

Title: *An integrated nutrition intervention through the Part C Early Intervention Services to promote healthy eating habits for children with ASD.*

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STATISTICAL DESIGN AND POWER

DATA COLLECTION, DATA MANAGEMENT, AND RANDOMIZATION

All the data will reside at the College of Public Health. The PI and Dr. Kim (Co-I statistician) will ensure the confidentiality of the data at all times. Participants will be assigned a participant ID (PID) at the time of screening. The PID will be a unique 8-digit number that includes a check digit. Access to the computer at the PI's office both internally and externally will be restricted by using individual user accounts and passwords. Study participants will be randomized after collection of the baseline data. Dr. Kim will design the randomization, and a data entry and management system for this project. We will use Research Electronic Data Capture (REDCap™), a widely used secure web-based software package designed for clinical trials.

SAMPLE SIZE CALCULATION AND POWER ANALYSIS

We will enroll a total of N=30 EI providers and parent-child dyads with a 1:1 randomization between Autism Eats intervention and Enhanced Usual Care (EUC) comparison group. The sample size calculation is not required for this pilot study. While evaluation of outcomes is more appropriate for a fully-powered R01, we will examine variance and effect sizes of key outcomes from pre- to post-intervention, and post-intervention to 5-month follow-up using non-parametric tests and confidence intervals.

DATA ANALYSIS

Descriptive analyses of baseline characteristics and outcomes will include means and standard deviations for continuous variables and frequencies for categorical variables. Treatment compliance will also be evaluated. The primary analysis will be conducted based on the intent-to-treat principle. Distributional assumptions will be checked and appropriate transformations or non-parametric methods will be applied as necessary.

Specific Analyses for the Individual Study Aims:

Aim 2a. Test the feasibility of enrollment, implementation, and evaluation of Autism Eats. We hypothesize that Autism Eats will be feasible and well received by EI providers and parent-child dyads, which will be assessed with (1) reach/participation; (2) attrition; (3) completion; (4) fidelity; (5) compatibility; and (6) qualitative feedback from participants. The rates of reach, participation, attrition, and completion will be computed as described in the measures section. Descriptive statistics will be used to examine data distributions and frequencies. If there is substantial variability in attrition, completion, fidelity, and compatibility, we will examine the relations of such variables with any other variables we collect during the study such as demographic variables of EI providers and parent-child dyads. (See Table 3).

Table 3. Benchmarks for Feasibility

Indicators	Measures and Benchmarks
Reach/Participation	Tracking log. >75% of approached eligible providers and parent-child dyads agree to participate (until n=30 parent-child dyads recruited)
Attrition	Tracking log. <20%
Completion	Lesson completion checklist, assessment tracking sheets, and attendance records. >75%
Fidelity	Lesson observations – 5-point scale (5=completed with fidelity; 1=not completed at all) per lesson. Mean >3.0
Compatibility	Observations & provider interviews. Qualitative coding: positive feedback.
Participant feedback	Provider and parent interviews. Qualitative coding: positive feedback.

Aim 2b. To assess the preliminary efficacy of Autism Eats on child dietary intake and mealtime behaviors.

While evaluation of outcomes is more appropriate for a fully-powered R01, we will examine variance and effect sizes of key outcomes from pre- to post-intervention, as well as post-intervention to 5-month follow-up using non-parametric tests and confidence intervals. We expect differences in children's food intakes, variety, diet quality,⁹ and mealtime behaviors¹⁶ between children who participate in Autism Eats and those in the EUC groups at post-intervention and 5-month follow-up from baseline. We will first assess whether

Autism Eats and EUC groups are balanced through randomization in terms of demographic variables at baseline. For each outcome variable, we will use boxplots and scatterplots with confidence intervals to visually inspect the changes across pre-intervention, post-intervention, and 5-month follow-up by group along with descriptive statistics. Also, nonparametric longitudinal analysis will be conducted for each outcome variable with time as a within-subject factor and treatment condition as a between-subject factor to examine the difference in changes between Autism Eats and EUC groups. (See Table 4).

Exploratory Aim. We will explore whether weight status of children are different between Autism Eats and EUC groups at 5-month follow-up assessment. Descriptive statistics and visual inspection will be used to summarize weight status by group and effect sizes will be computed. Similar to the analysis of the primary outcomes, we will conduct nonparametric analysis to compare the changes in weight status at 5-month follow-up between Autism Eats and EUC groups. Note that parent BMI will be included as a covariate in the analysis.

Table 4. Efficacy Outcomes

Outcomes	Measures / Expected Outcomes	Time
Dietary intake	3-day food records (ASA24 TM) / Food intakes (e.g., fruit and vegetables ↑), daily food variety ↑, diet quality (e.g., HEI fruit ↑, vegetables ↑, plant protein ↑)	T1, 2,3
Mealtimes behaviors	Brief Autism Mealtime Behavior Inventory ¹⁶ via REDCap / Problematic behaviors ↓.	T1,2,3
Weight status (height and weight)	A stadiometer/ruler and a scale; birth to 36 months, weight-for-length%tile based on the CDC growth chart. ¹⁷ BMI for parents	T1 & 3
Demographics	A survey through the REDCap.	T1
Health conditions	Family history of ASD and comorbid health conditions such as epilepsy, sleep disorders, and anxiety disorders through the REDCap.	T1

Biological variables. Sex: Given the sex difference in ASD prevalence, in addition to the primary data analyses as described above, data distributions will be analyzed by sex. We will then explore how male and female students respond to our intervention differently through qualitative interviews with selected sub-samples. Recommendations will be created to address any sex differences.

Genetic factors: Family history of ASD and parent BMI will be measured and considered as covariates.

Potential confounding factors to be considered in the analytic models. Parent age, sex, race/ethnicity, baseline child's weight status, parent education, and family income.

Examine demographic variations in response to the Autism Eats intervention. Correlation will be used to examine associations between demographic variations (age, sex, race/ethnicity, SES, and baseline weight status) outcomes of the Autism Eats (food intakes, food variety, diet quality, mealtime behaviors, and weight percentile).

Attrition and Missing Data. See Benchmarks for feasibility (Table 3). We aim < 20% dropout due to study withdrawal. Every effort will be made to prevent dropouts/missing data, and to complete relevant assessments for participants who drop out or are withdrawn, including reasons why the intervention was ended. To handle the dropout problem in this trial, we will first analyze data to see whether dropout was related to certain baseline measures and demographic variables. We will report the dropout rate and compare the distributions of baseline measures and demographic variables.