Early Communication Intervention for Toddlers With Hearing Loss

NCT03803943

Statistical Analysis Plan uploaded to clinicaltrials.gov on

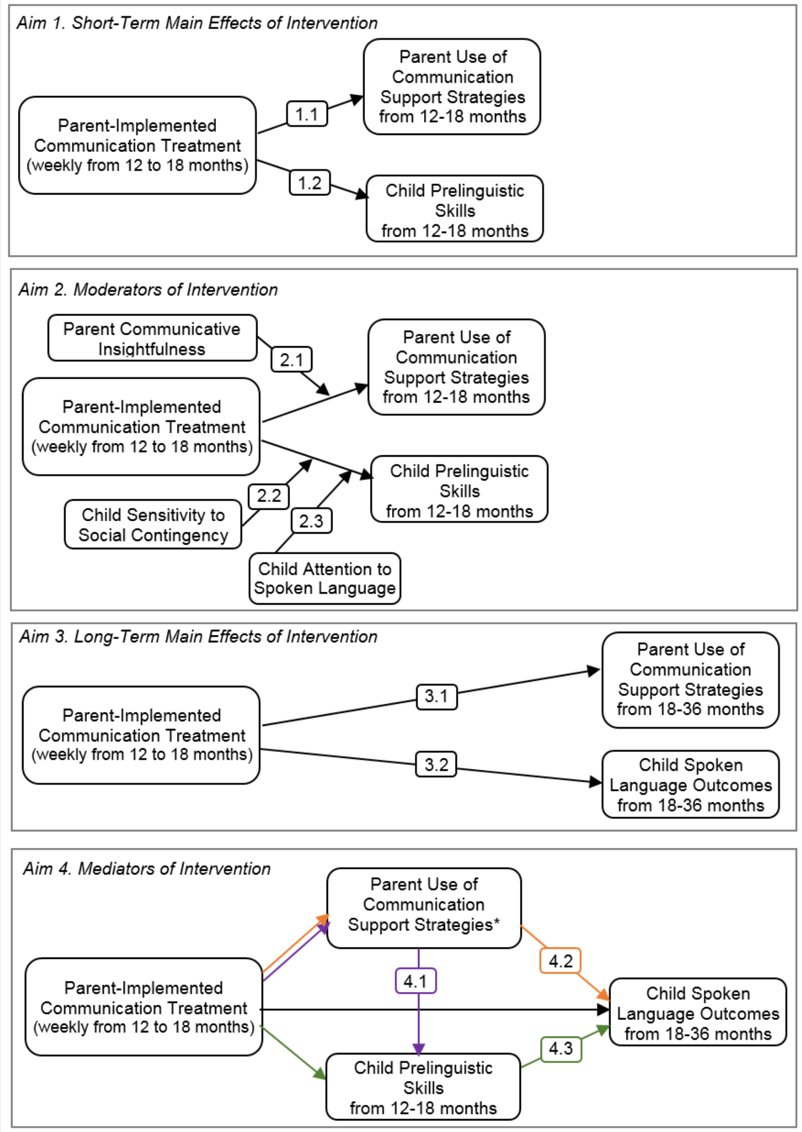
08/04/2025

STATISTICAL DESIGN AND POWER

Overview

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 (prelinguistic skills, 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.

Figure 1. Conceptual Model of the Study



*We will test the extent to which parent use of communication support strategies from 12 to 18 months of age mediates child prelinguistic skills and also the extent to which parent use of communication support strategies from 18 to 36 months of age mediates spoken language outcomes.

Structural Equation Modeling (SEM). 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)[87] 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. For example, prelinguistic communication skills are measured both: (a) continuously during intervention (via a language sample) and (b) after intervention (via the CSBS). As such, analysis of the effects of intervention on prelinguistic skills features two similar analyses: a latent growth curve of the monthly language sample (analysis 1.2a) and a linear regression for CSBS scores (analysis 1.2b). These two analyses answer similar questions (e.g., what is the direct effect of intervention on child prelinguistic skills) that differ based on the data on which they depend. Analysis 1.2a predicts month-to-month growth in child prelinguistic communicative acts, while 1.2b predicts a single CSBS score. These two modeling frameworks vary in their complexity and their modeling assumptions, specifically that latent growth curves estimated via SEM have more robust missing data handling than conventional regression software that requires complete cases. Estimating all models as SEMs means that all models retain the same underlying full sample sizes and assumptions, so that disparate results can be more directly attributed to constructs. In this example, stronger effects on monthly prelinguistic skills would reflect more proximal effects of intervention rather than a weakness of conventional regression methods and their missing data assumptions.

Data reduction of primary outcomes. 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 prelinguistic communication, 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). See Table 1 for a summary of primary outcome constructs.

Table 1. Primary outcome constructs by analysis

Construct	Measurement Structure	Measures	Variables Extracted	Measurement Occasions	Variable Type by Analyses
Parent Use of Communication Support Strategies	Latent	Parent use of communication support strategies coded from a parent-child interaction	The following measures from the coded parent-child interaction sample: • Percentage of intervals in which the adult is communicating within the child's line of sight • Percentage of adult communication that is paired with a gesture in the child's line of sight • Percentage of intervals in which the adult's play is related and is in close proximity to the child • Percentage of child non-verbal actions that are mirrored and mapped • Percentage of child communication that is followed by a contingent response • Percentage of adult communication that is in response to child communication • Percentage of adult communication that contains a child linguistic target • Percentage of child communication to which the adult imitates and adds a word	Monthly from 12 to 18 months of age (6 time points between pre and post)	• Analysis 1.1: Dependent • Analysis 2.1: Dependent • Analysis 4.1a: Mediator • Analysis 4.1b: Mediator
				Monthly from 18 to 36 months of age (18 time points between post and follow-up)	• Analysis 3.1: Dependent • Analysis 4.2a: Mediator • Analysis 4.2b: Mediator
Child Prelinguistic Communicative Acts	Latent	Language Sample	Number of child prelinguistic communicative acts coded from the language sample	12 to 18 months of age (6 time points between pre and post)	• Analysis 1.2a: Dependent • Analysis 2.2a: Dependent • Analysis 2.3a: Dependent • Analysis 4.1a: Dependent • Analysis 4.3a: Mediator
Child Overall Prelinguistic Skills	Observed	Communication and Symbolic Behavior Scale (CSBS)	Total Scaled Score	At 18 months of age (post)	• Analysis 1.2b: Dependent • Analysis 2.2b: Dependent • Analysis 2.3b: Dependent • Analysis 4.1b: Dependent • Analysis 4.3a: Mediator • Analysis 4.3b: Mediator
Child spoken words	Latent	MacArthur-Bates Communicative Development Inventory; Language Sample	• Total number of Words Said from the MacArthur-Bates Communicative Development Inventory • Total number of different spoken word roots from the language sample	18 to 36 months of age (18 time points between post and follow-up)	• Analysis 3.2a: Dependent • Analysis 4.2a: Dependent • Analysis 4.3a: Dependent
Child overall spoken language	Observed	Preschool Language Scale-5th Edition	Total Standard Score	At 36 months of age (follow-up)	• Analysis 3.2b: Dependent • Analysis 4.2b: Dependent • Analysis 4.3b: Dependent

Multicollinearity. This proposal includes a large set of prelinguistic and linguistic variables, some of which will be included in the same analyses. Our data reduction is one part of our solution to multicollinearity, such that latent constructs that account for shared variation between comparable predictors will be used when possible. In other cases, we will control for multiple collinear variables in the same analysis, specifically when using multiple coded variables from naturalistic parent-child interactions. In those cases, we will use alternative decomposition and transformation methods. Principle components analysis (PCA) can transform a set of collinear predictors into a set of uncorrelated variables representing variance in the original data. For example, a simple PCA of one parent and one child variable would yield two components: one indicating shared family level behavior and the other representing scaled differences between parent and child. We will further explore non-linear transformations to make sure non-linear associations and distributional assumptions are accounted for, including both simple (e.g., polynomial or logarithmic transformations to improve distributions) and complex (e.g., adjusting observed child communication for proportion of time spent communicating) transformations. This set of methods integrates well within our SEM framework and multivariate longitudinal design.

Missing data. Given this is an intent-to-treat trial, all 96 children randomized will be included in the analyses of primary outcomes even if data are missing. However, our preliminary studies showed high retention rates (e.g., 95% retention in the pilot study - R03DC012639), but missing data occurs in all longitudinal studies. All models will be estimated using full information maximum likelihood (FIML), which uses all available data and yields unbiased parameter estimates under the most common missingness mechanisms. We will further use our set of predictors and covariates to predict missingness, and include those variables as covariates to conform to FIML assumptions. For non-ignorable missing data, we will conduct sensitivity analyses using non-ignorable pattern-mixture and selection models to investigate the robustness of our conclusions across the different models for missing data.

Covariates. Controlling for covariates is an important part of any analysis. While randomization and stratification should remove effects of these variables, additional statistical control curtails potential unhappy randomizations and other threats to internal validity. As such, we will examine differences between experimental conditions for the following variables: non-verbal cognitive skills, degree of hearing loss in the better ear, hearing age, hours of hearing device use, SES, sign exposure in the home, other spoken languages in the home and amount of community-based early intervention therapy services. Should a difference exist at any point in the study, we will include that variable in all statistical analyses.

Multiple testing. Our proposed analyses and rich multivariate data collection will allow us to test hypotheses in multiple ways. Our focus on SEM will allow for complex hypotheses to be tested with a single model, obviating part of the need for multiple testing corrections. However, we will further employ Benjamini-Hochberg corrections[88] as needed to correct for multiple testing. This procedure is a more sophisticated alternative to traditional Bonferroni corrections that better account for multiple simultaneous significant parameters.

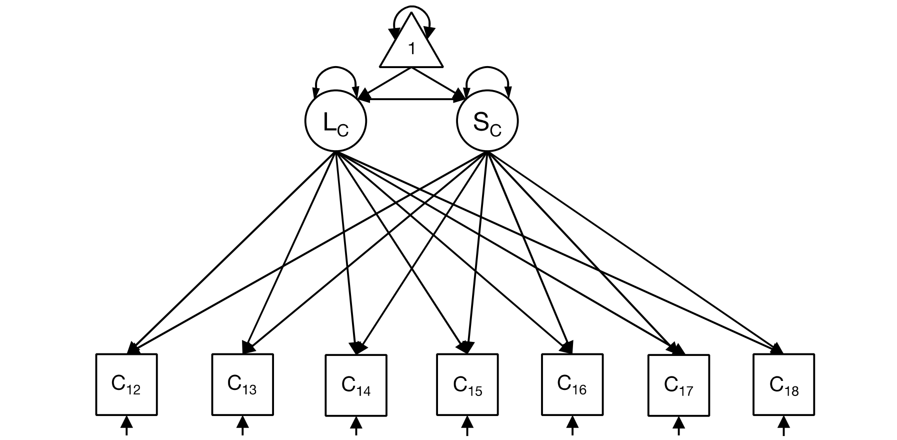
Aim 1 Analyses

This aim tests the main effects of the intervention, both on parental use of communication support strategies and on child prelinguistic skills. We predict that: (a) parents in the intervention group will use more communication support strategies during intervention than parents in the control group (analysis 1.1); (b) children in the intervention group will have greater growth in rate of prelinguistic communicative acts between 12 months (pre) and 18 months of age (post) (analysis 1.2a) and greater overall prelinguistic skills at 18 months of age (post) (analysis 1.2b) than children in the control group. We will employ a mix of traditional and advanced statistical methods, balancing simplicity of linear regression and related methods with sophisticated SEMs that handle attrition and missing data and allow for more flexible integration of time-varying covariates.

Regression for primary intervention effects. The simplest analyses used in this proposal are multiple regressions, which allow for direct comparisons between intervention and control groups with minimal assumptions and the inclusion of covariates. We will use multiple regression for analysis 1.2b, which looks at the effect of intervention on prelinguistic skills using the CSBS Total Scaled score at 18 months (post). This regression will include experimental condition (intervention, control) as one predictor along with pre-test scores and other relevant covariates. These models can be fit either in traditional omnibus software (e.g., R, SPSS, SAS) or via SEM software to take advantage of FIML when attrition is present, as the primary difference between traditional and SEM manifest variable regression approaches is missing data handling.

Latent Growth Curve Modeling. Latent growth curve models are common tools for assessing both the direction and magnitude of how people change, as well as individual differences in the rates of change. These models hypothesize latent variables that represent between-person differences in both overall level (intercept) and rates of change (slopes). These models are commonly fit as structural equation models, but can be equivalently specified within mixed effect models (also called multilevel modeling and hierarchical linear modeling). Latent growth curves can also: (a) be easily extended into non-linear change, (b) incorporate intervention and covariate effects, and (c) include cross-lagged regression terms like those used in our mediation analyses. While many applications of growth curve models use observed outcomes (e.g., monthly assessments of prelinguistic communication from the language sample), latent growth factors can predict latent variables just as easily under the CUFFS, or curves-of-factors approach.[89] This will allow us to jointly apply our dimension reduction plan to multivariate outcomes and simultaneously estimate growth, which we will do in Analyses 1.1 and 1.2a.

Figure 2. Latent growth curve model



One example of a latent growth curve model is shown in Figure 2, where latent intercepts (level) and slopes (indicated by the circles labeled “L_c” and “S_c”) represent unmeasured variables that describe how children differ from each other in their overall level of prelinguistic development. These two latent variables predict and describe how children grow in their prelinguistic communicative abilities from age 12 months (C_{12}) to age 18 months (C_{18}). Latent growth models will be used for analyses 1.1 and 1.2a, all of which use a slope factor as a dependent variable.

Aim 1 analytic plan. Analyses for Aim 1 will utilize SEM equivalencies of both traditional regressions and growth curve extensions of these models. We will estimate all models in SEM to minimize the impact of attrition.

Analysis 1.1. Intervention will predict the slope factor in a latent growth curve model of overall parent use of communication support strategies, which is a latent variable of parent use of communication support strategies estimated monthly from 12 months (pre) to 18 months of age (post). This will utilize the CUFFS method (McArdle, 1988) of estimating growth in latent variables.

Analysis 1.2a. Intervention will predict the slope factor in a latent growth curve model of child prelinguistic communicative acts from a language sample from 12 months (pre) to 18 months of age (post). This will be accomplished by including intervention as a predictor in the child prelinguistic communicative acts growth curve.

Analysis 1.2b. CSBS Total Scaled Scores at 18 months of age (post) will be regressed on intervention status controlling for CSBS Total Scaled Scores at pre-test and other relevant covariates.

Aim 2 Analyses

This aim builds on the analyses of the first to identify moderators of intervention effects by way of SEM-based regression. Identifying moderators of intervention effects will allow us to better understand the effects of intervention and better identify factors that influence response to intervention. In Aim 2, we predict that: (a) parents who show greater insight regarding the intent of their child’s prelinguistic communicative behaviors (have greater communicative insightfulness) at pre-test will have a larger intervention effect (2.1) and (b) children who associate their prelinguistic communicative behaviors with responses from their parents (have greater sensitivity to social contingency) at pretest (analyses 2.2a and 2.2b) and (c) have a greater attention to spoken language at pre-test will have a larger intervention effect (analyses 2.3a and 2.3b). Analysis 2.1 uses the proportion of child communicative acts that parents correctly identify (communicative insightfulness) as a moderator of a latent variable that describes overall parent use of strategies measured monthly from 12 (pre) to 18 months of age (post). Analyses 2.2a and 2.2b uses child sensitivity to social contingency (interaction ratio from a still-face procedure at pre-test) to moderate growth in child prelinguistic communicative acts from a language sample measured monthly from 12 months (pre) to 18 months of age (post) (analysis 2.2a) as well as CSBS Total Scaled Scores at 18 months (post) (analysis 2.2b). In analyses 2.3a and 2.3b, child attention to spoken language (orienting time toward speech from a sequential looking preference procedure at pre-test) moderates the same two outcomes as in 2.2a and 2.2b (growth in child prelinguistic communicative acts, CSBS Total Scaled Scores).

Moderation. Moderation in clinical trials deals with differential effectiveness of intervention as a function of other independent variables. This is typically accomplished with interaction terms, which mathematically state that the effect of an intervention goes up with increases in specific covariates. We will employ all current standards for regressions using interaction terms, including variable centering,[90] application of variance inflation factors to test for multicollinearity,[91] and residual diagnostics to ensure valid and interpretable estimates.

Multiple-group SEM. Interaction can be further implemented via multiple-group SEM due to the fact that our predictor (intervention status) is a categorical variable. Intervention and control groups are specified as separate groups in a multiple-group SEM framework, and all model parameters can either be constrained to equality across groups to measure main effects or freed to test interactions and moderation. This method allows for both equivalence to extant moderation approaches and flexibility to test for differences in non-traditional parameters, specifically residual variance terms.

Aim 2 analytic plan. Analyses for Aim 2 will utilize SEM equivalencies of both traditional regressions and growth curve extensions of these models. Interaction terms will be centered and included in models as described below. We will estimate all models in SEM to minimize the impact of attrition.

Analysis 2.1. Intervention effects for parent use of communication support strategies will be moderated by parental communicative insightfulness (i.e, proportion of child communicative acts correctly identified by parents in the Communicative Insightfulness Assessment at pre-test). This model will be estimated exclusively using SEM as a latent parent growth variable with parent use of communication support strategies measured monthly from 12 months (pre) to 18 months of age (post) as the primary outcome.

Analysis 2.2a. Intervention effects on a latent slope representing growth in child prelinguistic communicative acts from a monthly language sample from 12 months (pre) to 18 months of age (post) will be moderated by child sensitivity to social contingency (interaction ratio from a still-face procedure) at 12 months of age (pre). This model will be estimated exclusively using SEM with a latent child growth variable of prelinguistic communicative acts, measured during monthly language samples from 12 to 18 months of age, as the primary outcome.

Analysis 2.2b. Intervention effects on observed CSBS Total Scaled Scores at 18 months (post) will be moderated by child sensitivity to social contingency (interaction ratio from a still-face procedure) at 12 months of age (pre). This analysis will be carried out jointly using regression methods for residual diagnostics and estimation of variance inflation factors and as a structural equation model, with the former used for assumption checking and robustness to missing data and the latter used for final scientific decisions.

Analysis 2.3a. Intervention effects on a latent slope representing growth in child prelinguistic communicative acts from a monthly language sample from 12 months (pre) to 18 months of age (post) will be moderated by child attention to spoken language (orienting time toward speech from a sequential looking preference procedure) at 12 months of age (pre). Like analysis 2.2a, this model will be estimated using SEM due to the latent child growth outcome.

Analysis 2.3b. Intervention effects on observed CSBS Total Scaled scores at 18 months (post) will be moderated by child attention to spoken language (orienting time toward speech from a sequential looking preference procedure) at 12 months of age (pre). Like analysis 2.2b, this analysis will be carried out jointly using regression methods for assumption checking and SEM for robust estimation of final parameters.

Aim 3 Analyses

This aim tests the long-term effects of the intervention, both on parental use of communication support strategies and on child spoken language outcomes. We predict that: (a) parents in the intervention group will use more communication support strategies after intervention than parents in the control group (analysis 3.1); (b) children in the intervention group will have greater growth in spoken words between 18 months (post) and 36 months (follow-up) (analysis 3.2a) and greater overall spoken language outcomes at 36 months of age (follow-up) (analysis 3.2b) than children in the control group. As in Aim 1, we will employ a mix of traditional and advanced statistical methods, balancing simplicity of linear regression and related methods with sophisticated SEMs that handle attrition and missing data and allow for more flexible integration of time-varying covariates.

Aim 3 analytic plan. Analyses for Aim 3 will again utilize SEM for both regression and latent growth curve models, with the same benefits to attrition and estimation. The analyses here largely mirror those in Aim 1, looking at long-term rather than short-term intervention effects.

Analysis 3.1. Intervention will predict the slope factor in a latent growth curve model of overall parent use of communication support strategies, which is a latent variable of parent use of communication support strategies estimated monthly from 18 months (post) to 36 months of age (follow-up). This will utilize the CUFFS method[89] of estimating growth in latent variables.

Analysis 3.2a. Intervention will predict the slope factor in a latent growth curve model of child spoken language outcomes (a latent variable of total number of different words said from the MCDI and total number of different spoken words from a language sample) from 18 months (post) to 36 months of age (follow-up). This will be accomplished by including intervention as a predictor in the child spoken word growth curve.

Analysis 3.2b. Intervention will predict PLS-5 Standard Scores at 36 months via multiple regression. We will test PLS-5 Standard Scores controlling for pre-test scores as we did in Analysis 1.2b.

Aim 4 Analyses

This final aim addresses intermediary mechanisms of the intervention by way of mediation analysis. This aim is exploratory given that we cannot examine mediators of intervention outcomes if there is not a short-term (Aim 1) or long-term effect of intervention (Aim 3). Mediation analyses consist of a broad set of methods that test the extent to which causal pathways between variables can be explained through effects on a third variable. In Aim 4, we predict that parent use of communication support strategies will mediate the relationship between experimental condition and child (a) prelinguistic (analyses 4.1a and 4.1b) and (b) spoken language intervention outcomes (analyses 4.2a and 4.2b); and that (c) growth in child prelinguistic communication skills will mediate the relationship between experimental condition and spoken language outcomes (analyses 4.3a and 4.3b). As such, we propose three sets of mediational analyses. In analyses 4.1a and 4.2b, parent use of communication support strategies from a parent-child interaction measured monthly from 12 to 18 months will be tested as a mediator of growth in child prelinguistic communicative acts from a language sample from 12 months (pre) to 18 months of age (post) (analysis 4.1a) as well as CSBS Total Scaled Scores at 18 months of age (post) (analysis 4.1b). In analyses 4.2a and 4.2b, parent use of communication support strategies from a parent-child interaction measured monthly from 18 to 36 months will be tested as a mediator of growth in number of spoken words (latent variable from MCDI Words Said and number of different words from a language sample) measured monthly from 18 months (post) to 36 months of age (follow-up) (analysis 4.2a) as well as PLS-5 Total Standard Scores at 36 months of age (follow-up) (analysis 4.2b). In analyses 4.3a and 4.3b, growth in child prelinguistic communicative acts from a language sample measured monthly from 12 months (pre) to 18 months of age (post) will be tested as a mediator of growth in number of spoken words (latent variable from MCDI Words Said and number of different words from a language sample) measured monthly from 18 months (post) to 36 months of age (follow-up) (analysis 4.3a) as well as PLS-5 Total Standard Scores at 36 months of age (follow-up) (analysis 4.3b).

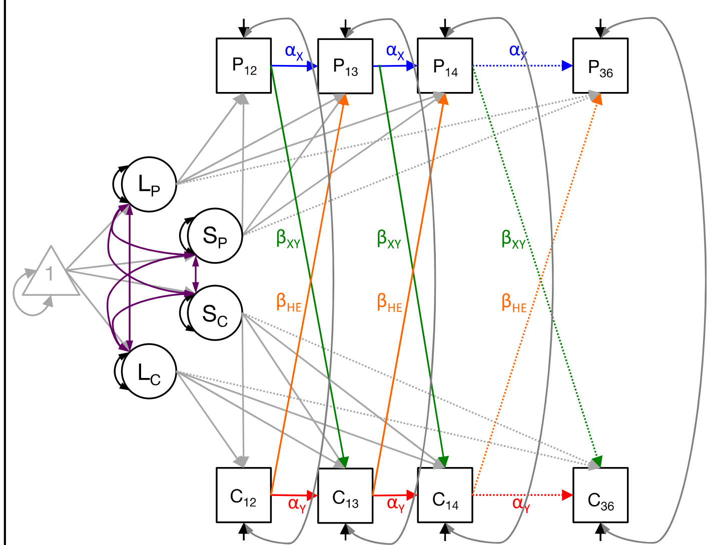
Cross-sectional mediation. Basic cross-sectional mediation analyses typically involve three regressions: the mediator is regressed on the predictor (the 'a' path), and the outcome is regressed on both the mediator (the 'b' path) and the predictor (the 'c' path or total effect of the predictor on the outcome). The total effect of the predictor on the outcome is then split into the indirect effect, which describes what part of the total effect goes through the mediator (calculated as a*b), and the direct effect, which describes what part of the total effect is independent of the mediator. While early methods for mediation involved the fitting of separate multiple regression models, more modern methods employ structural equation modeling to fit all model parameters simultaneously. This allows for more rigorous testing of indirect effects, including more accurate standard errors and improved missing data handling.

Longitudinal mediation. An important part of mediational tests is the passage of time, as predictors must precede the variables they cause. As such, mediation models have been extended into longitudinal modeling (as shown in Figure 3). This model extends the cross-lagged panel design model, such that both the 'a' path (from the predictor to the mediator) and the 'b' path (from the mediator to the outcome) span one lag (e.g., from age 13 months to 14 months, from 14 months to 15 months, etc.), while the direct effect of the predictor on the outcome (the 'c' path) spans two lags (e.g., from age 13 months to 15 months, 14 months to 16 months, etc.). The inclusion of these time lags allow for the use of all measurement occasions simultaneously while also ensuring that the effects required in any mediation analysis show the temporal ordering to test causal direction. As with all other analyses, we will include relevant covariates in all steps of both the cross-sectional and longitudinal mediation models.

Timing of effects and extensions of longitudinal mediation. Longitudinal mediation models provide many benefits over cross-sectional mediation, but a weakness of this approach is that it is tied to the lags inherent to our study design. The intervention predicts growth in child communication skills, which we assess monthly for longitudinal modeling. However, children may develop either more quickly or more slowly than this monthly interval, which is not traditionally accounted for in longitudinal mediation analyses.

Modern extensions of longitudinal mediation utilize the benefits of these approaches with a more continuous approach to lags. DeBoeck & Preacher's (2016)[92] continuous time longitudinal mediation model merges existing longitudinal mediation methods with dynamical systems modeling to estimate not only the size of the mediational paths, but also the optimal lag for each parameter. We hypothesize that intervention effects on parent use of communication support strategies will occur relatively quickly, while the effects on child outcomes will develop more slowly over time.

Figure 3. Longitudinal Mediation



Latent Growth Curves and Autoregressive Latent Trajectories. The above mediation models provide ways of testing our primary hypotheses, but also allows us to test secondary questions about the shape and timing of change in all studied constructs. Latent growth curve models specify that change in a measured variable can be modeled via latent variables representing initial level and change, each of which are free to vary across individuals.

The Autoregressive Latent Trajectories model (ALT[93]) is the combination of a latent growth curve and a cross-lagged regression model (Figure 3) which is commonly used in longitudinal mediation. Specifically, this model takes a bivariate growth curve model of parent and child language behaviors and adds autoregressions (such that parent use of communication support strategies at early time points predicts later parent use of communication support strategies, see the "alpha" parameters) and cross-regression (such that earlier parent use of communication support strategies predict later child communication skills, see the "beta" parameters). Use of the ALT model will allow improved model fit and greater accuracy in specifying the longitudinal trends in both parent behaviors and child language outcomes.

These growth curves will further allow a merging of the cross-sectional and longitudinal mediation paradigms described above. Analyses 4.1a and 4.2a use growth in child communication skills as an outcome, while analysis 4.3a uses different growth curves as mediators and outcomes, respectively. These approaches will use basic cross-sectional methods with single variables representing the predictor, mediator, and outcome. However, the mediators and outcomes in these models will be latent variables that are estimated within a latent growth curve model.

Aim 4 analytic plan. All models in this section will utilize SEM for estimation. Indirect effects will be defined as the product term of the intervention to mediator and mediator to outcome regressions, and the standard error and significance tests for this indirect effect will be estimated directly via likelihood-based confidence intervals rather than traditional multiple step methods (e.g., Sobel method[94]).

Analysis 4.1a. Intervention will predict a latent variable that describes overall parent use of communication support strategies from a parent-child interaction measured monthly from 12 months (pre) to 18 months of age (post). This latent parent variable will in turn predict the slope term from a latent growth curve of number of child prelinguistic communicative acts from a language sample measured monthly from 12 months (pre) to 18 months (post). This model will include simultaneous estimation of the intervention effect, parent use of a communication support strategy latent variable, and a child prelinguistic communicative acts latent growth curve model.

Analysis 4.1b. Intervention will predict a latent variable that describes overall parent use of communication support strategies from a parent-child interaction measured monthly from ages 12 months (pre) to 18 months of age (post). This latent parent strategy variable will in turn predict CSBS Total Scaled scores at 18 months of age (post).

Analysis 4.2a. Intervention will predict a latent variable that describes overall parent use of communication support strategies from a parent-child interaction measured monthly from 18 months (post) to 36 months of age (follow-up). This parent variable will in turn predict the slope term from a latent growth curve of spoken words (latent variable from MCDI Words Said and number of different words from a language sample) from 18 months (post) to 36 months of age (follow-up). This model will include simultaneous estimation of the intervention effect, a parent use of communication support strategy latent variable, and a child spoken words latent growth curve model.

Analysis 4.2b. Intervention will predict a latent variable that describes overall parent use of communication support strategies from a parent-child interaction measured monthly from ages 18 months (post) to 36 months of age (follow-up). This latent parent strategy variable will in turn predict PLS-5 Total Standard Scores at 36 months of age (follow-up).

Analysis 4.3a. Intervention effects will predict the slope term from a latent growth curve of number of child prelinguistic communicative acts from a language sample measured monthly from 12 months (pre) to 18 months of age (post), which in turn predicts a latent growth curve of spoken words (latent variable from MCDI words spoken and number of different words from a language sample) from 18 months (post) to 36 months of age (follow-up). This model will include two correlated growth curves, and free correlations between growth parameters outside of the regression from prelinguistic to spoken language slopes.

Analysis 4.3b. Intervention will predict the slope term from a latent growth curve of number of child prelinguistic communicative acts from a language sample measured monthly from 12 months (pre) to 18 months of age (post), which in turn predicts PLS-5 Total Standard Scores at 36 months. This analysis will be largely similar to 4.2b, as it also consists of intervention predicting a latent variable, which predicts a single observed outcome.

While the aforementioned analyses will be the focus of Aim 4, our analytic approach will also allow us to explore how the relationship between different types of communication support strategies and child communication outcomes may vary depending on the age or language level of the child. For example, it may be that responsive communication support strategies (e.g., responding to child communication) may mediate short-term intervention outcomes, while linguistically stimulating strategies (e.g., expanding communication) may mediate long-term intervention outcomes.

Power Analysis

Power for tests of intervention effects were estimated using G*Power[95] supplemented with custom simulations to verify accuracy and tailor assumptions to our research design. 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.

The above power analysis covers the primary analyses for Aims 1 and 3. However, these aims also include growth in parent and child outcomes assessed monthly. These analyses depend on latent growth curve models, as described above and require a simulation-based power estimate, as described in Zhang & Wang (2009).[96] We simulated our monthly assessments four thousand times, varying our predicted effect size and distribution of latent intercepts and slopes. This simulation yielded reliable power estimates for each effect size. The use of longitudinal data yield improved power over our simple pre-test-post-test designs in the previous paragraph. We project 80% power for d=.34, and 90% for d=.45. Furthermore, we have 80% power to detect moderators (aim 2) that account for 7.8% of variance in the outcome or greater, and 90% for 10.4% of variance. In summary, this study is well-powered to test the effects of intervention on parent and child outcomes.