Title:	**Literary Promotion Using Automated Hovering to Improve Development in Young Low-Income Children**
Short Title	**Literacy Promotion using Automated Hovering**
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ABBREVIATIONS AND DEFINITIONS OF TERMS

ROR	Reach Out and Read
LDI	Leonard Davis Institute
AH	Automated Hovering
NICHD	National Institute of Child Health and Human Development
StimQ	Measure of Cognitive Stimulation Provided in the Home
PSI-SF	The Parenting Stress Index-Short Form
CDI	MacArthur Communicative Development Inventory
DECA	Devereux Early Childhood Assessment

ABSTRACT

Context:

Early childhood is a sensitive period in which young children develop language and socio-emotional skills foundational for school readiness. Unfortunately, poor vulnerable children experience disparities in these critical areas of development. Parent-child shared reading can help ameliorate these disparities, yet low-income parents do not consistently engage in this activity. Behavioral economics approaches utilizing automated hovering (AH) have the potential to increase parent-child shared reading through text messages and financial inducements.

Objectives:

1) To assess the feasibility and acceptability of 3 novel AH interventions of increasing complexity hypothesized to increase the frequency of parent-child shared reading.
2) Explore relevant outcomes related to parenting stress, the home reading environment, and language and socio-emotional development.

Study Design:

The study design has two phases, Phase 1 and Phase 2. Phase 1 is a brief, rapid cycle design process. Phase 2 is a prospective, randomized comparative group trial to test the effects of AH approaches to increase parent-child shared reading.

Setting/Participants:

We plan to recruit 3-4 urban CHOP-affiliated pediatric practices from CHOP's Pediatric Research Consortium (PeRC) to participate in the study. These practices care for a diverse, complex urban population and have onsite social workers to assist with family crises.

A total of 65 eligible children and their parents will be recruited from participating practices to achieve a diverse sample of children. Ten will participate in Phase 1 and 55 will participate in Phase 2. Inclusion and exclusion criteria for Phase 1 will be the same as Phase 2. Children will be eligible to participate if they are 6-24 months old, and have a parent with daily access to a smart phone in order to receive and send text messages. Children born <35 weeks EGA or with congenital anomalies or genetic syndromes that place them at high risk for developmental disabilities will be excluded.

Study Intervention and Measures:

Ten participants in phase 1 will undergo an audio-recorded qualitative interview that will be used to develop coaching tips for phase 2.

Forty-five participants in phase 2 will be randomized to receive one of the 3 AH interventions: daily text message reminders, daily text message reminders with coaching or daily text message reminders with coaching and weekly lottery entries. The weekly lottery is related to principles of behavioral economics so that participants in this group will be externally motivated. The lottery is testing a methodology and is not a non-permissible form

of payment. There will be 15 participants per group to adequately assess feasibility and acceptability.

The result of this application would be expected to inform future R01 applications on the effects of AH to improve parent-child shared reading in a larger and more diverse population of low-income children.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	Screening/ Study Visit 1 (Baseline)	Intervention Period (8 weeks)	Follow-up Study Visit (8-12 weeks)
Phase 1			
Informed Consent	X		
Review Inclusion/ Exclusion Criteria	X		
Audio-recording of Qualitative Interview	X		
Phase 2			
Informed Consent	X		
Review Inclusion/ Exclusion Criteria	X		
Randomization	X		
8 Weeks of Daily Text Messaging +/- Coaching +/- Weekly Lottery		X	
Demographics	X		
StimQ-Read	X		X
PSI-SF	X		X
CDI			X
DECA			X
Satisfaction Rating			X
Parent Questionnaire			X

1 BACKGROUND INFORMATION AND RATIONALE

Early childhood is a sensitive period in which young children develop foundational skills necessary for communication.[1] Early stimulation of brain centers involved in language processing promotes the development and sustainment of critical neuronal connections leading to growth and proficiency in language and social functioning.[1] Unfortunately, language and socio-emotional delays are common among children under 3 years of age,[2] particularly for children residing in impoverished communities.[3] These delays contribute to poor educational and functional outcomes later in childhood and represent an important cause of disparities in child educational achievement.[4] Lifetime costs for individuals with resulting disabilities have been estimated to exceed $60 billion in 2003 U.S. dollars.[5] The etiology of these delays are multifactorial but have been associated with deficits in early parent-child verbal interactions.[6,7]

Parent-child shared reading represents an important source of language stimulation that can enhance language and socio-emotional development in young vulnerable children and help mitigate disparities in later educational achievement.[8] Previous studies have found that parent-child shared reading is associated with improved language functioning, better school performance, less harsh parenting, and fewer disruptive behaviors especially for children from low-income families.[9-12] Yet parents of young children from low-income communities do not consistently engage in reading activities with their children until they are older, due to numerous barriers such as lack of time, lack of understanding of importance, difficulty developing daily reading habits, stress and fatigue, and competing priorities.[13] From an economics viewpoint, these barriers can impose a time bias that discounts future language and socio-emotional benefits in favor of the current costs of shared reading.

Early shared reading strategies, such as Reach Out and Read (ROR) and Imagination Library, promote parent-child shared reading and distribute board books to low-income children.[8,14] These strategies have demonstrated greater interest in shared reading and improved child language development compared to usual care among poor children and their families. However despite these beneficial effects, low-income children and their families engaged in these programs have only shown modest improvements in the frequency of shared reading and still lag behind their higher income peers in language development.[15]

1.1 Introduction

The overall goal of this LDI pilot grant proposal is to incorporate behavioral economics approaches using automated hovering (AH) to improve the frequency of early parent-child reading behaviors among low-income families. Such approaches have previously shown benefit in medication adherence, smoking cessation, immunization rates, health care utilization, and weight management and have the potential to shape parent-child reading behaviors and improve language and socio-emotional development in young children.[16-21] This application addresses the care of vulnerable populations, one of LDI's four priority research areas. If successful, behavioral economics approaches can be incorporated into current early literacy promotion strategies to maximize their potential and further improve early language and socioemotional development. For example, children participating in ROR at participating pediatric practices can be signed up to receive automated text message reminders with or without financial inducements at the same time as they receive a board book and reading promotion counseling from their pediatric clinician at a corresponding well child visit.

1.2 Name and Description of Intervention

The intervention will incorporate behavioral economic approaches utilizing AH to improve frequency of early parent-child shared reading through text messages. The intervention consists of daily text messages for 8 weeks in 3 AH intervention groups. The text messages were part of the aforementioned trial on early literacy promotion (see Appendix 1).

Group 1 of the program will consist of daily text messages on shared reading, which will be sent to participants using the Way to Health Platform. Participants will be asked to reply to the text message on daily shared reading activities including the titles of the books and time spent reading (see Appendix 1).

Group 2 will consist of Group 1 plus personalized coaching. Personalized coaching content will be made available to participants through links in the text messages.

Group 3 will consist of Group 2 personalized coaching plus availability of a weekly lottery. The lottery is related to principles of behavioral economics so that participants in group 3 will be externally motivated. The lottery is testing a methodology and is not a non-permissible form of payment. Participants who report back that they read on a particular day will be entered into a weekly drawing to receive $20. Each reported daily reading behavior will provide a single lottery entry so that participants who report they read all 7 days in a given week will have 7 entries in the weekly drawing. Lottery entries will begin on Mondays and close at 12:00 AM on Sundays for all 8 weeks of the program. The following Monday morning the lottery will be drawn. The participants in Group 3 will begin their 8- week intervention the first Monday after enrollment.

1.3 Compliance Statement

This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonization. All episodes of noncompliance will be documented.

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

2 STUDY OBJECTIVES

Our long-term goal is to test the effects of AH approaches to promote child language and socio-emotional development. As such, we will incorporate behavioral economic approaches using automated hovering (AH) to improve the frequency of parent-child shared reading in low-income children and help ameliorate disparities for school readiness.

2.1 Primary Objective (or Aim)

Specific Aim 1: To determine the feasibility and acceptability of automated hovering of varying intensity designed to improve the frequency of parent-child reading behaviors among low-income families.

2.2 Secondary Objectives (or Aim)

Specific Aim 2: To explore differences in reading frequency, the home reading environment, parenting stress, and child language and socio-emotional development by the intensity of the automated hovering strategy among low-income families.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

To be eligible to participate, children must be aged 6-24 months old, and have a parent with daily access to a smart phone in order to receive and send text messages. Inclusion and exclusion criteria for Phase 1 will be the same as Phase 2. In our previous study utilizing text messaging with low-income families for a study of early literacy promotion, only 28 (18.9%) of 148 eligible participants approached for recruitment were ineligible because they didn't have access to a smart phone. Children and their parents will be recruited from participating practices at any 6 through 24-month well child visit in which parents receive board books and reading promotion from their child's clinician as part of the ROR program.

3.1.1 Phase 1

Prior to conducting the RCT, we will develop the text messages and personalized coaching that we will employ in the RCT. The text messages were previously developed as part of the aforementioned trial on early literacy promotion (see appendix). Using a rapid-cycle design process developed by Dr. Buttenheim, data from brief interviews with N=10 parents will be used to identify specific behavioral barriers to more frequent reading with children, and to edit reminder messages and develop coaching content to target those barriers with behaviorally-informed solutions. Personalized coaching will consist of a menu of various instruction and tips on reading that participants can select based on their needs. The interviews will be audio recorded and transcribed in order to analyze content. In the event that the baseline visit cannot be completed in-person, an alternative method of obtaining informed consent will be used, and the interview will be completed over the phone. All interviews will be audiotaped and transcribed for analysis. Interview transcripts will be analyzed and coded using NVivo, a qualitative software. The information can inform the motivational tips in phase 2 to address barriers to shared reading.

Following the telephone screening, caregivers of eligible children will be sent the informed consent document electronically through REDCap. The study team will then go over the document in detail with the eligible caregiver by phone and use the e-consent function to obtain their signature. The signed e-consent form will be stored within REDCap and a copy will be made available to download and email securely to the caregiver.

3.1.2 Phase 2

After conducting the rapid-cycle design for phase 1, forty-five eligible children and their parents will be consented and enrolled in the study. In the event that the baseline visit cannot be completed in-person an alternative method of obtaining informed consent electronically through REDCap will be used. Following informed consent and completion of baseline surveys, participants will be stratified by site and randomized 1:1:1 to receive one of the 3 AH interventions for an 8-week duration. Using a similar recruitment strategy, we were able to successfully recruit 120 (81%) of 148 low-income infants and their parents who were approached for the aforementioned study on early literacy promotion.

Group 1 will consist of daily text messages on shared reading, which will be sent to participants using the Way to Health Platform. Participants will be asked to reply to the text message on daily shared reading activities including the titles of books and time spent reading. Group 2 will consist of Group 1 plus personalized coaching. Personalized coaching content will be made available to participants through links in the text messages and will provide comparisons of their reading frequency with that of other participants. These comparisons will be blinded to preserve confidentiality. Finally, Group 3 will consist of Group 2 plus availability of a weekly lottery. Group 3 participants who report back that they read on a particular day will be entered into a weekly drawing to receive $20. Each reported daily reading behavior will provide a single lottery entry so that participants who report they read all 7 days in a given week will have 7 entries in the weekly drawing.

3.1.3 Randomized Trial

All participants across groups will be asked to report on daily reading behaviors by replying to daily text messages. In addition, participants will be asked to complete study measures using a RedCap survey at baseline and following the 8-week intervention period. Responses to daily reading text messages will be provided by the Way to Health platform and will be assessed as the mean overall number of days/weeks of reading for each group. Participants will also be provided with an opt out of the daily text messages option if they no longer desire to receive daily text messages. Participants will be queried at follow-up on their overall satisfaction (5-point Likert scale) with their intervention group and asked to answer survey questions regarding likes and dislikes concerning the intervention group they received following the intervention period. The survey questions at the end of phase 2 will be based on input from the rapid-cycle design process of phase 1 interviews.

At baseline, parents will complete a measure of demographics (child and parent age, race/ethnicity, sex, highest education completed, and family income category) (see Appendix 2). To explore differences in the home reading environment, parents will complete the Read subscale of the StimQ, a validated 14-item parent report measure of the home reading environment, at baseline and follow-up.[23] To explore differences in parenting stress, participants will complete the Parenting Stress Index-short form (PSI-SF), a validated 36-item parent report of parenting stress, at baseline and following the 8-week intervention in order to assess changes.[24] Finally to explore differences in child language and socio-emotional development, parents will complete at follow-up the MacArthur Communicative Development Inventory (CDI), a validated parent-report scale of early language development, and the Devereux Early

Childhood Assessment (DECA), a validated 33-item parent report of socio-emotional problems.[25,26]

3.2 Allocation to Treatment Groups

Participants will be recruited at the time of a well child visit for their infant using a recruitment flyer and will undergo written informed consent at their first visit. Caregivers of eligible children will be consented in person or electronically through REDCap. Following informed consent and completion of the baseline surveys participants will be randomized 1:1:1 to one of 3 AH groups: 1) daily text message reminders on shared readings using the Way to Health Platform or 2) daily text message reminders plus personalized coaching and social comparisons through links in the text messages or 3) daily text message reminders, coaching and the availability of a weekly lottery. Randomization will be accomplished in advance using computer generated numbers. Allocation concealment (blinding of the treatment assignment) will be implemented and sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization).

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration for Phase 1 of the study will be approximately 30 minutes. For Phase 2, the intervention duration will be 8 weeks for the intervention, but total study duration will last 12 weeks to allow for completion of follow-up measures.

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

The study will be conducted at approximately 3-4 CHOP primary care practices in Philadelphia. Recruitment will stop when approximately 55 subjects are enrolled.

3.4 Study Population

We plan to recruit 3-4 urban CHOP-affiliated pediatric practices from CHOP's Pediatric Research Consortium (PeRC) to participate in the study. These practices care for a diverse, complex urban population and have onsite social worker to assist with family crises. Using well-established methods that have proven effective in multiple large-scale trials, 3-4 practices located in Philadelphia will be recruited to participate using letters of invitation and in-person presentations. Incentives to participate will include provider education on parent-child shared reading. A total of 55 eligible children and their parents will be recruited from participating practices to achieve a diverse sample of children. Inclusion and exclusion criteria for Phase 1 will be the same as Phase 2. Children will be eligible to participate if they are 6-24 months old, and have a parent with daily access to a smart phone in order to receive and send text messages.

3.4.1 Inclusion Criteria

Parent who:

1) Have an infant aged 6-24 months

2) Have access to a smart phone with text messaging capabilities

3) Have completed an informed consent

Children who:

4) Are aged 6-24 months old

3.4.2 Exclusion Criteria

Parents who:

1) Non-English speaking

Children who:

1) Were born premature (estimated gestational age < 35 weeks)

2) Have been diagnosed with congenital malformations or genetic syndromes which place them at risk for developmental delays

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

4 STUDY PROCEDURES

4.1 Phase 1 Rapid-Cycle Design

Informed Consent: Parents will participate in-person consent visits. In the event that the baseline visit cannot be completed in-person an alternative method of obtaining informed consent electronically through REDCap will be used. Modified Verbal consent will be collected if the COVID-19 pandemic persists to limit study staff exposure. Parents will be called to obtain verbal consent for participation using the written informed consent document. Parents who agree will be sent the written consent form for signature through RedCap. In the event that the baseline visit is conducted remotely, parents will be given the option to complete the interview over the phone.

Review of Inclusion/Exclusion Criteria

Interview: The interviews will be audio recorded and transcribed. We will be using ADA Transcription services. The outline of content of the interview will use open-ended questions to identify specific behavioral barriers to more frequent reading with children (see appendix 3 for Interview Guide). Data from the interview will be used to edit reminder messages and coaching content in phase 2 to address perceived barriers. The interviews will occur in the primary care practice following the completion of their child's well visit.or over the phone if COVID-19 is still ongoing to limit study staff exposure.

Demographics

4.2 Phase 2 Screening/Enrollment (Baseline) Visit

Informed Consent: in-person

Review of Inclusion/Exclusion Criteria

Demographics

Measure of Cognitive Stimulation Provided in the Home – (StimQ-Read)

Parenting Stress Index- short form (PSI-SF)

4.2.1 Phase 2 Two Month Follow-Up

Measure of Cognitive Stimulation Provided in the Home – (StimQ-Read)

Parenting Stress Index- short form (PSI-SF)

CDI

DECA

Satisfaction Rating

Survey

4.3 Study Treatment Phase

Over the course of each subject's participation, the subject will have a baseline and a 2-month follow-up visit. After being screened at baseline, participants will complete demographics, StimQ-Read and PSI-SF. At the follow-up visit, StimQ-Read, PSI-SF, CDI, DECA, Satisfactory rating and survey questions will be completed. If the baseline and follow up study visits cannot be completed in-person, surveys may be administered online through REDCap.

4.4 Unscheduled Visits

Unscheduled visits are not anticipated.

4.5 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to the study visit schedule or any AEs. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. Additionally, if a subject is enrolled but does not complete the baseline surveys within 30 days of enrollment, they will be disenrolled from the study. It will be documented whether or not each subject completes the study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

Date of birth

Gestational age, sex, developmental assessments

5.1.2 Other Evaluations, Measures

At the start of phase 2, following written informed consent, participant families will complete a baseline visit. In the event that the visit cannot be completed in person, study procedures may be conducted virtually online through REDCap. Measures of demographic and biological variables (child age, sex, race/ethnicity, family income, maternal education level, and family structure), parenting stress, and the home reading environment will be collected by research staff blinded to randomization assignment at this visit (See Appendix 2).

The Read subscale of the StimQ is a validated 14-item parent self-report questionnaire designed to measure of the home reading environment, at baseline and follow-up for children ages 5 to 72 months of age.[23] The StimQ contains 4 subscales (availability of learning materials, reading, parental involvement in 1developmental advance, parental verbal responsivity) and is available in English and Spanish. Internal consistency (Cronbach α=0.88-0.93) and test-retest reliability (ICC=0.93) of the StimQ is excellent, and it correlates well (r=0.55) with the IT-HOME Inventory, another measure of the home environment.[78] Poverty will be assessed by examining family income (<100% of the Federal Poverty Level) and maternal education status (≤ High School). Parenting stress will be measured at baseline and at follow-up 2 months later using the Parenting Stress Index-Short Form (PSI-SF). [24]

Parenting Stress Index-Short Form (PSI-SF): Baseline and follow-up. The PSI-SF is a validated 36-item scale that measures parenting stress. It has been shown to have excellent internal consistency and to be positively associated with maternal psychological distress. Scores on the PSI-SF correlate well with the full PSI. The total score will be used.

MacArthur Communicative Development Inventory (CDI): 2-month follow-up. CDI is a validated parent-report scale of early language development which captures important information including language comprehension, production and grammar. [26]

Devereux Early Childhood Assessment (DECA): 2-month follow-up. DECA is a validated 33-item parent report of socio-emotional problems used to identify children at risk for language deficits. [25]

5.2 Safety Evaluation

Subject safety will be monitored by adverse events reporting. As this study is not greater than minimal risk serious adverse events are not anticipated.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

For phase 1, the primary endpoint will be the qualitative interview responses used to inform texts and survey for phase 2. For phase 2, the primary endpoints will be acceptability and feasibility of the intervention. To determine feasibility and acceptability of the intervention, we will assess the number of participants who complete the daily text messages and query participants on their overall satisfaction measure (5-point Likert scale) with their intervention group and provide survey questions regarding likes and dislikes concerning the intervention group they received following the intervention period.

6.2 Secondary Endpoints

Secondary outcomes will be explored in phase 2 to determine the differences in reading frequency, the home reading environment, parenting stress, and child language and socio-emotional development at 2 months.

6.3 Control of Bias and Confounding

Randomization and allocation concealment are the primary means of avoiding bias. Analytic strategies will also be used to control for residual confounding: (1) Stratification will control for imbalance not controlled by design. (2) Additional potential confounders will be evaluated for any residual association with treatment and included in model as needed. (3) Post randomization effects: The primary source of bias will arise after randomization from dropout and loss to follow-up. To address this problem and avoid missing data, we shall implement the following measures: (a) incentives to each family to complete the study, (b) collection of multiple contact numbers and tracking of changes, and (c) contact all randomized participants, even if they do not continue with their clinical contacts.

6.4 Statistical Methods

6.4.1 Baseline Data

Descriptive statistics for demographic, home reading environment, and parenting stress measured at baseline will be examined across the three groups to assess the success of the randomization.

6.4.2 Sample Size Justification

The planned sample size for Phase 1 is 10 participants and for Phase 2 is 15 participants per group. Ten participants in phase 1 will be sufficient to provide information to develop coaching tips and identify the main obstacles to parent child reading in phase 2. Our target sample size for phase 2 is 45 participants with 15 participants per group. This sample size is based on the availability of funds and ability to complete the study within a 1 year time period.. These sample sizes were determined to adequately assess feasibility and acceptability. As a pilot study, a power calculation is not necessary.

6.4.3 Analysis of Primary Outcomes of Interest

6.4.3.1 Specific Aim 1

Primary outcomes:

To determine the feasibility of each group of the intervention, we will assess the proportion of participants who receive and report a daily reading behavior each week across all groups, the proportion of participants who access coaching content in group 2 & 3, and the proportion of participants who participate in the weekly lottery in group 3. To determine acceptability of the intervention, we will assess the number of participants who opt out of the daily text messages and query participants on their overall satisfaction (5-point Likert scale) with their intervention group and provide survey questions regarding likes and dislikes concerning the intervention group they received following the intervention period. The survey questions at the end of phase 2 will be based on input from the rapid-cycle design process of phase 1 interviews. Differences in weekly reading frequency and satisfaction scores between groups will be assessed using standard inferential statistics and intention-to-treat analysis. Survey question responses will be assessed using qualitative methods in which codes will be developed and emerging themes identified by consensus of investigators using NVivo software.

Secondary outcomes:

To explore differences in reading frequency, the home reading environment, parenting stress, and child language and socio-emotional development, we will examine differences in mean weekly reading frequency, mean changes in StimQ Read Subscale scores and PSI-SF scores, and mean CDI and DECA scores between groups using standard inferential statistics and intention-to-treat analysis. In addition, effect sizes will be computed to assess differences between Group 1 and each of the other 2 groups and to power future studies.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study. The main risks of participation are disclosure of PHI and distress with answering study measures.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the CHOP IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

Children and their parents will be randomized following informed written consent 1:1:1 to 1) daily text message reminders on shared readings using the Way to Health Platform or 2) daily text message reminders plus personalized coaching through links in the text messages or 3) daily text message reminders, coaching and the availability of a weekly lottery.

8.1.2 Blinding

Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization). Participants will not be blinded to their treatment assignment. However, research will be blinded to treatment assignment when collecting study data.

8.2 Data Collection and Management

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

To ensure confidentiality of information, data will be stripped of potential identifiers, and all written and computerized files will be indexed by a unique identification number. Only research staff will have access to this information and to a separate master list. All data for these study procedures will be maintained on CHOP's secure research server, and all analyses will be performed on de-identified data only. All collected study measures will be entered directly into a REDCap database maintained and protected on this secure research server. The unique identifiers will be used to track enrolled families over the course of the study. Confidentiality will also be maintained by use of subject code numbers in all presentations and publications. Each member of the research team, including investigators, research assistants, and stakeholder-investigators will receive appropriate training in human subject research and patient confidentiality.

For all data collection and management of audio recordings, a digital audio recorder will be used and all digital audio files will be stored on a CHOP server for the study. All audio files will be sent to ADA Transcription services for transcription with deletion of any identifying information. The de-identified transcripts will be returned and maintained on CHOP's secure research server. The ADA Transcription services is a CHOP approved vendor that have been used before for other research studies at CHOP and will continue to be used in the future.

Unique identifiers will be created for each subject in the study. REDCap will be used to store the data. A master list containing PHI and subject ID number will be kept separate from data forms (electronic and paper). The master list will be kept using password-protected files. These files will be encrypted and maintained on the CHOP secure server to ensure security. Participants'

information will be stored in the REDCap database and configured to export data without PHI. All de-identified records will be retained forever. De-identified data will be shared with the study sponsor. Stored data and patient identifiers will be kept for 6 years subsequent to the study completion, and possibly longer if required by the sponsor.

8.3 Confidentiality

All data and records generated during this study will be kept confidential and in accordance with institutional policies and HIPAA on subject privacy. Participation in all aspects of the proposed study is completely voluntary. The research team will institute strict procedures to maintain confidentiality. Subjects will be assigned a unique identification code that will be used as the sole identifier. The data will only be shared with the investigative team during the implementation of the study and results will only be presented in aggregate form. Any results obtained cannot be related to the original source, so no results would be provided to the patient, healthcare provider, or insurance provider. All study information will be maintained on a secure password-protected server with regular backup.

8.4 Regulatory and Ethical Considerations

8.4.1 Risk Assessment

The research involves the collection of sensitive and protected health information from participants. The risk of participation is considered minimal. For both phases of the study there is a potential risk of breach of confidentiality of information and study results about individuals. This risk is minimized by measures taken by the study team to ensure confidentiality: use of secure files, storing data on secure computers, using unique study identifiers, de-identification of data prior to analysis.

For participation with the rapid response phase of the study, there is a risk that participants may become uncomfortable answering questions. In addition, participants responses may be inadvertently disclosed outside of research. If participants feel uncomfortable answering questions, they may skip any question or stop the interview at any time. Additionally, the study team will take the necessary steps to ensure no breach in confidentiality with the audio-recordings as well. The study team will make sure to keep participant's information secure after the initial recording by using secure files, storing data on secure computers, using unique study identifiers and de-identifying all recording. No one other than the research team and the person who writes down the answers will hear the recordings. Also, if someone's name is mentioned, it will not be included on any notes made by the researchers. The transcripts will have all identifying information deleted.

For participation in the pilot clinical trial, there is a risk that participants may become uncomfortable in completing study measures. If this occurs, the protocol will allow participants to stop at any time. Should any specific concerns arise throughout the project period, the CHOP IRB will be promptly informed. Since the purpose of the intervention is to help parents improve parent-child shared reading, we expect that adverse consequences due to the intervention will be extremely rare and unlikely.

8.4.2 Potential Benefits of Trial Participation

There are no direct benefits to subjects. The results of this study may assist health care providers and researchers in testing the effects of AH approaches. The use of AH to test its effect to increase parent-child shared reading in a larger more diverse population of low-income children. This model may be replicated in different care settings and thus generate generalizable knowledge. Further, the information obtained will be disseminated as widely as possible, including publication in peer-reviewed journals and policy briefs and presentations at scientific and lay conferences. Given the minimal risk nature of the study, the risks are considered reasonable in relation to the potential benefit to be gained.

8.4.3 Risk-Benefit Assessment

Given the minimal risk nature of the study, the risks are considered reasonable in relation to the potential benefit to be gained.

8.5 Recruitment Strategy

8.5.1 Subjects

Eligible children and their parents will be identified in the clinic by either research staff or clinic providers through the use of a recruitment flyer (see Appendix 8). The flyer will be used to deliver information of the study to eligible children and parents. If permitted, research staff will recruit in person at the clinic. Parents who verbally agree to be contacted will be asked to scan the QR code on the flyer to complete a REDCap referral form (see Appendix 9). The contact form will be stored within REDCap and will then be available for research staff to use. Medical records of the potentially eligible subjects will be screened and assessed for eligibility prior to contacting the subject. Subsequent to screening the medical record, the subject will be called by the research staff to explain the study and arrange for a study visit. Research staff will briefly explain the study procedures, guided by the information set forth in the approved consent form. This includes reading the inclusion criteria to the potential participant, and asking whether or not this individual is interested in participating. Research staff will then schedule a time to meet with the parent in person- or remotely to complete the baseline visit. At this visit, parents will be asked to provide written informed consent to participate in the study. In the event that the baseline visit cannot be completed in-person, an alternative method of obtaining informed consent will be used. Following the telephone screen, caregivers of eligible children will be sent the informed consent document electronically though REDCap. The study team will go over the document in detail with the eligible caregiver by phone. The e-consent function in REDCap will be used to obtain the caregiver's signature. The signed e-consent will then be stored within REDCap and a copy of the form will be available to download and emailed securely to the caregiver.

The rationale for the involvement of children in the study is that the investigation addresses child development in pediatric care settings. The study does not involve any other special class of subjects.

8.6 Informed Consent/Assent and HIPAA Authorization

Following the screening via review of the medical record, eligibility for study participation will be explained via phone. During the research staff visit subsequent to the screening process, written informed consent will be completed. Research staff will discuss the study aims, procedures, risks and benefits, alternatives to participation, and confidentiality protocols with the parent. Research staff will speak to the parent about the voluntary nature of participation and provide the potential subject with the opportunity to ask questions about the study and its risks and benefits. Parents who consent to participate and who give parental permission for the child's participation, will sign two copies of the informed consent form: one will be kept for study purposes and the other will be provided to the consenting parent. In the event that the baseline visit cannot be completed in person, informed consent may be obtained electronically through REDCap. In order to give parental permission for the child to participate, the consenting mother must be at least 15 years old, or the consenting father must be at least 18 years old. Parents will be provided with plenty of time to ask questions and to decide whether they want to participate. Parents will be explicitly instructed that they are free to choose to participate and that their decision to participate will not affect the health care they or their children receive at participating practices. Participants who are already enrolled in the study and need to be reconsented due to study changes (such as the implementation of certain measures), will be contacted by study staff and re-consented over the phone (or in person if that is the preferred method of the participant). No information sheet or copy will be offered to subjects who are verbally re-consented due to the fact that these subjects already have a copy of the main consent form.

All activities stated in this proposal will be performed in accordance with the Health Insurance Portability and Accountability Act (HIPAA). CHOP personnel, including research staff and stakeholders, must complete training on the privacy measures of HIPAA. This training reviews the HIPAA policies relevant to research practice to protect the confidentiality of patients and research subjects. The protection of human subjects training provides formal, comprehensive education in order to protect children, adolescents, and parents from the risks associated with participating in research, and to reduce the risk to investigators and the institution that are associated with non-compliance. Training covers institutional policies and procedures, federal regulations and critical aspects of study implementation. These training requirements are fulfilled by completing the Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Subjects, an online program that covers the history and ethics of human subject research, the organizational structure and procedures of the Institutional Review Board, the protocol process, HIPAA for clinical research, and standards for conducting clinical research at CHOP.

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

Participants in Phase 1 will be paid up to a total of $25 for their participation.

Participants in Phase 2 will be paid up to a total of $75 for their participation. They will receive $25 upon completion of the initial study visit (Baseline). At the final study visit (2-month follow-up) they will receive $50. Group 3 participants will be entered into a weekly drawing with the opportunity to receive $20 for up to 8-weeks of lotteries. Participants in Group 3 have the opportunity to receive additional payments up to $160. All payments will be made in the form of pre-paid, CHOP-issued debit cards.

8.6.2 Gifts

No other gifts will be given.

9 PUBLICATION

This study will be registered with ClinicalTrials.gov following IRB approval of the final protocol and before any potential patients and their families are enrolled in the study. All study data will then be reported to the ClinicalTrials.gov site. Additionally, all arising publications of Study data and analyses will follow the set of guidelines outlined in the CHOP publications policy manual.

The research team plans to work closely with key stakeholders to disseminate and implement the findings of the research study into accessible and usable formats in research, clinical, and community-based settings. We will target findings to state and national policymakers, county EI agencies across the state, parent advocacy groups, and pediatric practices using social media, policy briefs, mass emails, and newsletters. We will work with PolicyLab at CHOP to develop dissemination plans. PolicyLab has extensive experience distilling research findings into policy-relevant summaries and disseminating research findings to end-users. We will also utilize traditional approaches such as peer-reviewed publications and presentations at national meetings to disseminate findings to other researchers.

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APPENDIX

See attached.