, intervention effects, and safety. In addition, the DSMB will: (1) identify specific safety concerns for participants and communicate these to the study PI; (2) consider the need for additional data concerning participant safety; (3) consider the rationale for the continuation of the study; (4) provide a written report concerning the protocol to the IRB and study PIs; and (5) review manuscripts reporting study results prior to submission.

c. Any safety concerns will result in suspension of the study however given the nature of the interventions and that study risks are not greater than minimal the probability of this occurring is very low.

6.4 Reporting Results

A. Individual Subjects' Results

Study participants will not receive survey assessments, but RAs will discuss the intent, use, and meaning of the surveys with participants in more detail than when originally describing the study if asked.

B. Aggregate Results

Aggregate results will be shared with health center leadership and their community board as well as through community presentations including our community advisory board.

C. Professional Reporting

Research findings will be shared with the scientific community through preparation of a manuscript.

D. Clinical Trials Registration, Results Reporting and Consent Posting

We will register the trial through ClinicalTrials.org and comply with reporting requirements required for this study.

6.5 Secondary Use of the Data

As required by the NIH data sharing policy, the principal investigator will respond to bona fide requests from researchers for de-identified data as follows:

1) Research resources and information developed in this project will be made available to the scientific community for non-profit research purposes in accordance with and where required by relevant NIH Grants Policy Statement and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts.

2) Data sharing plan: The data sharing plan for the proposed research is based on the NIH Data Sharing Policy and Implementation Guidance. The proposed research will include longitudinal data from up 630 parent-child dyads. The final dataset will include parent-reported demographic and behavior data as well as direct assessments of child development. Safeguarding the privacy of participants will be of the highest priority. We will make the data and associated documentation available to users conducting non-profit research only under a written data-sharing agreement. Individuals requesting data under the agreement will commit to (1) using the data only for research purposes and not to identify any individual participant; (2) securing the data using appropriate computer technology; and (3) destroying or returning the data after analyses are completed. The dataset will be stripped of all identifiers prior to sharing.

Only the PI will have access to data that is audio- and/or video-recorded for future research, as these data cannot be rendered fully de-identified.

3) Criteria, mechanisms and timetable: Written request by individuals for information pursuant to non-profit research will be made to Dr. Jimenez. Bona fide requests for information will be provided within a reasonable length of time in accordance with and where required by relevant NIH Grants Policy and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts.

7.0 Research Repositories – Specimens and/or Data

Not applicable

8.0 Approvals/Authorizations

See letters of cooperation from participating CHCs.

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