

NCT03076268: TREINTA MILLONES DE PALABRAS-VISITAS AL HOGAR RCT

PROTOCOL TITLE: TREINTA MILLONES DE PALABRAS-VISITAS AL HOGAR RCT

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TYPE OF RESEARCH: Longitudinal Randomized Control Trial

INTERVENTION: Experimental Technique To Change Knowledge And Beliefs

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TREINTA MILLONES DE PALABRAS-VISITAS AL HOGAR RCT **PROTOCOL NARRATIVE**

1. INTRODUCTION

A. BACKGROUND AND RATIONALE

a) Background

A child's early language exposure is a primary component in language development and in ultimate educational and intellectual achievement (Bruner, 1981; Chapman, 2000; Gallaway & Richards, 1994; Hart & Risley, 1995; Huttenlocher, Haight, Bryk, Selzer, & Lyons, 1991; Rowe, 2008). Betty Hart and Todd Risley (1992) conducted a landmark study that demonstrated the tremendous impact of a child's early language milieu on future learning, revealing a significant correlation between the number of words to which a child is exposed between the ages of 0-4 years and his/her ultimate IQ and academic success (Hart & Risley, 1992; 1995). Their findings were both significant and alarming, demonstrating the critical and time-sensitive role that early language exposure plays in a child's life. Their follow-up with the same children at 9-10 years of age confirmed that preschool and elementary school interventions came too late to alter these trajectories; the reverberations of early linguistic deprivation were likely to follow these children throughout their lives.

Children born into poverty experience an overwhelming inequality in their early language experience. Hart and Risley's study revealed a steep socioeconomic gradient in early exposure to language. At the end of their third year of life, children from high-socioeconomic status (SES) families heard approximately *forty-five* million words while children from low-SES backgrounds heard only approximately *thirteen* million. The tragedy for these children is not unalterable. It is neither genetics nor a lack of potential that lies at the heart of this inequality. Rather, it is inadequate parental knowledge of child language development. Rowe (2008) demonstrated that the relationship between SES and parental communication ability is mediated by parental knowledge. Other studies have corroborated this, showing that the effect of SES on a child's vocabulary was primarily dictated by maternal speech (Hoff, 2003). Encouragingly, studies have also demonstrated that a well-planned parent-directed language intervention may increase low-SES parents' use of facilitative language with their children (Oneil-Pirozzi, 2009; Suskind et al., 2013). The Thirty Million Words Initiative was founded, in part, to develop and implement such an intervention, via the TMW Curriculum.

The TMW Curriculum was developed to address the disparity in low-SES children's early language environments by increasing parent knowledge, impacting beliefs about language, and motivating behavior change. The TMW Curriculum is comprised of 1) 12 educational modules, 2) animations and videos of real parent-child interactions to teach parents about the science behind child brain development, and model strategies for improving parents' child-directed speech, 3) video modeling and collaborative goal setting, and 4) quantitative linguistic feedback from Language Environment Analysis (LENA) recordings.

The LENA system is a technology that provides day-long audio recordings from a digital recorder that is placed in the front pocket of specially-designed children's clothing. This 'word pedometer' records all of the child's vocalizations and everything spoken near the child continuously for 16 hours. Audio data are automatically analyzed using speech recognition technology, and reports are generated that provide daily and hourly summaries of: 1) the number of adult words spoken near the child, 2) the number of turn-taking interactions in which the child engaged with an adult, and 3) the amount of television to which the child was exposed. The processing software also produces a report on the general audio environment, including information about the amount of time TV/electronic media was audible in the recording. This technology makes it possible to obtain an objective and representative picture of the early language experiences of infants and toddlers. Given prior research on the importance of early language exposure, the device's feedback reports can be used as an intervention tool to measure and influence parental behavior. Research on the efficacy of the LENA feedback reports, in conjunction with information about strategies for language environment enrichment, shows that the system may have a substantial effect on parent behavior, influencing them to talk and interact more with their children (Gilkerson & Richards, 2008; Suskind et al., 2013).

Although the literature suggests that the LENA technology provides useful quantitative feedback to parents, the underlying costs of the technology prevent it from being used on a wide-scale. Thus, we seek to develop an innovative mobile word counting application to incorporate into the TMW intervention. The Three T's App is built on completely free open-source speech recognition algorithms, and when completed, the mobile application will provide quantitative feedback to parents and introduces them to the TMW intervention. This application was developed by Luai Zakaria, a medical student in the Pritzker School of Medicine at the University of Chicago. The ability to provide accurate quantitative feedback has yet to be evaluated. By including this new technology into the intervention, the application can be further tested and evaluated.

Research shows that language exposure and usage appear to play a significant role in Spanish-English bilingual children's language development, including vocabulary learning, phonological awareness, etc. (Hammer, Hoff, Uchikoshi, Gillanders, Castro, & Sandilos, 2014). Yet, findings in the current literature are still preliminary. Moreover, there is no conclusive findings regarding early environments in Spanish-English bilingual young children's math understanding. Future research is needed to better understand factors promoting early language environments in order to foster language learning and math understanding among Spanish-English bilingual young children during toddlerhood.

b) Past research

TMW conducted a randomized, controlled feasibility trial with 23 low-SES families to evaluate whether the curriculum improved parents' knowledge of child language development and changed the way parents talk with their toddlers. The TMW Curriculum was delivered to 12 treatment families in eight weekly one-on-one home visits. Home visits included educational module review, video modeling, collaborative goal setting, and quantitative linguistic feedback from weekly LENA recordings. The control

condition received a nutrition pamphlet at short weekly home visits to control for a possible attentional effect experienced by those in the treatment group.

The results of the feasibility trial suggest that the intervention has a significant impact on parent knowledge of child language development and parent-child language behavior. During the intervention period, families receiving the TMW Curriculum demonstrated a significant increase in 1) parent knowledge of child language development, 2) parent language input, 3) parent-child conversational turns, and 4) child vocalizations, as assessed through surveys, coded video interactions of parent-child natural play, and LENA recordings. Taken together, the LENA recordings and video-coding results suggest that parent-directed language enrichment interventions can change home language environments of children from low-SES backgrounds. Posttest assessments revealed a significant increase in parent utterances, word types (unique words), and word tokens (all words combined, including repetitions) as well as child word types. At a four-month follow-up assessment, intervention effects were significant for parent knowledge of child language development. For all other measures, effects were positive, but not statistically significant, possibly due to the small sample size and relatively short follow-up period. While we did see an increase in child vocalizations during the intervention period (which were not sustained post-intervention), as well as significant gains in child word types (with a marginally significant effect post-intervention), the sample was not sufficiently large, nor was the study period sufficiently long to see the long-term effects of the intervention.

The feasibility trial represented a first step toward developing a parent-directed curriculum that has the potential to improve the language learning trajectories and subsequent academic readiness of low-SES children. The results indicate the potential to change both parent-child language interactions and child language learning trajectories during and immediately after the administration of the curriculum. Overall, the results show that the curriculum can provide parents with the tools to successfully enrich their child's early home language environment, thereby reducing academic disparities among low-SES children. A longitudinal study with a sufficiently large population is the next step in determining the effectiveness of the curriculum.

c) Rationale for conducting this research

Treinta Millones de Palabras (TMP) Visitas al Hogar is a cultural and linguistic adaptation of the TMW-Home Visiting curriculum into Spanish. The 12-module curriculum has been translated into Spanish and adapted to address concerns that are vital to mono- and bilingual Spanish-speaking families, including when to introduce a second language to a child and the benefits of bilingualism. TMW-Español Home Visiting will be delivered one on one with a trained TMW home visitor and a participant.

We will deliver the TMP Curriculum to 45 Treatment families, and we will be following the families for one year to determine the impacts of the translation and cultural adaptation of the Home Visiting curriculum. We will deliver a Nutrition Curriculum to 45 Control families in order to control for the possible attentional effects experienced by those in the Treatment group. Moreover, as an ethical consideration we wish to also

provide families in the Control condition with valuable education that may enhance their children's development.

d) Rationale for research design and population

The research design (i.e. a randomized controlled trial) is necessary to determine the efficacy of the TMW Intervention. Incorporating knowledge gained from the feasibility and longitudinal trials, the intervention has been translated into Spanish and adapted to address concerns that are vital to mono- and bilingual Spanish-speaking families, including when to introduce a second language to a child and the benefits of bilingualism.

Participants in both the Control and the Treatment condition will receive text messages to remind them to complete their LENA recording on the day that they had previously scheduled. For the Treatment group only, a text message reminder for a specific goal will be sent as well. This will help parents be mindful of their goals at the time that they plan to achieve them by reminding parents to engage linguistically with their children. This text reminder portion of the study will piggy-back on the goal setting portions in which the parent will set specific, personalized goals. Reminders of these goals will be sent to their phones at a day and time that parents choose. Both the Treatment and Control participants will be given the option to opt out of the text messaging if they do not wish to receive these messages.

The sample size (i.e. 45 dyads in the Treatment group and 45 dyads in the Control group) was determined based on a Monte Carlo simulation power analysis has been conducted based on the frequency of token (during parent-child video-tape observation) pre- and post-intervention as a function of group (TMW vs. Nutrition) and child gender, using the existing data from the TMW-Longitudinal Home Visiting study. The effect size of the intervention on token count is estimated to be very large (cohen's $d = 1$) and the attrition rate is assumed to be 25%. The estimated sample size is 91 dyads in total at the beginning of the study.

B. OBJECTIVES

a) Hypothesis

We hypothesize that the primary effects of the TMW Intervention will significantly 1) improve low-SES Spanish-speaking mothers' knowledge of child language development and beliefs about the malleability of intelligence, 2) increase mothers' linguistic interaction, responsiveness, and overall engagement with their children; and 3) increase children's language outcomes, as measured by the LENA (child vocalization count, conversational turn count), coded video interaction (number of types, tokens, and utterances for both children and adults), and a battery of assessments targeting linguistic and cognitive development. Furthermore, we hypothesize that increased parental interaction will result in 4) an improvement in children's social-emotional development, as measured through the ASQ-SE, and 5) an improvement in children's math skills, as measured through the "Give N Task".

2. STUDY DESIGN

a) Type of study, duration of study, and schedule of events

Thirty Million Words-Español Home Visiting Pilot RCT is a randomized control trial that will take place over the course of one and a half years. The study will consist of two groups, the Treatment group and the Control group. During the Recruitment Phase, a TMW research assistant (RA) will recruit participants for the study. If interested in joining the study, participants will complete the Preliminary Enrollment Consent either in their home or in a convenient public space of their choosing. To follow the completion of the Preliminary Enrollment Consent, the participant will complete a recorded video session with their child, two questionnaires and a home language environment survey. RAs will facilitate the collection of these measures. Following satisfactory completion of the baseline measures, participants will move on to the Enrollment Phase 2 weeks later at which point they will complete the Enrollment Consent. Additionally, participants will complete three questionnaires administered by an RA. This RA will also go over how to use the LENA device. Following the Enrollment Phase, participants will move on to the Intervention Phase. During the Intervention Phase, participants will first complete Assessment 1. A fully trained TMW Assessor will conduct this and all subsequent assessments. Following Assessment 1, participants in the treatment group will receive 12 bi-weekly home visits over a six-month period from trained TMW Home Visitors. The Treatment group will receive the TMW Curriculum. The control group will receive informational packets dropped off every 6 weeks by a TMW RA. The control group will receive the alternative Nutrition Curriculum, which provides information about the importance of healthy nutrition for child development, strategies for healthy eating, and meal preparation.

In addition to receiving the home visits, participants will also complete LENA recordings on a regular basis. Treatment participants will complete 3 LENA recordings in between the enrollment consent and Assessment 1. Then they will complete 12 LENA recordings on a bi-weekly basis in between their home visits as a behavioral feedback tool incorporated in the home visits. They will complete one final LENA recording in between Assessments 2 and 3, for 16 total LENA recordings. The control group will also complete three LENA recordings before Assessment 1, one before Video Session 2, one before Assessment 2, and the final one before Assessment 3.

b) Summary of sequence and duration of all study periods, including follow up periods (as applicable)

The Recruitment Phase will take place in a rolling manner throughout the first six months of the study until the full sample of n=91 is reached. Sequence and duration of all study periods are subject to recruitment needs and will be extended accordingly if necessary. The Preliminary Consent and Baseline Measures Phase of the study will last *at least* six months. For each individual participant, this phase will take place over a 2-week period before the official start of the study. Because of the rolling recruitment, the Enrollment Phase will last *at least* one year. Participants will go through the Enrollment Phase 1 week before the official start of the study. The Intervention Phase marks the official start of the study and will take place during a minimum of 12 months. Each individual participant will receive the intervention for 6 months. The Follow-up Phase will take place between month 6 and 12. Individual participants' schedules may vary and will be

adjusted based on their availability. The Data Analysis/Publication Phase begins in Year 2 and will last indefinitely.

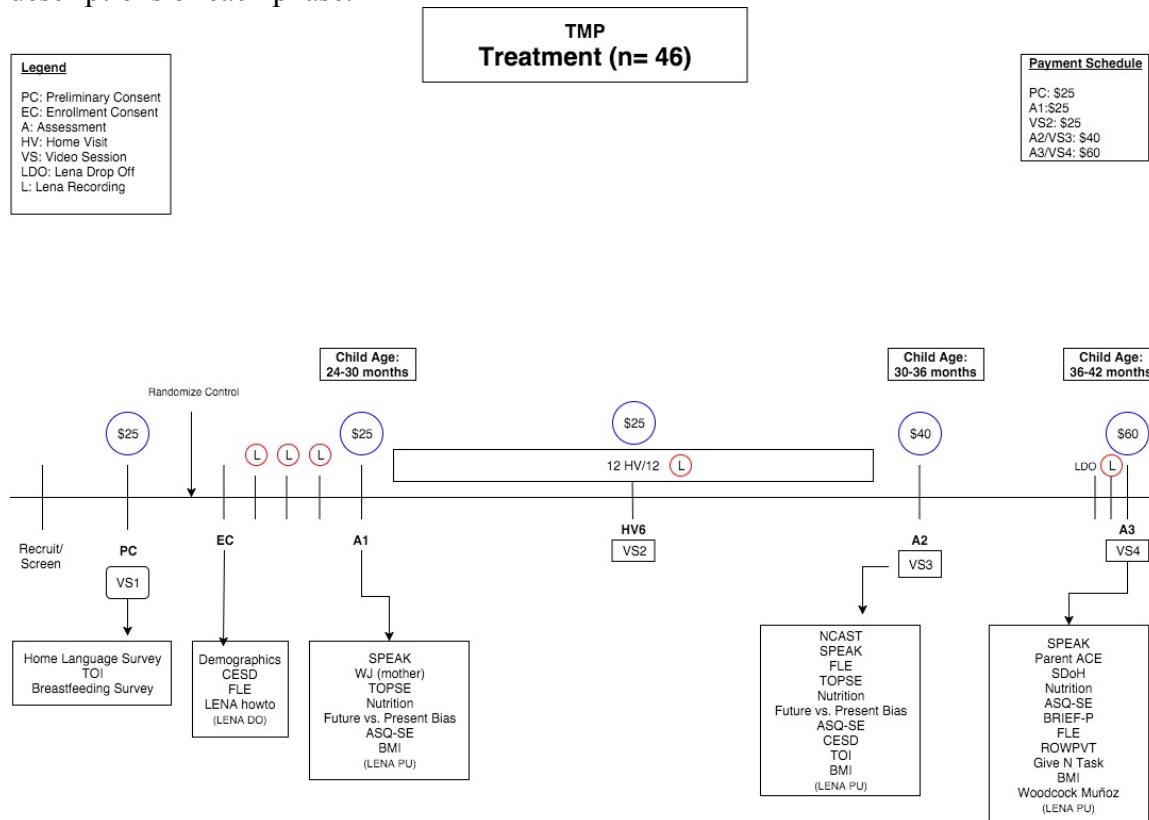
c) Discuss randomization processes and use of controls

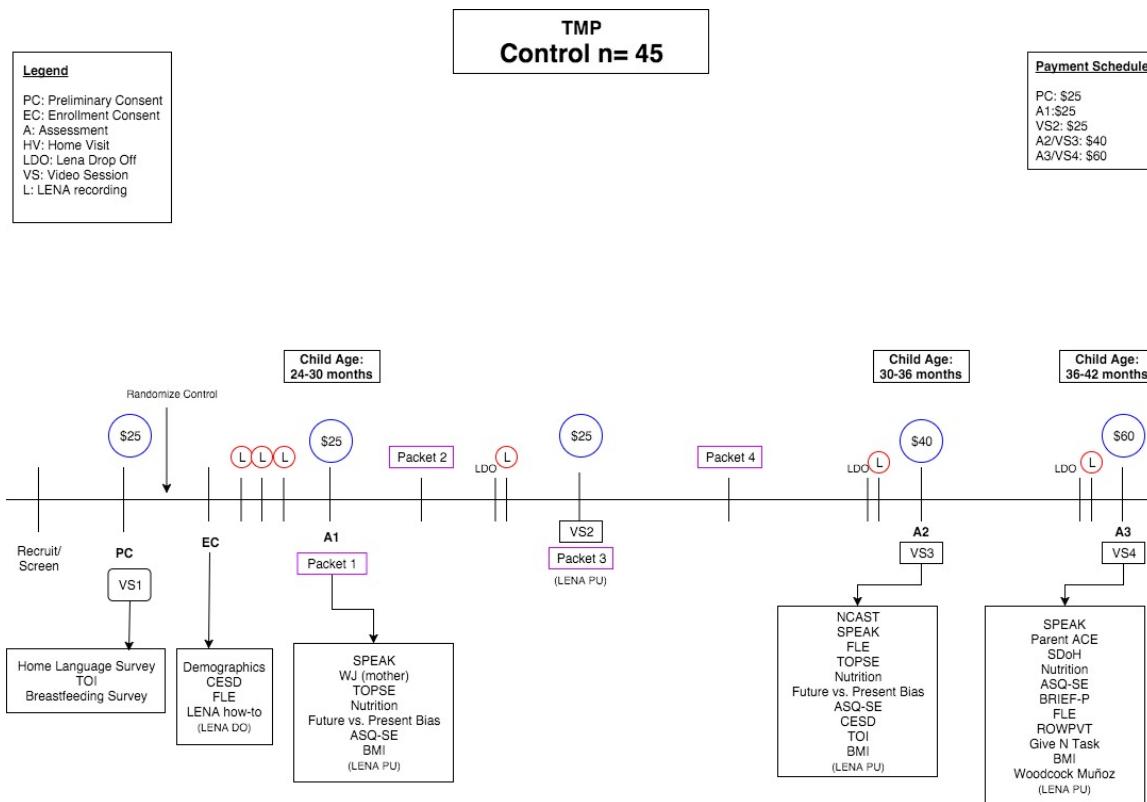
Participants (i.e. parent-child dyads) will be randomly assigned to one of two groups: 1) Treatment group (i.e. TMW Curriculum) or 2) Control group (i.e. Nutrition Curriculum) just before the enrollment consent meeting. Participants will be randomly assigned to either the Treatment or Control. Assignment to Control or Treatment of each member is decided through a randomization table. The website Research Randomizer will be used to generate a set of 91 unique, unsorted numbers. The resulting numbers will be entered into an excel spreadsheet where the 91 unique, unsorted numbers will be sorted into the two groups: Treatment group and Control group. The range of data in the columns will be sorted in excel using the “Sort” function to ensure equal sample sizes per group.

3. STUDY PROCEDURES

a) Methods and procedures

The study consists of 4 phases: Pre-intervention, (including recruitment, preliminary consent baseline measures (Month 0) and enrollment), Intervention (Month 1 through Month 6), Follow-up (Month 7 through Month 12), and Data Analysis/Publication (Month 12 through Month 24). Please refer to the following timelines and the detailed descriptions of each phase.





1. Recruitment Phase

Recruitment

A member of Dr. Suskind's research team will speak with potential participants in person at Recruitment Sites or over the phone.

Additionally, recruitment advertisements will be placed on some Chicago CTA bus and train routes. Note: the advertisement is a general advertisement that is used for recruiting families for multiple studies. Based on the language they speak and the age of their child, the participant is funneled to the appropriate study line.

Screening

If potential participants are interested in participating in the study, a member of the research team will obtain verbal consent and administer the Screening in order to determine eligibility. If potential participants are eligible, they will move on to the Preliminary Consent and Baseline Measures Phase (for eligibility requirements, see Subject Selection and Withdrawal).

2. Preliminary Consent and Baseline Measures Phase

Preliminary Informed Consent

The participant will first complete the Preliminary Informed Consent Form. This form explains the purpose of the study, potential risks and benefits, and the measures taken to ensure confidentiality.

Home Language Interview

This survey probes about which languages are spoken in the home and how frequently. It is conducted via interview with a trained member of the study team.

Measurements

Participant will complete two questionnaires at the preliminary consent meeting, which will include a Breastfeeding survey and the Theories of Intelligence (TOI) survey. The Breastfeeding questionnaire asks parents about their child's weight at birth and their decisions about breastfeeding their child as an infant. We will also ask parents to complete the Theories of Intelligence (TOI) questionnaire to understand participant's preconceived ideas about intelligence.

Video 1

An RA will complete Video 1 in the participant's home. The parent and child will engage in a 15-minute videotaped session consisting of Natural Play and Book Read. During Natural Play, the parent and child will engage in undirected, unstructured play. During Book Read, the parent will read a book to the child. During Video 1 and all subsequent Videos (2-4), the 15-minute session will be simultaneously recorded by the new mobile phone application, the Three T's App. The extra recording taken with the Three T's App will be explained to the participants, detailing that "the app" functions like the LENA, except it links to a Bluetooth microphone and a mobile device, instead of the LENA recorder. The TMW staff member will set up the Three T's App recording, and the participant will not see the application itself or be told the full name of the application, as these characteristics are related to the Treatment condition.

3. Enrollment Phase

Following successful completion of the preliminary phase measures, participants will be randomized into either Control or Treatment group and move on to the Enrollment Phase of the study. The Enrollment Phase of the study will take place in the participant's home or other location preferred by participant (University of Chicago offices, public library, etc.) by a member of Dr. Suskind's research team.

Enrollment Informed Consent

The parent will first complete the Enrollment Informed Consent Form.

Demographics Questionnaire

The parent will then complete the Schedule and Demographics Questionnaire (see [Appendix I](#)). This questionnaire gathers information about the participants' race and ethnicity, the family's childcare schedule, household information (including housing stability and household makeup) and contact information.

Measurements

To follow, the parent will complete measurements including the Center for Epidemiologic Studies Depression Scale (CESD-10) (see [Appendix J](#)), because severe

depression may be a confounding variable. (However, evidence of parental depression will not exclude participants from the study.) They will also complete the Family Life Events Questionnaire (FLE), which collects data regarding adverse events experienced by the child.

At the enrollment meeting, families will receive the first 3 LENAs to be recorded within a 3 week timeframe. Baseline LENA redos will only be done in the case that a participant has not recorded a LENA- as long as a LENA has some data on it, we will accept it with whatever amount of time (no redos). No LENA redos will be accepted for recordings following baseline LENAs

4. Intervention Phase

Following enrollment, participants will move on to the Intervention Phase, which will last six months. The Intervention Phase consists of three components: Assessment 1, Home Visits for Treatment participants or Nutrition packet drop offs for control participants, and LENA recordings.

Assessment (Survey Meeting) 1

A TMW Assessor will conduct Assessment 1 in the participant's home. Assessment 1 will take approximately 90 minutes to complete.

Assessment 1 Measures

At this assessment meeting, the parent will complete six different measures. The mother will complete the Survey of Parental Expectations and Knowledge (SPEAK), which assesses parents' understanding of children's learning process. Then, the mother will complete the Woodcock Johnson Picture Vocabulary and Oral Comprehension subtests in both English and Spanish. Then, the mother will complete the TOPSE questionnaire (measures parental self-efficacy), the nutrition questionnaire, the future vs. present bias questions, and finally the ASQ-SE. Child's Body Mass Index (BMI) will also be measured by collecting their height and weight. At this time, the RA will also pick up the completed baseline LENA recordings.

Home Visits

Home Visitors will deliver the TMW Curriculum (Treatment group) biweekly over the course of the six-month Intervention Phase, for a total of 12 Home Visits. Visits are scheduled biweekly, and will be completed by a TMW home visitor in the participants home or another agreed upon meeting place. TMW Home Visits will last approximately 60 minutes.

TMW Curriculum: The TMW Curriculum consists of 12 modules, one per home visit, and will be implemented in the following way:

- 1) The Home Visitor delivers the educational module, one per Home Visit.
- 2) The Home Visitor and the parent have a discussion to review and reinforce the parent's understanding of the concepts.
- 3) The Home Visitor does the Showtime activity (video modeling) with the parent, which demonstrates how to put concepts into practice. During modules 5 through 12 parents participate in a social network mapping activity during Showtime.

- 4) The Home Visitor discusses LENA feedback reports with the parent. LENA feedback reports are generated based on the previous week's LENA recordings. Based on the report, the parent sets goals for the forthcoming week. In support of these goals, the Home Visitor discusses strategies for increasing word counts, increasing conversational turns, and reducing TV/electronic media.
- 5) The parent and the Home Visitor collaboratively set goals for his/her next week's recording. Parents will set up a time and day that they would like to be reminded of their LENA recording day and their specific goal. This goal and recording reminder will then be sent to their phone via text message the day of their LENA recording.
- 6) Home visitor will leave behind a Fidelity of Implementation (FOI) questionnaire that will be filled out by participant after the home visit is complete and sealed in an envelope for complete confidentiality of completed questionnaire. The FOI questionnaire is used to assess whether the curriculum is being implemented as intended.

Nutrition Curriculum: The Nutrition Curriculum consists of 4 printed handout packets that provide education to parents about the importance of healthy nutrition for child development, strategies for healthy eating, and meal preparation. The Nutrition Curriculum will be implemented in the following way:

- 1) Over the course of the 6-month intervention phase of the study, a trained RA will deliver informational nutrition packets to the participant's home and review them with the parent every 6 weeks. The first packet will be dropped off and reviewed with the participant at the end of Assessment 1. The packets will include nutrition information and resources to help support child's healthy development.

LENA Recordings

Participants in the treatment group will complete 16 LENA recordings (3 before home visiting begins, 12 bi-weekly recordings over the course of the six-month intervention phase, and 1 before Assessment 3). Recordings will be 8 hours long each. Each recording will be completed during the week following a Home Visit.

The control group complete 6 LENA recordings total. Three before Assessment 1, one before Video Session 2, one before Assessment 2, and one before Assessment 3.

Video 2

Videos 2 will be conducted half way through the Intervention Phase. An RA will complete Video 2 in the participant's home. The parent and child will engage in a 15-minute videotaped session consisting of Natural Play and Book Read. During Natural Play, the parent and child will engage in undirected, unstructured play. During Book Read, the parent will read a book to the child. The 15-minute session will be simultaneously recorded by the new mobile phone application, the Three T's App. The extra recording taken with the Three T's App will be explained to the participants, detailing that "the app" functions like the LENA, except it links to a Bluetooth microphone and a mobile device, instead of the LENA recorder. The TMW staff member

will set up the Three T's App recording, and the participant will not see the application itself or be told the full name of the application, as these characteristics are related to the Treatment condition.

5. Follow-up Phase

This is the final phase requiring participant involvement. The Follow-up Phase will last 6 months. The Follow-up Phase consists of the following components: Video Sessions, Assessments, and LENA recordings.

Assessment 2/Video Session 3

Assessment (Survey Meeting) 2

A TMW Assessor will conduct Assessment 2 in the participant's home. Assessment 2 will take approximately 90 minutes to complete.

Assessment 2 Measures

At this assessment meeting, the parent will complete eight different measures. The mother will complete the Survey of Parental Expectations and Knowledge (SPEAK), which assesses parents' understanding of children's learning process. Then, the mother will complete the Family Life Events (FLE), TOPSE, Nutrition questionnaire, the Future vs. present bias questions, the ASQ-SE, TOI, and CESD-10. At this time, the RA will also collect child's height and weight for BMI measurement and pick up the completed LENA recording.

Video 3

An RA will complete Video 3 in the participant's home. The parent and child will engage in a 15-minute videotaped session consisting of Natural Play and Book Read. Following the 15-minute videotaped session, parent and child will engage in a 5-minute teaching task (NCAST). The NCAST Parent-Child Interaction Teaching Scale is an activity that measures parent-child interaction in a teaching situation where parent chooses a task to teach their child in 5 minutes or less. The 15-minute session will be simultaneously recorded by the new mobile phone application, the Three T's App. The extra recording taken with the Three T's App will be explained to the participants, detailing that "the app" functions like the LENA, except it links to a Bluetooth microphone and a mobile device, instead of the LENA recorder. The TMW staff member will set up the Three T's App recording, and the participant will not see the application itself or be told the full name of the application, as these characteristics are related to the Treatment condition.

Assessment 3/Video Session 4

Assessment (Survey Meeting) 3

A TMW Assessor will conduct Assessment 3 in the participant's home. Assessment 3 will take approximately 120 minutes to complete.

Assessment 3 Measures

At this assessment meeting, the parent will complete seven different measures. The mother will complete the Survey of Parental Expectations and Knowledge (SPEAK), which assesses parents' understanding of children's learning process. Then, the mother will complete the parent ACE questionnaire which assesses adverse childhood experiences (ACE) a parent might had experienced as a child, a Social Determinants of Health (SDoH) survey which screens for essential social needs a participant may have,

the Nutrition questionnaire, the ASQ-SE, the Family Life Events (FLE) questionnaire that measures child's exposure to adverse experiences, and the BRIEF-P questionnaire which assesses child's executive function behaviors. The child will complete the ROWPVT measure to assess child's receptive language ability, Test:1 (Analogies) and Test: 3 (Picture Vocabulary) from the Woodcock-Muñoz Language Survey III (WMLS III), and the Give N Task. The child's BMI will be measured at this time and, the RA will also pick up the completed LENA recording.

Video 4

An RA will complete Video 4 in the participant's home. The parent and child will engage in a 15-minute videotaped session consisting of Natural Play and Book Read. The 15-minute session will be simultaneously recorded by the new mobile phone application, the Three T's App. The extra recording taken with the Three T's App will be explained to the participants, detailing that "the app" functions like the LENA, except it links to a Bluetooth microphone and a mobile device, instead of the LENA recorder. The TMW staff member will set up the Three T's App recording, and the participant will not see the application itself or be told the full name of the application, as these characteristics are related to the Treatment condition.

6. Data Analysis/Publication

Dr. Dana Suskind will serve as the PI. Dr. Suskind and her research team will publish the primary findings of the initiative. Dr. Suskind and her research team will co-author publications with select collaborators. These collaborators will Dr. Erika Hoff at Florida Atlantic University.

b) Scales, Assessments & Questionnaires:

The following Scales, Assessments & Questionnaires will be used throughout the course of the study:

Center for Epidemiologic Studies Depression Scale (CESD-10): The CESD-10 screens for parental depression.

Family Life Events Questionnaire (FLE): The FLE collects data regarding adverse events experienced by the child.

Theories of Intelligence (TOI) Questionnaire: The TOI questionnaire collects data regarding parent's ideas of intelligence.

Breastfeeding Survey: The Breastfeeding survey collects background health information of the child participating in the study, as an infant.

Survey of Parental Expectations And Knowledge (SPEAK): SPEAK is a questionnaire that assesses parents' understanding of children's learning process.

Woodcock-Johnson Psycho-Educational Battery (WJ): The WJ assesses an adult's cognitive abilities, scholastic aptitude, and performance in the areas of reading, mathematics, and written language.

Nutrition Questionnaire: The Nutrition Questionnaire assesses parents' understanding about healthy eating habits and healthy nutrition for children.

Ages & Stages Questionnaire: Social-Emotional (ASQ: SE): The Ages & Stages Questionnaire: Social-Emotional is a series of questions that aims to identify any social or emotional problems in a developing child.

Future vs. Present Bias: These questions assess an individual's preference for instant gratification or delayed rewards.

Home Language Environment Questionnaire: These questions assess which languages are spoken in the home and in what frequency.

Video Recordings:

Natural Play: The parent and child will engage in natural play.

Book Read: The parent will read a book to the child.

NCAST: parent and child will engage in a 5-minute teaching task of their choice.

TOPSE: This standardized measure assesses parental self-efficacy.

ROWPVT: This standardized measure assesses an individual's receptive vocabulary.

Give N Task: in this math assessment, the task will ask child to generate sets of a given number. Child will be given a set of objects (15 plastic fish) and will be asked to give a certain number of the objects to the stuffed animal. This assessment measures procedural knowledge vs. conceptual knowledge in their math ability.

Parent ACE questionnaire: parent ACE questionnaire assesses adverse childhood experiences (ACE) a parent might have experienced as a child.

Social Determinants of Health (SDoH): this questionnaire screens for essential social needs a participant may have.

Woodcock-Muñoz Language Survey III (WMLS III): This standardized measure is a set of individually administered tests that provides a broad sampling of academic language proficiency in areas of speaking, reading, comprehension, and writing for ages 3 years+. Only two of the eight tests will be administered to collect data for receptive and expressive child language in both English and Spanish. The two tests that will be administered are Test 1: Analogies and Test 3: Picture Vocabulary.

Behavior Rating Inventory of Executive Function-Preschool (BRIEF-P): The questionnaire is for parents of preschool-aged children (ages 2 years-5 years 11 months) to assess executive function behaviors.

The Three T's App Recordings: The Three T's App is an educational tool for parents participating in the Thirty Million Words Initiative. The application is being developed, tested, and evaluated by Luai Zakaria, a student of the Pritzker School of Medicine at the University of Chicago. In this study, the application will only be used by TMW researchers to take an additional recording of all families at all Video Sessions (1-7) to further evaluate and test the recording and results capacity of the application. The name of the application will not be disclosed to participants, as it directly relates to the treatment condition. Additionally, only a trained TMW staff member will be able to set up the recording device and connect it to the application, as the interface of the application contains features directly related to the treatment condition, such as a note that says "Research shows that the more words your child hears, the smarter they will

be!” For all participants, the Three T’s App will only be referred to as “the app” and that “the app” functions like the LENA device, but the recording is taken using a Bluetooth microphone headset that links to a mobile device instead of the LENA recorder. Only the recording and results features of the application will be used by the TMW staff to further evaluate and test the Three T’s App.

c) Contact between study visits

Participants in both the Treatment and Control group will be able to contact members of Dr. Suskind’s research team between study visits in order to reschedule visits as needed. Moreover, the research team will send periodic postcards and make periodic phone calls to both the Treatment and Control Group in an effort to maintain engagement with participants, thereby reducing attrition.

d) Future contact regarding research studies

We will request permission from participants to keep their contact information on file in order to contact them about their participation in this study and to inform them about future research opportunities.

4. SUBJECT SELECTION AND WITHDRAWAL

a) Number of subjects

The study will consist of 91 participants. ‘Participants’ refers to the parent/child dyad. (182 individuals) 91 participant dyads will be randomly assigned to the Treatment group and Control group.

b) Gender of subjects

Only female caregivers will be eligible for the study, but their children can be any gender.

c) Age of subjects

Children will be between the ages of 24-30 months old at the start of the study. Mother/female caregivers will be at least 18 years old.

d) Racial and Ethnic Origin

Participants of all racial and ethnic origins will be accepted into the study.

e) Inclusion Criteria

Inclusion criteria includes 1) participants (i.e. parents and their children) who live at or below 200% of the federal poverty line, 2) female caregivers with a child between the ages of 24-30 months old, 3) whose preferred home language is Spanish, 4) whose education level is less than or equal to a bachelor’s degree.

f) Exclusion Criteria

Exclusion criteria is as follows: 1) participants (i.e. parents and their children) who live over 200% of the federal poverty line, 2) parents under the age of 18, 3) non-female primary care giver 4) children younger than 24 months old or older than 30 months old (at start of study), 5) parents who do not have legal custody of their child, 6) parents whose child does not live with them, 7) parents who are not with their child at least two full days per week, 8) parents who are unable to commit to the intervention requirements, 9) foster parents, 10) children with significant cognitive or physical impairments, (specifically Autism Spectrum Disorder, Epilepsy, Cerebral Palsy, hearing impairment, Down Syndrome and blindness), 11) parents who have earned or are currently working toward a graduate or professional degree (e.g. M.A., M.S., M.B.A), and 12) parents whose preferred home language is not Spanish.

g) Subject Identification & Recruitment

91 low-SES participants in the Chicago area will be recruited for the study from Chicago Commons, SGA, and other community sites in the Chicagoland area. Recruitment will take place at these sites 1) with the in-person recruitment script and 2) via CTA advertisements. Participants that call in after seeing this ad will go through the incoming call recruitment script.

h) Location where research is to be conducted (building, floor, clinic/suite number)

The TMW Curriculum, video recordings and Assessments will be conducted in participants' homes or another agreed location (i.e., community sites) if family is unable to meet in their home. Data analysis will occur at the TMW office.

The TMW office is located at:

University of Chicago Medical Center
5841 S. Maryland Ave, MC 1035
Lying-in Hospital, Room L161
Chicago, IL 60637

i) As applicable, the coordination of any interdepartmental faculty, and where necessary, the inclusion of those faculty as participants

TMW will collaborate with the following individuals and organizations:

Center for Research Informatics (CRI) at the University of Chicago: CRI will host, maintain, and support the web platform that hosts the TMW Curriculum, facilitates intervention delivery, and securely stores intervention and assessment data. The web platform has been built by One-Six Solutions, an outside vendor, and is built to industry standards for data security and HIPAA compliance.

Chicago Commons: TMW will collaborate with Chicago Commons sites to recruit participants.

SGA: TMW will collaborate with SGA sites to recruit participants.

j) Describe plans for remuneration to subject, as applicable:

Participants in the Treatment and Control groups will be compensated equally.

Participants can receive up to a total of \$175. If participants complete the study, they are guaranteed \$175 in cash (\$25 post-Preliminary Consent and Baseline Measures, \$25 post-Assessment 1, \$25 post-Video Session 2, \$40 post-Assessment 2/Video Session 3, and \$60 post-Assessment 3/Video Session 4.).

Subjects that decide to meet at the TMW offices will be offered one way bus passes or parking validation to ease the costs of transportation.

k) Informed consent process

The participant will be given written consent forms and taken through the informed consent process with a member of the research team. The member of the research team will verbally review the written consent form with the participant prior to signing.

Participants will be given ample time to review the consent form and ask the member of the research team any questions before they decide to participate in the study. Participants will first complete the Preliminary Informed Consent Form. If he/she continues past the Preliminary Phase to enroll in the full study, the participant will then complete the Enrollment Informed Consent Form. There will be two versions of the Enrollment

Consent Form, as subjects in these groups will complete different activities. All informed consents explain the purpose of the study, potential risks and benefits, and the measures taken to ensure confidentiality.

1) Method of withdrawing participants before completion (i.e., early termination)

Participants will be removed from the study at the discretion of the Principal Investigator after demonstration of repeated nonadherence to study protocol (i.e.: multiple incomplete or unsuccessful LENA recordings; multiple unsuccessfully completed Home Visits or Assessments; unable to contact after significant effort by research team). If participants choose to no longer be in the study and do not want any of their future health information to be used, participants can inform the research team in writing.

5. STATISTICAL PLAN AND CONSIDERATIONS

An interrupted time series design (i.e. regression discontinuity) will be used to analyze data from this study. The goal of the statistical analyses will be to assess the effects of the TMW Curriculum. The interrupted time series design will allow us to model children's growth as a function of time and development while modeling the independent effects of receiving the intervention.

The outcome measures (LENA, assessments, video) will be entered into a regression that includes children's demographic variables as covariates (e.g. child age in months) as well as dummy variables for each time point data was obtained. Separate analyses will be carried out for parents and children because some data will only be collected on parents and some data will only be collected on children.

Further, because some data are only collected at pre- and post-intervention, separate repeated measures ANOVAs and paired tests will be carried out on these data. The aim of these analyses will be to 1) examine within-subject change from pre to post-intervention in the Treatment and Control conditions and 2) compare change in the Treatment condition with change in the Control condition.

The new mobile phone application, the Three T's App, linguistic feedback data will be statistically compared to the manual transcription of all video recording sessions. The exact number of words and turns transcribed will be correlated with the amount estimated by the mobile phone application. An average error rate and a linear regression for the mobile application will be calculated. This will allow us to further evaluate and develop the Three T's App.

6. RISKS AND BENEFITS

a) Risks associated with study intervention and any study procedures

Given the nature of this research, minimal risks are anticipated. All audio data on the LENA recording device is encrypted so confidentiality will not be breached even if the recorder is lost or stolen. Data remains encrypted until processed using the LENA System software. Risks include a theoretical loss of confidentiality related to recording language via the LENA recordings. However, the LENA audio data will not be listened to by any member of the research staff. It will be kept for 7 years past the end of the study for

possible re-analysis with improved analytical algorithms. Non-audio data will be kept indefinitely. Risks also include a theoretical loss of confidentiality related to Home Visitors, TMW assessors, and RAs entering participants' homes. To minimize these risks, all research personnel will be trained to maintain the utmost confidentiality. Moreover, data will be carefully monitored to ensure the privacy of participants is protected. Data will be kept in a locked cabinet with the participant names replaced with numerical codes. LENA Recording audio and data files will be stored on a password-protected computer in a locked office. Master lists of participant names, consent forms, and the key to the numerical codes will also be kept under lock and key.

All of the audio data recorded by the mobile phone application will be on encrypted iPod Touches owned by the Thirty Million Words Initiative. Thus, these recordings will be handled in the exact same way as the LENA audio recordings have been handled in the past. All audio data and devices used to record the data will be stored in the aforementioned locked office.

There is one instance in which confidentiality will not be maintained. In the consent form, participants are notified of the legal responsibility of Dr. Suskind and members of her research team to report any suspicion of child abuse or neglect to DCFS. Every member of Dr. Suskind's research team who will have contact with participants will complete the DCFS Mandated Reporter online training (<https://www.dcfstraining.org/manrep/index.jsp>) prior to interaction with participants. The abuse reporting hotline (1-800-25-ABUSE) will be made readily available to the research team at all times.

b) Potential direct benefits to participant

Benefits will include increased parental knowledge regarding healthy child development. Moreover, we hope the information learned from this study will benefit other low-SES children and families in the future.

c) Describe how the benefits in this research justify the potential risks.

The benefits to both individual participants and, potentially, the broader low-SES population, outweigh the minimal risks involved in the study.

7. SAFETY AND ADVERSE EVENTS

Adverse events and safety information will be monitored and analyzed on an ongoing basis. Serious and unexpected adverse events will be immediately reported to the IRB. Given the educational nature of this study, there is a low likelihood of adverse events.

8. DATA HANDLING AND RECORD KEEPING

Data will be carefully monitored on an ongoing basis to ensure the privacy of participants is protected. Data will be kept in a locked cabinet with the participant names replaced with numerical codes. LENA Recording audio and data files will be stored on a password-protected computer in a locked office. LENA audio data will not be listened to by any member of the research staff. It will be kept for 7 years past the end of the study for possible re-analysis with improved analytical algorithms. Non-audio data will be kept

indefinitely. Master lists of participant names, consent forms, and the key to the numerical codes will also be kept under lock and key. Depending on the measurement, data will be collected in both paper and electronic form. Electronic data will be entered via the TMW Web Platform and in REDCap, an online, secure database. Both online databases are password protected and only accessible by TMW staff. Paper data will be stored in locked cabinets in a locked office only accessible by the TMW research team. All audio data from the new mobile phone application will be stored with the exact same precautions as the LENA audio recordings.

9. FINANCIAL CONSIDERATIONS

a) Remuneration to subject

Participants in the Treatment and Control groups will be compensated equally. Participants can receive up to a total of \$175. If participants complete the study, they are guaranteed \$175 in cash (\$25 post-Preliminary Consent and Baseline Measures, \$25 post-Assessment 1, \$25 post-Video Session 2, \$40 post-Assessment 2/Video Session 3, and \$60 post-Assessment 3/Video Session 4.).

There are no financial costs to participants.

10. ETHICAL CONSIDERATIONS

a) Confidentiality

Data will be carefully monitored to ensure the privacy of participants is protected. Data will be kept in a locked cabinet with the participant names replaced with numerical codes. LENA Recording audio and data files will be stored on a password-protected computer in a locked office. Master lists of participant names, consent forms, and the key to the numerical codes will also be kept under lock and key. Depending on the measurement, data will be collected in both paper and electronic form. Electronic data will be entered via the TMW Web Platform and REDCap. Both online databases are password protected and only accessible by TMW staff.

There is one instance in which confidentiality will not be maintained. In the consent form, participants are notified of the legal responsibility of Dr. Suskind and members of her research team to report any suspicion of child abuse or neglect to DCFS. Every member of Dr. Suskind's research team who will have contact with participants will complete the DCFS Mandated Reporter online training (<https://www.dcfstraining.org/manrep/index.jsp>) prior to interaction with participants. The abuse reporting hotline (1-800-25-ABUSE) will be made readily available to the research team at all times.

11. CONFLICT OF INTEREST

There is no COI with regard to the conduct of this study.

12. PUBLICATION PLAN

Discuss the following in detail:

a) Who expects to publish results from this research?

Dr. Dana Suskind will serve as the PI. Dr. Suskind and her research team will publish the primary findings of the initiative. Dr. Suskind and her research team will co-author

publications with select collaborators. These collaborators Dr. Erika Hoff at Florida Atlantic University.

b) When are results expected to be submitted for publication?

First results will be submitted for publication during or after the second year of the study.

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