PROTOCOL TITLE:

Communication Intervention for Toddlers with Hearing Loss

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1.0 Purpose of the study:

While children with hearing loss (HL) are experiencing greater gains in spoken language than ever before, considerable variability exists and many children with HL continue to have poorer language skills than their hearing peers. Critical to reducing this variability is the identification of: (a) effective early communication interventions for children with HL and (b) child and parent characteristics that influence intervention outcomes (moderators and mediators). However, to date, only the pilot study for this proposed study has directly examined the effects of an early communication intervention for children with HL within the context of a randomized clinical trial. The overarching goals of the proposed study are to: (a) evaluate the effects of teaching parents to use communication support strategies on child communication outcomes and (b) examine parent and child characteristics that moderate and mediate intervention outcomes. The central hypothesis is that systematic parent training will result in greater parental use of communication support strategies, greater child prelinguistic behaviors, and greater child spoken language outcomes. The specific aims include: (a) comparing parent use of communication support strategies and child prelinguistic outcomes between intervention and control groups during and immediately following intervention, (b) examining parent (communicative insightfulness) and child (sensitivity to social contingency; attention to spoken language) moderators of intervention outcomes; (c) comparing parent use of communication support strategies and child spoken language outcomes between intervention and control groups after intervention (from T7 to T24 months); and (d) examining parent (use of communication support strategies) and child (prelinguistic skills) mediators of intervention outcomes. The proposed study will enroll 96 children with mild to profound bilateral hearing loss.

2.0 Background / Literature Review / Rationale for the study:

Although advances in hearing aid (HA) and cochlear implant (CI) technology have improved language outcomes for children with hearing loss (HL), these children continue to have poorer language outcomes than their hearing peers. Children with HL produce significantly fewer communicative acts, take longer to acquire their first 50 words, have poorer vocabulary knowledge, have difficulty using grammatical structures in writing and in spoken language, have poorer narrative outcomes, and fail to achieve age-appropriate reading levels in high school. These persistent language difficulties extend beyond those children with the highest degrees of HL. Children with mild to moderate levels of HL also experience poorer language outcomes than children with typical hearing. Determining effective early interventions is essential for maximizing communication outcomes for children with HL. A critical step in this process is understanding child and parent factors that predict response to intervention, as not all dyads respond equally well to the same intervention.

However, only the pilot study for the proposed study has examined the effects of an early communication intervention for children with HL within the context of a randomized clinical trial.

3.0 Inclusion and Exclusion Criteria:

Child inclusion criteria include: (a) have bilateral HL (b) enroll in the study between 12 and 18 months of age (c) have no known additional disabilities (e.g., Down syndrome, cerebral palsy, seizure disorder, blindness etc.) as measured by parental report, (d) have English as the primary language spoken at home, (e) a parent or caregiver that is willing to participate who understands spoken English, and (f) are exposed to some degree of spoken language by parents (total communication, auditory/oral).

Children inclusion criteria for typically developing children include (a) no hearing loss, (b) no known disabilities or developmental concerns, (c) less than 14 months old and (d) have English as the primary language spoken in the home.

4.0 Sample Size:

The sample consists of 96 children with bilateral hearing loss and one of their caregivers (mother, father, grandparent). Children of all races and genders will be included in the sample. All children will be between 12 and 18 months of age) at the start of the study. Children will have a diagnosis of bilateral hearing loss. This age was chosen for several reasons. First, this is the age at which intentional communication usually emerges and prelinguistic communication skills develop. As such, this age is necessary to study the effects of early intervention on prelinguistic skills for young children with hearing loss. Second, children are typically seen for an audiology visit during this time, so it is an easy time to enroll study participants. Third, the majority of children are wearing hearing aids at this time. Fourth, 12 months is an age when we are able to test developmental processes that may influence response to intervention. Fifth, parents may be more likely to participate in research when their baby is older and after they have had time to process the diagnosis. Children will start the study around 12-18 months of age and continue in the study for 24 months.

Given a sample size of 86 (96 recruited participants with 10% attrition), we project greater than 99% power for main effects of the intervention (Aim 1) as large as those shown in our pilot study (d=1.07) (see Justification and Feasibility in Research Strategy). We further project 80% power for effects as low as d=.61 and 90% for d=.71. Each of the three previous estimates assume control for pre-test and 10% attrition (e.g., n=86). Our research group has maintained greater than 95% retention in comparable studies over the last two years. We would retain power for smaller effect sizes of d=.58 (80% power, down from d=.61) and d=.67 (90% power, down from d=.71) if no attrition occurs.

5.0 Research Locations:

All study procedures will occur in the homes of participants or at the Early Intervention Research Group at Northwestern University under the supervision of the principal investigator (Dr. Roberts). Video conferencing services (such a zoom) will be used for all sessions, with the exception of "baseline only" activities and "eye tracking" activities.

6.0 Multiple sites: NA

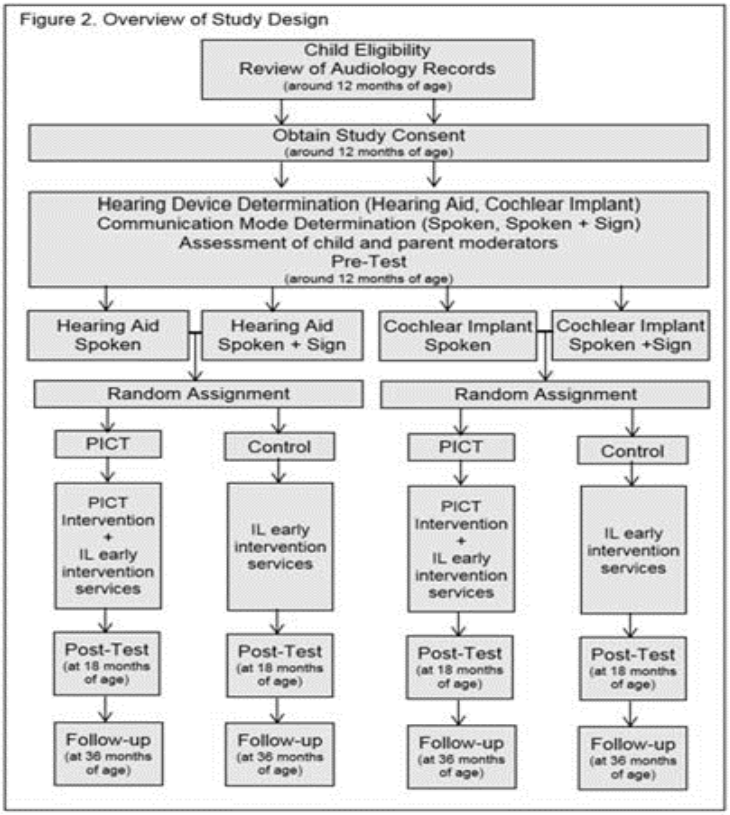
7.0 Reliance Agreements/Single IRB: Dr. Matthew Hall, Dr. Stephanie DeAnda, and Dr. Derek Houston have Individual Investigator Reliance Agreements on this IRB.

8.0 Procedures Involved:

This study will use a parallel stratified randomized clinical trial design with repeated measures to examine the effects of a parent-implemented communication treatment (PICT) on parent use of communication support strategies and on pre-symbolic communicative acts and spoken language outcomes for children with HL. Children and their caregivers will be randomized to either PICT or a business-as-usual (BAU) control group. Children assigned to the PICT group will receive weekly, hour-long intervention sessions in their homes for 6 months. Parents and children will be assessed prior to intervention (at baseline, T0, pre), immediately after intervention (at T7, 7 months after baseline, post), 18 months after intervention (at T24, 24 months after baseline, follow-up), and monthly using abbreviated measures for the entire study (T0 – T24).

Parent-child dyads will be randomized individually following phone screening, completion of baseline assessments, and determination of hearing device status and communication mode. Randomization will be stratified by hearing device status (hearing aid or bone conduction device, cochlear implant) and communication mode (spoken only, sign + spoken). Given that hearing profiles will likely vary among participants, we chose to use hearing device as a stratification factor because it is categorical (hearing aid/bone conduction device or cochlear implant). Children who are a cochlear implant candidate will be assigned to the cochlear implant stratum. In addition, a child with one hearing aid and one cochlear implant will be assigned to the cochlear implant stratum.

Parents in both the intervention and BAU control groups will continue to receive early intervention services according to their individualized family service plan. Figure 2 illustrates the order of study procedures and stratification factors.



All study activities will take place virtually, via a video call, with the exception of the eye tracking tasks, which will take place in the EIRG lab. After consent (explained below), all participants will complete the following pre-test child assessments, outlined in the table below. Given the nature of home testing the numbers of visits may vary based on timepoint and family. **Baseline only for children without hearing loss**: Children within the same age range who are typically developing without hearing loss will be invited to participate in pre (T0) testing only. Testing will remain in person (if allowed) for baseline only children.

Following pre-test, the naïve assessor and parent will complete monthly assessment visits with each child and parent in their home via video call for the entirety of the study (T1 – T24). During these visits, the assessor will collect a 12-minute language sample and a 12-minute parent child interaction. Parents will also complete parent surveys, which will be sent via email and include a REDCap link.

In addition to the monthly assessment sessions, the naïve assessor will also complete additional assessments with parent assistance at T0 (baseline, T7 (post-test) and T24 assessment (follow-up) via video call.

The parent and child will also participate in recorded video sessions with their speech therapist (SLP) two times throughout the study. For parents in Illinois, they parent and child will also be asked to participate in a video session with the child's developmental hearing therapist (DTH). This will not be done with parents in other states, since DTH services can vary by state. The parent videotape a typical early intervention session that takes place in the home. The video recorded sessions will be

stored with all other research data, on password protected servers and drive. This component of the study allows researchers to see what other services parents and children are receiving in the community. After each early intervention therapy visit, the parent will also complete several surveys about the visit and the therapist.

The child's SLP and/or DTH will be consented separately. They will each complete separate video-taped sessions up to 2 times over the course of the child's participation in the study – around month 4 and when the child is 30 months old. After each session, the therapist will be asked to complete surveys. If the child is not receiving speech or developmental services in the home, or if the therapist does not consent to this research, the child and parent can still participate in this research study.

Table 1. Summary of assessments

Assessment	Description	Participant	Duration	Location	Time Point
Communication and Symbolic Behavior Scales (CSBS)	The child is presented with toys and activities designed to elicit prelinguistic communication. The interaction is video recorded and then scored.	Parent and Child	30 min.	Home or Lab	Pre (T0) Post (T7)
Preschool Language Scale - Fifth Edition (PLS-5)	The child is presented with different receptive and expressive tasks such as following simple directions and labeling pictures until the child provides an incorrect response to six consecutive items for both auditory comprehension and expressive communication subscales	Child	30 min.	Home or Lab	Pre (T0) Post (T7) Follow-up (T24)
Language Sample	The child plays with four different sets of toys and looks at a wordless picture book, while the parent engages with the child but does not talk.	Child	12 min.	Home or Lab	Pre (T0) Monthly
Parent-Child Interaction	The child and parent play "as they usually would" with a set of toys for 12 minutes.	Parent and Child	12 min.	Home or Lab	Pre (T0) Monthly
TELE-ASD-PEDS	Virtual screening assessment for autism, Parents will be offered this assessment if the parent or the clinical team has concerns the child may have autism during the regular course of the study. Parents will also have the opportunity to consent to this assessment at 36-months.	Parent and Child	35-60 min.	Home	At parent request or with parent consent at 36-months
Parent Surveys (for children with hearing loss)	The MacArthur-Bates Communicative Development Inventories (MCDI): Words and Gestures or Words and Sentences (the parent selects which words their child says and understands out of 680 words). English, Spanish, and American Sign Language versions (if applicable) Use of Community-Based Intervention Services and Hearing Device Log (the parent answers questions about how many and what types of other therapy services their child received in the last month; indicates how often the child wears their hearing device across 8 different routines, such as meal times) LittlEars Auditory Questionnaire (the parent	Parent	Surveys (90 mins)	Home	Pre (T0) Post (T7) Follow-up (T24)

	answers 35 questions about how their child responds to different auditory stimuli such as music or distant sounds) Demographics Survey (the parent answers questions about demographic information such as occupation, level of education, family members living in the home). Communication Decision Making – Survey about parent's believes about communication Intervention surveys - Questionnaire for the treatment group about their expectations and experiences with the research intervention. CSBS parent questionnaire – Asks for parent report of child communication. Cognitive survey – There will be one standardized cognitive development survey to gather information about cognition at two timeponits. The Ages and Stages questionnaire - ASQ (standardized) at T0 and the Parent Report of Children's Abilities - PACA (standardized) when the child is 24 months old. Parent Feedback about research – Survey asking parents for feedback about experience after major timepoints ASD screening survey – Survey asking parents about common behaviors associated with ASD. Completed when child is 20 months and 24 months old. This is completed by the parent to inform the clinical team if the parent has some developmental concerns about their child. Exit Survey (T24 only) – Gather thoughts from the family about their participation and preferences.				
Parent Interview	The Deaf Language Exposure Assessment Tool (the parents report on language exposure across the day by different speakers. The number of questions depends on the number of language and number of speakers). (Video/Phone Interview)		DLEAT (60 mins) Video call		Pre (T0) When child is 24 months old When Child is 36 months old Follow-up (T24) – only if child is older than 38 months old at study exit
Parent Interview	Receptive-Expressive Emergent Language Scale-3 (REEL-3) parent report		REEL (30 mins)		Pre (T0) Post (T7)

			Video call		
Parent Surveys/Interviews (for children **without** hearing loss)	The MacArthur-Bates Communicative Development Inventories (MCDI): Words and Gestures or Words and Sentences (the parent selects which words their child says and understands out of 680 words) Demographics Survey (the parent answers questions about demographic information such as occupation, level of education, family members living in the home).	Parent	Surveys (40 mins)	Home	Pre (T0)
Monthly Parent Surveys/Interviews	The MacArthur-Bates Communicative Development Inventories (MCDI): Words and Gestures or Words and Sentences (the parent selects which words their child says and understands out of 680 words). English, Spanish, and American Sign Language versions (if applicable) Use of Community-Based Intervention Services and Hearing Device Log (the parent answers questions about how many and what types of other therapy services their child received in the last month; indicates how often the child wears their hearing device across 8 different routines, such as meal times) Child's Communication – Survey about child's communication	Parent	60 min.	Home	Monthly
Visual Reception scale of the Mullen Scales of Early Learning (MSEL)	The child is presented with different non-verbal tasks such as looking for a ring under a washcloth until the child fails to complete three consecutive tasks correctly.	Child	20 min.	Home or Lab	Post (T24)
Goldman-Fristoe Test of Articulation – 3rd edition (GFTA-3)	The GFTA-3 will take 20 minutes to administer. The GFTA-3 measures phonological skills by assessing an individual's articulation of the consonant and consonant cluster sounds of Standard American English. It provides information about an individual's speech sound ability by sampling both spontaneous and imitative sound production in single words and connected speech. GFTA-3 provides age-based normative scores separately for females and males for the Sounds-in-Words and Sounds-in-Sentences tests. Intelligibility is reported as a percentage score, and Stimulability information is reported in table format.	Child	20 min.	Home or Lab	Follow-up (T24)
Attention to Speech vs Sine-Wave Eye-Tracking Task	Children will be presented with two types of trials: speech sounds, and sinewave-transformed complex sounds. Once the child is attending to the screen, a trial will begin. Children will see either a red and white checkerboard pattern or a red and white bullseye. On speech trials, children will hear a random sequence of syllables ("lif" and "neem"). On sinewave trials,	Child (Chicagoland participants only)	5 min.	Lab (if allowed by the state)	Pre (T0)

	children will be presented with a similar sequence of sinewave-transformed sounds. Once children look away from the screen for 2 seconds, the trial will stop and an attention getter will be displayed on the screen. When the child fixates on the attention getter, the next trial will begin. There will be ten trials total, and the experiment will stop after the 10 trials are completed.				
Preference for Pantomime vs ASL Eye-Tracking Task	Children will be presented with two side-by-side videos. In one video, a female adult will convey a story about an everyday activity (getting in the car, brushing her teeth, etc.) through pantomime. In the other video, the same adult will describe similar events using American Sign Language (ASL). Each trial will be approximately 45 seconds in length, and a short attention getter will be displayed on the screen between trials. The side on which each type of video will change from trial to trial to control for infants' side bias. Six trials will be presented, and the experiment will last approximately 6 minutes altogether.	Child (Chicagoland participants only)	6 min	Lab (if allowed by the state)	Pre (T0)
Concept Formation from ASL Eye-Track Task	Children will be presented with 10 trials total. On the first and last trial, children will see an image of a fish and of a dinosaur on the left and right sides of the screen. After the initial trial, children will be presented with images of either different fish or different dinosaurs. Images will alternate between the left and right side of the screen. During each of these 8 trials, a video of an adult female will appear on the top of the screen. The adult will point to the fish or dinosaur on the screen and produce a phrase in American Sign Language (ASL), such as "Look at that! It's a fish." After these 8 trials, children will be presented with a test trial of a fish and a dinosaur on the screen. The experiment will last approximately 8 minutes.	Child (Chicagoland participants only)	8 min	Lab (if allowed by the state)	Pre (T0)
Social Engagement Eye-Tracking Task	The child participates in two consecutive engagement conditions with animal hand puppets as the stimuli: (a) joint attention, (b) unavailable. Each condition includes six trials (six different puppets coming out of an opening). In the joint attention condition, the caregivers will respond only after the child vocalizes or gestures by looking back and forth between the puppet and the child and talking about the puppet. In the unavailable condition, the caregiver will read a book silently and will ignore all child communicative behavior.	Child (Chicagoland participants only)	5 min.	Lab (if allowed by the state)	Pre (T0)
Communicative Insightfulness Assessment	The parent watches video clips of their child and determines when and why their child is communicating.	Parent (Chicagoland participants	30 min.	Lab (if allowed by the state)	Pre (T0)

		only)			
Word Learning Eye-Tracking Task	Children will be presented with 29 trials total. On the first two trials, children will be familiarized to the task by seeing two familiar objects on the screen and asked to find one of them. Children will then be presented with images of two novel objects in order to familiarize them with the objects. Following this, children will see 2 movies, each 24 seconds long, that teach the child the name for reach of those new objects ("blick" and "modi"). After this, children are presented with four blocks of test trials. In each test block, children are given 4 test trials in which they are asked to find one of the new objects, and two reminder trials, where the new objects are shown and named in isolation.	Child (Chicagoland participants only)	6 min	Lab (if allowed by the state)	Follow-up (T24)
Audiology Record Requests	Audiology records will be obtained to confirm degree of hearing loss. The parent will be asked to sign a specific hospital release form, so that we can request the child's audiology records.	Parent	NA	NA	Pre (T0) Post (T7) Follow-up (T24)
SLP/DTH Measures					
Early Intervention Therapist Observation (SLP, DTH)	The parent and child will participate in their typical therapy session with their SLP or DTH in their home and the session will be video recorded.	Parent/Caregiver and Child and SLP or DTH	60 min.	Home	Beginning of study (~T4) End of study (~30 months old)
Early Intervention Therapist Observation Surveys for parent	Parents will complete the following surveys after each individual observation with either their SLP or DTH: (1) About my SLP, (2) Satisfaction Survey, (3) Working Alliance Short Form, (4) Measure of Process of Care, (5) Communication Method Advice	Parent or Secondary Parent	30 min.	Home - but not during the home visit	Beginning of study (~T4) End of study (~30 months old)
Early Intervention Therapist Observation Surveys for therapist	After the videotaped session, the E.I. therapist will be emailed several surveys asking about their clinical background and experience, knowledge of evidence-based practice, and rapport with the parent. Surveys could include: Working Alliance Short Form, Believe About Participation-Based Practices, SLP/DTH Demographics, SLP/DTH Background, SLP/DTH Approach, Hearing Loss Education and Experience, Hearing Loss Approach, Communication Method Advice	SLP or DTH	60 min	Home - but not during the home visit	Beginning of study (~T4) End of study (~30 months old)

Participants assigned to the PICT condition will receive weekly 60-90 minute long intervention sessions in their home via video call for 6 months. Parents will learn four sets of communication support strategies: (a) visual (e.g., modeling language within the child's line of sight), (b) interactive (e.g., following the child's attentional focus), (c) responsive (e.g., responding to all communicative attempts), and (d) linguistically stimulating (e.g., modeling language targets, expanding child communication). Intervention sessions will include the following components:

1. CCX: a 6-minute parent child interaction

2. Teach: 10 minutes of the therapist describing the target intervention strategy
3. Video Feedback: 8-15 minutes of video feedback for the parent to watch themselves practicing the strategies (review phase only)
4. Model: 6-10 minutes of watching standard video clips of parents using the strategy
5. Coach: 20 minutes of the parent practicing the strategy with their child with coaching from the therapist
6. Review: 5-10 minutes of the therapist reviewing the session with the parent, summarizing the session, and answering the parent's questions

After intervention (post), parents in the PICT condition will complete an intervention satisfaction survey. This measure has been used in previous studies of parent-implemented interventions and includes questions about how comfortable parents feels using the communication support strategies, their perceptions about their child's progress, and their rating of different parent instructional methods such as coaching and modeling. Participants assigned to the control group will not receive the PICT intervention. Participants in both groups will continue to receive early intervention services according to their Individualized Family Service Plan.

Participants will be asked if they would like to complete an additional, optional phase of the study around the time their child is 34-36 months old. At the 3rd DLEAT interview, parents will discuss the study with the lab manager and will be asked if they would like to participate. Participation would include an optional 1-hour appointment to complete the TELE-ASD-PEDS with research staff for $50. If the research team has concerns, it will be recommended that a formal evaluation is scheduled in the participant's home state. This will help researchers understand more about social communication delays in deaf and hard of hearing populations.

Data obtained from participants will include standardized, observational, and parent-report measures. All standardized and observational measures will be conducted by independent observers and assessors naïve to the experimental condition. Pre-test assessments will be administered in the participant's home via video call, with the exception of eye tracking measures for local participants. All additional time points will be conducted in the family's home. All standardized assessments and observational measures will be video recorded and coded. Parent report surveys will be collected using REDCap online surveys. Parents will be sent a unique link that gives them access to their unique list of surveys to be completed for that study time point. All surveys and assessments should be completed within a 10-day window to ensure data accuracy at each timepoint. Personal identifiable information (PII) (name, address, phone number, email address) will be collected on all parent/child dyads for the purposes of scheduling assessment visits, for conducting home intervention sessions, and for collecting survey data. Images of the face will be collected by video for the purpose of transcribing and coding parent-child interactions. Date of birth will be collected to determine child age at each time point so that we may include age in months in statistical analyses.

We propose a set of statistical analyses that firmly integrate our hypotheses and research design into a structural equation modeling framework to create a cohesive analytic plan that spans all study aims. Our aims further bridge the divide between

clinical trials and mechanistic research via our multivariate longitudinal design. Defined clinical trial endpoints provide structure to our analyses and support the rigor of classic analytic methods for clinical trials to assess the extent to which the proposed treatment has an effect on parent (parent use of communication support strategies) and child (pre-symbolic communicative acts, spoken language) outcomes. The use of advanced multivariate longitudinal methods allows us to assess not only the extent to which the intervention works (Aims 1 and 3), but for whom (Aim 2) and how (Aim 4) the intervention improves communication outcomes in children with hearing loss. All statistical models will be fit within a structural equation modeling (SEM) paradigm. Our proposed models vary in complexity, from simple linear regressions of main intervention effects to longitudinal mediation analyses. Providing a unified modeling framework for all models will allow for comparability of related analyses due to identical model assumptions. While SEM was traditionally developed as covariance structure analysis, modern or extended SEM (xSEM) can flexibly handle both linear and non-linear relationships between sets of continuous and categorical raw data. This flexibility allows us to specify SEMs that are equivalent to alternatives ranging from linear regression to mixed-effect models to complicated mediation analyses, all using the same state-of-the-art optimization and data handling methods. Our multi-method approach requires data reduction and integration within and across time points. We will create a set of continuous latent indicators of child spoken language outcomes and parent use of communication support strategies. We will create these latent indicators using confirmatory item factor analyses, which allow us to combine the categorical data handling of an item response model with the flexibility to incorporate multidimensionality and specific measurement hypotheses common to factor analyses. We will further use multi-trait, multi-method approaches and related bifactor models when constructs span multiple modes of assessment (observational, elicited, parent report).

9.0 Incomplete Disclosure or Deception: NA

10.0 Recruitment Methods:

Children will be recruited through Lurie Children's Hospital, pediatricians, Early Intervention providers, conferences, and online advertising. Participants are recruited in the Chicagoland area and nationally in the U.S. Clinicians who work with families of young children with hearing loss will be given a flyer to give to potentially eligible families. Clinicians may also direct them to our eligibility screener via the text-to-contact number on the flyer, where the caregiver will answer basic self-reported eligibility questions and give permission for EIRG study staff to contact them about their potential study participation. Study staff will then contact families that may be eligible for the study. Interested families may also contact EIRG directly via email, phone, or completing a recruitment survey on the EIRG website. **Baseline only for children without hearing**

loss: Parents of children without hearing loss and with typical development will be invited to participate in baseline testing only.

11.0 Consent Process:

All consent forms will be approved by Northwestern University's Institutional Review Boards (IRB). All informed consent documents will contain the following: (a) an explanation of the purpose of the research, (b) expected duration of participation, (c) a description of research procedures, (d) foreseeable risks, discomforts, and benefits, (e) confidentiality and privacy of records and data, (f) contact information for who to contact to answer questions about the research process or participant rights and, and (g) a statement that participation is voluntary and that refusal will not result in penalty or change in their clinical services. Additional consent elements will also include financial information, alternative treatments, funding source, mandated reporter language, clinical trial information, and optional elements. All consent documents will contain layman's terminology when possible and use language appropriate to an 8th grade reading level. Consent documentation will include the date of IRB approval.

The consent form will be discussed over the phone or a video call and sent to the parent via email prior to their first visit, when their child is 12-18 months old. Participants will receive a blank copy of the consent form in their email before the consent phone call, once the signature is obtained, parents will download the e-consent directly. An additional "consent guide" is to the parent, which is a supplemental document that will help to explain important elements of the study. The consent discussion will occur over the phone or via call. Parents will pick a time that is convenient for them and will receive a copy of the full consent before the call so that they have an opportunity to review and discuss questions and concerns before they schedule their first appointment. The consent form will be reviewed again and officially signed in person at NU's EIRG lab, in the participant's home or online via the REDCap e-consent module. Participants will be consented by a trained research staff member. Parents who are completing baseline testing only will sign the consent form at their first T0 visit.

The participating caregiver will sign an online consent form using REDCap's e-consent module. The e-consent framework mirrors the paper copy exactly and will have a place where the participant can complete their name, their child's name, and provide an electronic signature using their mouse pad or finger. The e-consent will also note the date that the IRB approved the consent at the top of the form. Participants will also then have the option to download the consent form for their records directly on their device. They will then "verify" that the consent form is correct and accurate. Once a consent form is verified, it is automatically archived in the database and this copy cannot be manipulated, even if the database version changes. Research personnel will review the consent form with all participating caregivers over the phone or a video call before any study visits occur, and caregivers will be a given a chance to ask questions about their participation before signing the consent. The caregiver will have the option to download the consent form directly from REDCap after they sign the form. The consenting staff member will sign the form after the consent form has been reviewed with the parent. Consent forms will be stored electronically on a secure and password protected server and on REDCap,

and a hard copy will be kept in a locked filing cabinet behind a locked door. Child assent will not be sought due to the child's age. Although permission for child participation is obtained from the caregiver, children will be watched for dissenting behaviors. Caregivers will also remain with or be able to view the child at all times so they can monitor their child.

Parents will also agree or disagree to four optional elements at the time of full study consent: 1) The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study; 2) Video recordings of my participation and my child's participation may be shown to researchers, students, educators, and clinicians at workshops, seminars, trainings, and conferences; 3) Video recording clips (1-2 minutes) of my participation and/or my child's participation may be shown to future families participating in the Early Intervention Research Group's research studies; and 4) If in the Chicagoland area, participant is willing to complete eye-tracking activities at the start of the study and at the end of the study, for an additional $50 per visit ($100 total); and 5) Data collected in this study may be used for future research questions and analysis. These data could include video recordings, survey data, or assessment data. These data will not be connected to your name or contact information. Your data will not be shared with anyone outside of the research team. The video clips will be used for training purposes to demonstrate and explain strategies that parents can use with their children.

Early Intervention therapists will be consented separately from the parent. A research staff member will call, text, or email the early intervention provider(s) to explain the procedures.. Texting will be the preferred method of contact via Mosio. If the therapist is unresponsive, their number will be deleted from the Mosio platform. Parents will be asked to give the therapist study flyer to their therapist. The therapists will be texted a link to the FAQ guide for therapists and sent a link to agree or decline study participation. Online consent will be obtained. Therapists will have the option to reply to a text message that they do not want to proceed if they are not interested in participating or to schedule a call with the research coordinator to discuss questions.

The child's other caregiver may also be consented electronically if they participate in the child's typical speech or developmental hearing sessions in the community. This ensures that the research team has their consent to video record them and complete surveys about the video-recorded community session. Second caregivers will be sent an electronic version of the consent form to sign and date. This will only be obtained if the primary study parent is not also the primary parent who participates in the other sessions.

Parents will also have the opportunity to opt-in to an additional portion of the study to complete an autism screening when their child is 34-36 months old. Parents will discuss the additional procedures with the lab manager during their DLEAT appointment (which takes place around 34-36 months) and asked if they would like to participate. If so, they will sign a separate REDCap electronic consent. Parents do not have to participate in this additional phase of the study.

12.0 Financial Compensation:

Parents will be paid $100 for T0, T7, and T24, which involve more assessments. For all other timepoints (T1-T23), parents will receive $25 for completing assessments and surveys for a total of $950. Parents in the Chicagoland area will be paid $50 for coming to the lab to complete eye-tracking at T0 and T24, if they wish. Additionally, parents will receive an additional $25 for completing surveys about their SLP and DTH Early Intervention therapists if they have one at the beginning and end of the study for up to an additional $100. For parents who agree to complete the TELE-ASD-PEDS at 36-months, parents will be compensated an additional $50 for this appointment. If parents complete all activities, they could be compensated up to $1200 over the two-year study.

All payments are made using the Stored Value Card Program (virtual card) (http://www.northwestern.edu/controller/treasury-operations/depository-services/stored-value-visa-card-program.html). Participants will receive payment within one week of signing their receipt and completing the research activity.

Parents will also receive a tablet with accessories (case, headphones, tripod, and cellular service, if needed) to use throughout their time in the study to aid with gathering quality video data. Participants may receive a cellular enabled tablet, after completing an internet speed test, if their internet is not ideal for video calls, which would require a stable internet connection with high upload speeds. The participant will sign a contract provided by NU IT acknowledging that it is property of Northwestern and that they are responsible for loss or damage. Participants will keep the tablet and accessories as an incentive, if they complete the entire 24-month study.

Participating therapists will be paid $50 for completion of surveys at the beginning and end of the study. Each therapist has the potential to be compensated up to $100 per participant over the two year study.

13.0 Audio/Video Recording

All testing and intervention sessions will be video recorded via a video platform (such as zoom) or on lab cameras if at the EIRG. All video and audio recordings will be stored on the Roberts Lab server. These files will be stored by ID number. Hard copies and video cameras will be stored in a locked lab office until upload. Following upload to the server video files on the audio and video recorders will be deleted.

14.0 Potential Benefits to Participants:

Benefits to parents who participate in the intervention are expected to include: (a) improved strategies for working on their child's language and communication skills and (b) more accurate perceptions of the child's language and communication abilities. Parents have rated our training as helpful to them and their children and they have reported high levels of satisfaction with the training protocol. Parents in the control group will have the benefit of additional language development results. After each major assessment period at T0, T7, and T24 months, all parents will receive a comprehensive report describing their communication skills.

15.0 Risks to Participants:

There are no obvious serious risks for any of the participants. The time involved in the study for families assigned to the PICT group is considerable; however, the perceived benefits outweigh the costs to families in personal time. Parents have rated our parent training as helpful to them and their children. The only potential risk to study participants associated with this project is the risk of confidentiality being violated. There are safeguards in place, as described below in section 16 to protect against breach of confidentiality. Given these safeguards, the likely impact of this risk of breach of confidentiality to participants is minimal. No risks to the participant's physical, psychological, social, cultural, financial, or legal risks are anticipated. Overall, the risks associated with this study are very low.

16.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

All data, including assessment protocols, surveys, and video recordings are stored by a unique identification number assigned to each study participant. All study data will be stored using: (a) REDCap (Research Electronic Data Capture) a secure, web-based, and HIPAA compliant system for collecting and managing data and (b) a secure password-protected server at each research site and also on Northwestern University's server for cross-site monitoring and data analysis. Only study research personnel will have password-protected access to both the databases and the secure server. Two separate databases will be created in REDCap in order to keep personal identifying information and study ID number separate. The first database includes de-identified study data, which is stored by ID number. The link between name/contact information and ID number is stored in a separate second database to which only the PI and research personnel have access.

All hard copies of study documents will only contain the child's unique study identification number. All hard copies will be scanned onto a secure server and uploaded electronically to REDCap. Hard copies and video cameras will be stored in a locked lab office until upload. Following upload, data entry, and verification, the hard copies will be shredded and the electronic files on the audio and video recorders will be deleted. Research Personnel will be responsible for these data management tasks. All hard copies of the informed consent will be kept in a locked filing cabinet behind a locked door that only research personnel can access.

As a part of downloading and using the video software (such as Zoom), personal data may be collected to enhance the user experience. Any videos recorded will be downloaded directly on a research staff member's computer (or saved on a HIPPA compliant cloud), then saved to our password protected and encrypted server, and then deleted from the desktop

Videos may also be shared with the participant (of themselves or of other families who have consented to using their video clips) through a secure platform to enhance video quality, which often suffers on video platforms. These platforms may include Northwestern Box, which is only accessible through a link or through sharing rights directly with the participant. We may also use another video streaming service, such as

vimeo or youtube, with password protection enabled if unable to use box for some reason.

Research staff that have access to study information include: the principal investigators, research assistants, research clinicians, the statistician, and the project manager. We foresee no circumstance in which personal identifiable information would be released to a third party, including the funding agency or representatives of the University's IRB. If any data are shared with a third party, no personal identifiable information will be included and participants will only be identified by their unique identification number.

Should we incidentally discover other developmental or medical concerns, we will refer the child to the appropriate medical professional. Should we incidentally discover signs of suspected child abuse or neglect, we will call the Illinois or Tennessee Department of Children and Family Services 24-hour child-abuse hotline.

Data will be stored for at least seven years after the completion of the study. Findings will be reported in the aggregate with no individual identification associated with any reported data. Should the results of the project be presented at conferences, seminars, and/or workshops, the identity of the participants will not be disclosed. The video recordings will be shown only if permission is obtained from the specific parent for that purpose.

Participant communication will take place via phone call, email, and text. In order to accommodate that most families respond to texting more quickly, we will utilize the web-based program, Mosio which will allow staff to text via the online platform about upcoming study activities. This eliminates the need for staff to use their personal cell phones and allows the team to use a password protected platform that only research personnel can access. Inside Mosio, data is stored in security-controlled, HIPAA-compliant servers. Personal information is never shared outside Mosio without permission.

17.0 Data Monitoring Plan to Ensure the Safety of Participants:

Safety Monitoring

Overall framework for safety monitoring. Adverse events (AE), serious adverse events (SAE), unanticipated problems, and unusual participant behavior will be documented in an online database (REDCap) after every assessment or intervention session with the parent/child. Adverse events include: (a) parental psychological stress (parent crying that last more than 2 minutes), (b) child distress (crying for more than 5 minutes), and (c) child injury (e.g., an injury such that results in a child crying for more than 5 minutes or the parent expressing concern about the incident). In this trial a serious adverse events include hospitalization or death of the parent or child.

Frequency of monitoring, interim analysis and stopping rules. Safety monitoring reports will be gathered every Thursday, placed into a central document, and reviewed by the PI every Friday during weekly research meetings.

Process for managing and reporting adverse events. After each assessment or intervention visit, research staff will complete a session log in which they are prompted to report if an adverse event occurred. Adverse events are predefined before the start of the study (as described above) and research staff are prompted for specific AEs. These session logs are monitored weekly by the project manager and discussed with the PI. Additionally, all study staff members will be trained at the start of the study that when an AE occurs, they should inform the PI and project manager immediately. We will follow up on all adverse events by calling or emailing the parent within 24 hours. Any adverse events without a causal relationship with the intervention will be reported to the NIDCD Program Officer and Northwestern University's IRB within 15 calendar days. Any serious adverse event (SAE) will be reported to the NIDCD Program Officer and Northwestern University's IRB within 24 hours. In addition, a detailed written report will be submitted within 7 days to NIDCD and the Northwestern University's IRB.

Data Monitoring

The data will be monitored by the staff statistician and Dr. Roberts. They will conduct the randomization, oversee data entry procedures, manage the database, train study staff on data entry procedures, and be responsible for maintaining the quality and integrity of the database as outlined below. Data entry will be completed using a centralized internet-based system (REDCap), which makes the project database instantly available to all authorized researchers in the system and permits access from any computer with an internet connection from multiple locations (via password protected logon). Summary reports (e.g., recruitment, assessment progress) can be generated immediately and are automatically updated with additional data. Reports can be created that document participant progress to-date and track missing data. These missing data reports will be reviewed weekly by the study team, such that we may try to acquire missing data in a timely manner (re-emailing or calling study participants to complete surveys; re-administering test items in the event that not all items were completed).

All data will be independently entered by two different research staff. Discrepancies between records will be automatically identified and verified. Additional quality assurance checks will be completed to check for missing data, range, and outliers. Once the data have been verified, they will be stored in a second "clean" dataset. Summary reports of the "clean" dataset will be organized by time point and measure. The "clean" dataset and summary reports will be reviewed quarterly by the independent biostatistician on the Data and Safety Monitoring Board. Outcomes by experimental condition assignment (intervention, control) will not be included in any interim reports.

Risks related to incorrect or biased scoring of measures will be minimized in the following ways. All standardized and observational measures will be conducted by independent observers and assessors naïve to the experimental condition. All testing sessions will be video recorded and procedural fidelity for test administration will be measured monthly to assess and ensure accuracy of test administration. Observers for all observational measures will be trained to point-by-point reliability of 90% for three consecutive administrations prior to coding the observational data. A second independent observer will code 20% of the observational measures. When reliability

falls below 90%, coders will discuss discrepancies and document additional rules as needed. Furthermore, scoring of all norm-referenced assessments will be verified by a second person.

Staff fidelity and reliability training is also tracked using a project management tool that outlines all training procedures and notifies other research personnel when tasks are completed. If at any time a research member is consistently producing errors, they will be re-trained on all procedures with oversight from the project manager. All reliability and fidelity training and monitoring will be documented in a database that captures each research member's fidelity score.

18.0 Data, and if applicable, Specimen Banking:

Data will stored for at least seven years after the end of the study. Study data will be banked in a statistical file in which all identifying information on each participant will be separated from the data; the only identifiers available on the statistical records will be a random research number. The statistical file will be located on a password-protected secure server.

19.0 Data Sharing:

The proposed research will include data from 96 children with hearing loss and their parents. The final dataset will include elicited, parent-report and observational data of child prelinguistic skills and spoken language. The dataset will also include observational measures of parent use of communication support strategies. All baseline, intervention and follow-up data for covariates, moderators, and outcomes will be included. Data from both treatment and control participants will be included. The final dataset will not include video recordings, which could results in identification of participants. The final dataset will be stripped of identifiers prior to release for sharing. However, we believe that there remains the possibility of deductive disclosure of participants with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for a commitment: (a) to use the data only for research purposes and not to identify any individual participant; (b) to secure the data using appropriate computer technology; (c) to destroy or return the data after analyses are completed; and (d) to cite the grant and key publications describing the database and measures in any resulting presentations and publications.

Transcripts from parent-child and assessor-child language samples will also be deposited into the Child Language Data Exchange System (http://childes.psy.cmu.edu), an international repository of child language data. Access to the data will be openly available. Researchers who access the transcripts will be expected to abide by the established guidelines for use of TalkBank data http://talkbank.org/share/irb/options.html.

Because we will not be able to complete our aims until all longitudinal data are collected and analyzed, we will archive all files at the end of Year 5. Data archiving and sharing will be overseen by Dr. Roberts. All raw datasets will be archived for at least five

years after the completion of this project. We will document all data files using standardized, high-fidelity methods to increase efficiency in accessing and manipulating archived data. We will use the Inter-University Consortium for Political and Social Research (ICPSR) Guide to Archiving, which defines industry standards for data archiving documentation (http://icpsr.umich.edu/ICPSR/access/dataprep).

For participants enrolled in the at Robert H. Lurie Children's Hospital, "Neural Predictors of Language Outcomes in Young Children with Cochlear Implants" (IRB 2018-1959), the Language Exposure Assessment Tool will be shared. Only de-identified data (only scores) will be shared and videos will not be shared.

20.0 Qualifications to Conduct Research and Resources Available:

Dr. Roberts is a clinician who serves children with developmental delays and their families. Dr. Roberts is a licensed speech-language pathologist with 10 years of experience working with children from birth to 36 months of age. Dr. Roberts is a certified Early Intervention Provider for the state of Illinois and she has worked on three federally funded intervention research projects involving children from birth to 60 months of age. Dr. Roberts teaches a graduate class on advanced issues in family intervention in which she routinely teaches graduate students how to work with young children and their families.

Dr. Nancy Young, the PI of the subcontract at Lurie Children's Hospital, is Head of Otology & Neurotology and the Medical Director of Audiology & Cochlear Implant Programs.

Dr. Derek Houston, a consultant on the project, is associate professor in the Department on Otolaryngology at Ohio State University. Dr. Houston specializes in early language development for children with hearing loss and will act as a consultant on the eye-tracking methodology for the project.

Dr. Matthew Hall is assistant professor in the Department of Psychology at University of Massachusetts, Dartmouth. Dr. Hall specializes in language and psycholinguistics. Dr. Hall will be interacting with participants by administering the D-LEAT for several participants, as well as training EIRG staff on how to administer the measures. Dr. Hall will have access to PII, as he is interacting directly with participants. Dr. Hall will also help the study team analyze data from the D-LEAT.

Dr. Stephanie DeAnda is assistant professor in Communication Disorders and Sciences at the University of Oregon. Dr. Stephanie DeAnda is a licensed speech-language pathologist. Dr. DeAnda will be interacting with participants by administering the D-LEAT for several participants, as well as training EIRG staff on how to administer the measures. Dr. DeAnda will have access to PII, as he is interacting directly with participants. Dr. DeAnda will also help the study team analyze data from the D-LEAT.