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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UNIVERSITY of SOUTH FLORIDA
Research & Innovation

PROTOCOL 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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V.3. October 24th , 2022

REVISION HISTORY

***This table should only be used during submission of a Modification application to the IRB.**

Revision #	Version Date	Summary of Changes	Consent Change?
2	01/23/2022	• Data sharing agreement added, complying with the NIH requirement (Section 16.). Parent consent form has been updated to include this data sharing details. This does not impact the EI providers' consent. • Recruitment email address change on recruitment letters. • Height and weight measurement procedure and exit interview guides have been modified to improve clarity.	Yes
3	09/21/2022	• Eligibility criteria for the parent-child dyads has been updated • The timing of asking the autism spectrum disorder (ASD) diagnosis or at risk/monitored for ASD status has been updated by adding another time point at the 5-month follow-up assessment • The health conditions questionnaire timing has been updated to add "T3" – follow-up time point (Table 4. in Section 5.7). A short self-report questionnaire with the same 4 items on health conditions/medications	Yes

		assessed at baseline through the demographic questionnaire will be used • Consent forms have been updated to reflect the eligibility criteria and the timing of asking the ASD diagnosis or at risk/monitored for ASD status • A new recruitment flyer is added for the Early Steps to use on their Facebook page • ClinicalTrials.gov registration number has been updated	

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1.0 Study Summary

Study Title	An integrated nutrition intervention through the Part C Early Intervention Services to promote healthy eating habits for children with ASD
Study Design	Randomized controlled trial
Primary Objective/Purpose	Aim 1: To refine the Autism Eats manual and intervention materials. Aim 2: To evaluate the feasibility and preliminary efficacy of Autism Eats in improving dietary intake and mealtime behaviors of children with ASD.
Secondary Objective(s)/Purposes	To explore whether child weight status differs between Autism Eats and enhanced usual care groups at 5-month follow-up assessment.
Research Intervention(s)	Autism Eats – Early childhood nutrition intervention
ClinicalTrials.gov NCT #	NCT05194345
Study Population	Early intervention providers and parent-child dyads (child aged 0-36 months clinically diagnosed with ASD)
Sample Size	146 individuals Aim 1: 10 EI providers, 10 parents Aim 2: 30 EI providers, 48 parent-child dyads (48 parents and 48 children)
Study Duration for individual subjects	Aim 1: up to 3 hours per participant to review manual and provide feedback. Aim 2: *Parent-child dyads:* The Autism Eats intervention group will spend about 8.5 hours over 5 months (baseline, post intervention, and 5-month follow-up assessments are 30 minutes each, 25-30 minutes weekly sessions for up to 10 weeks, two 25-30 minutes monthly booster sessions, and a 60-minute exit interview), and the We Can! EUC control group will spend about 3 hours over 5 months (baseline, post intervention, and 5-month follow-up assessments are 30 minutes each, one 25-30 minute nutrition session, and a 60-minute exit interview). *EI provider:* The Autism Eats intervention group EI provider will spend about 12 hours over 5 months (two 90-minutes training sessions, 25-30 minutes weekly sessions for up to 10 weeks, two 25-30 minutes monthly booster sessions, 10-minute fidelity checklist completion

	after each session, and a 60-minute exit interview), and the We Can! EUC control group EI provider will spend about 4.5 hours over 5 months (two 90-minutes training sessions, one 25-30 minutes session, 1-2-minute written material distribution at their 9 weekly EI sessions, and a 60-minute exit interview).
Study Specific Abbreviations/ Definitions	EI=Early Intervention; EUC=Enhanced Usual Care; ASD=Autism Spectrum Disorder; BAMBI=Brief Autism Mealtime Behavior Inventory; IDEA=Individuals with Disabilities Education Act

2.0 Objectives

2.1 There is an unmet need for nutrition interventions that address both autism spectrum disorder (ASD) specific feeding challenges and unbalanced eating habits among children with ASD to prevent future chronic health conditions. Children with ASD tend to consume few fruits and vegetables and mainly high-energy dense foods, including sugar-sweetened beverages and processed snacks. Obesity prevalence in children with ASD is up to 40% higher than in typically developing children, and recent studies show significantly elevated risks of hyperlipidemia and hypertension among individuals with ASD, regardless of using psychotropic medications. Considering the increased risks for diet-related diseases and the fact that many children with ASD develop various feeding problems such as selective eating patterns and food refusal, a novel intervention approach that addresses both ASD-specific feeding challenges and healthy eating development is urgently needed to prevent serious feeding problems and reduce chronic disease risks. Our interdisciplinary team conducted a preliminary study to examine diet quality and mealtime behaviors among diverse children with ASD in Florida (34% Hispanic/Latino) and parental preferences for nutrition interventions. Based on the study findings, we developed the manual for our nutrition intervention, Autism Eats, for children with ASD enrolled in the Part C of Individuals with Disabilities Education Act (IDEA) Early Intervention (EI) services. Our Autism Eats manual and parent materials are based on ASD-specific feeding strategies such as escape extinction and food chaining combined with behaviorally-focused nutrition intervention strategies such as goal setting and weekly meal planning to promote healthy eating. We pilot-tested the intervention with a small number of EI providers and parent-child dyads (n=5) to examine how intervention components fit with the Part C service setting. Preliminary fidelity and provider interview data indicated that the intervention manual was easy to follow and has potential to be widely implemented in the EI services, indicating a good fit. Herein, our goal is to refine our intervention materials and conduct a pilot RCT to test the feasibility and preliminary efficacy of this innovative nutrition intervention program, Autism Eats, to prevent problematic mealtime behaviors and promote development of healthy eating habits among children with ASD enrolled in Part C EI services in Florida. The Specific Aims are:

Aim 1. To refine the Autism Eats manual and intervention materials.

Aim 2. To evaluate the feasibility and preliminary efficacy of Autism Eats in improving dietary intake and mealtime behaviors of children with ASD.

2a. Test the feasibility of enrollment, implementation, and evaluation of Autism Eats.

2b. Assess the preliminary efficacy of Autism Eats for improving child dietary intake and mealtime behaviors.

Exploratory Aim. To explore whether child weight status differs between Autism Eats and EUC groups at 5-month follow-up assessment.

2.2 Hypothesis 1: We hypothesize that Autism Eats will be feasible and well-received by EI providers and parent-child dyads.
Hypothesis: 2: We hypothesize that there will be differences in children dietary food intakes, variety, diet quality, and mealtime behaviors between children who participate in Autism Eats and those in the EUC groups at post-intervention and 5-month follow-up from baseline.

3.0 Background

3.1 The prevalence of ASD has increased drastically in recent years, with current estimates at 1 in every 54 (more than 2 million) children affected in the United States, which is approximately 10% higher than the estimate in 2014 and 175% or 2.8 times higher than the first estimates reported in 2000.[1] In addition, Florida has the highest prevalence of ASD (4.88% compared to 2.9%, the national average).[2,3] Without intervention, individuals with ASD are at significant risk for developing diabetes, coronary heart disease, and cancer by midlife.[4]

Unhealthy food choices in children with ASD are a growing concern with potential for lifelong impact. Children with ASD tend to consume few fruits and vegetables and excess calories from high-energy dense foods, including starches, sugar-sweetened beverages, and other highly processed foods and snacks,[5-8] contributing to increased rates of obesity and other diet-related diseases. ASD-specific problematic mealtime behaviors and food selectivity should be addressed. Prior research reported that children with ASD experience up to 5 times more feeding problems, including problematic mealtime behaviors (e.g., not staying seated and showing aggressive behaviors or tantrums during mealtime) and food selectivity (i.e., only eating a narrow variety of foods), compared to their neurotypical peers, which may increase the risk for developing poor eating behaviors and inadequate nutrient intakes.[9] Lower intakes of protein, calcium, phosphorus, riboflavin, and vitamin B_{12} have been reported in children with ASD.[9] Due to these feeding problems, parents' attempts to expand their children's diets may be more challenging. Therefore, interventions for this population should address ASD-specific feeding challenges.

Early childhood nutrition interventions have shown promise of improving eating behaviors and slowing weight gain in typically developing children,[10,11] but their effectiveness is understudied among children with developmental disabilities. Currently, there is no evidence on whether an early childhood nutrition intervention emphasizing both ASD-specific mealtime behaviors and healthy eating behaviors has benefits of mitigating problematic eating behaviors and developing healthy dietary habits for children with ASD. Our study proposes to explore whether early childhood is an optimal time period for starting nutrition intervention and the long-term goals is to examine how dietary risk factors can be managed in early childhood to improve health trajectories in population with ASD.

3.2 We pilot-tested the intervention with a small number of EI providers and parent-child dyads (n=5) to examine how intervention components fit with the Part C service setting. Preliminary fidelity and provider interview data indicated that the intervention manual was easy to follow and has potential to be widely implemented in the EI services, indicating a good fit.[12] Participants further suggested innovative ways to improve the intervention such as adding more hands-on activities, booster sessions, and social media components.

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4.0 Study Intervention

4.1 Autism Eats intervention (Table 1): Lessons integrate ASD-specific feeding strategies such as escape extinction, food chaining, and making regular mealtime routines and behaviorally-focused nutrition content and activities utilizing goal setting, healthy meal planning, monitoring progress, strategies to overcome barriers, and creating healthy home food environment. The EI providers are well-trained to use personalized intervention and coaching approach in their EI services, which will be applied to Autism Eats activities as well (e.g., using the child's favorite foods for lesson activities). There is no content difference between in-person and telehealth versions of the program, except those instructions for providers are tailored to in-person vs. telehealth settings.

Table 1. Components of *Autism Eats* nutrition intervention

Components	Example Activity
Lessons: topics and objectives	
L1. Feeding Milestones: Understand feeding milestones for infants and toddlers.	Feeding milestone screening
L2. Sensory Properties of Foods: Taste, Flavors, & Textures: Explore the role of senses as it pertains to taste, flavor, and texture in the development of food preferences.	Exploring senses activity
L3. Introducing New Foods: Understand and utilize strategies for introducing new foods into the child's diet.	Repeated exposure
L4. Balanced Eating and Nutrition: Examine the benefits of healthy foods and learn how to integrate them in a daily menu.	Creating a meal plan
L5. Food Allergies, Special Diets, and Supplements:	Food sorting activity

Understand food allergies, special diets, and supplements that may affect or be beneficial for their child.	
L6. Beverages: Identify age-appropriate beverages and examine the benefits of healthy beverage selection.	Family beverage goal setting
L7. Mealtime Routines and Schedules: Establish a mealtime routine and create a consistent eating schedule.	Mealtime routine
L8. Restructuring Food Environment: Develop strategies to make healthy choices and have a pleasant experience while eating outside the home.	Strategies for eating out
L9. Hunger and Fullness Cues: Build confidence in recognizing when the child is hungry or full.	Responding to hunger and satiety
L10. Maintaining Healthy Nutrition: Create long-term strategies to sustaining healthy eating habits.	Restructuring the home food environment
Booster L1. Where are We Now?: Review previous lessons and discuss barriers for healthy eating and ways to overcome them.	Goal reinforcement
Booster L2. Celebrating Achievements Celebrate healthy eating achievements with positive reinforcement.	Positive reinforcement practice
Static website repository *Project description and lesson resources*	Handouts available online
Social media *Private social media (Facebook) group page*	Extra motivational resources and parent engagement

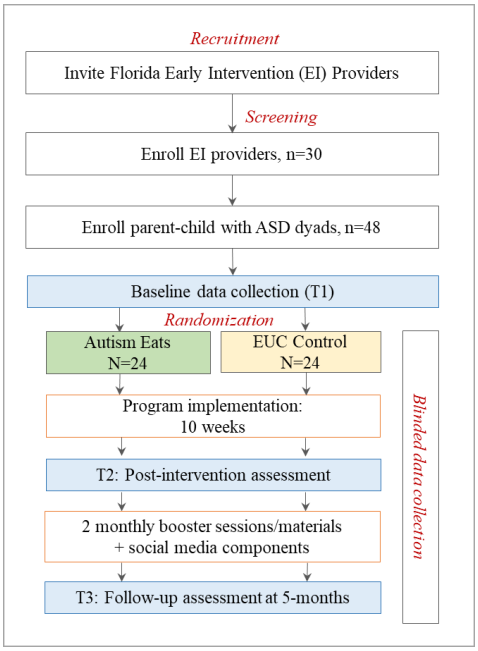
L = Lesson

EUC control group materials are from the evidence-based materials that are already developed and available online (in both English and Spanish): https://www.nhlbi.nih.gov/health/educational/wecan/index.htm
We will download one handout for each week and email EI providers to distribute for parent-child dyads who are randomly assigned into the EUC group.

5.0 Procedures Involved

5.1
Aim 1: The EI providers (n=10) and parents (n=10) will be invited to review the intervention manual and materials and provide their feedback. Participants will receive a survey link for the manual review which is described in 5.2 below. Based on the results of the review, all intervention materials will be further refined and finalized.

Aim 2: The protocol for this project is designed to conduct a preliminary RCT. This pilot RCT compares Autism Eats (n=24 parent-child dyads) to the EUC condition using We Can! materials (n=24 parent-child dyads). EI providers (n=30) in two Florida counties (Hillsborough and Polk Counties) will be recruited on a rolling basis and parent-child dyads will be recruited through those EI providers. Baseline assessment will be scheduled. Study participants will be randomized into two intervention groups (Autism Eat and EUC We Can!) after collection of the baseline data. Random assignment will be conducted by Kim (Co-I) utilizing a random number generator. Participants in Autism Eats will receive the intervention components while those in the EUC group receive comparison We Can! materials. Data collection will be performed at three time points. Study design is also described in Figure 1.



5.2

☒ Audio/Video Recording	☐ Psychophysiological Recording
☒ Behavioral Interventions	☐ Record Review - Educational
☐ Behavioral Observations and Experimentations	☐ Record Review - Employee
☐ Deception	☐ Record Review- Medical
☐ Focus Groups	☐ Record Review - Other
☒ Interviews	☐ Specimen Collection or Analysis
☐ Investigational Device – Non-Significant Risk (e.g. Mobile Applications)	☒ Surveys and/or Questionnaires
☐Psychometric Testing	☐ Other Social-Behavioral Procedures

Aim 1: We will invite EI provides and parents to review the intervention manual and materials and provide their feedback. The review invitation will be sent out through an online survey link (RedCap).

For EI providers, the feasibility scale used in our pilot study will be used. Seven questions will address feasibility of implementing each lesson, clarity of instructions, relevance to the EI services, acceptability by parents, satisfaction of resources/references, and clarity and relevance to the overall goal. Open-ended questions on each lesson will allow EI providers to share recommendation regarding each session's content and materials. The manual review will take up to 3 hours per participant.

For parents, the feasibility scale will be tailored to parent participants and address clarity of instructions, acceptability, satisfaction of intervention materials, and feasibility of implementing feeding practices at home. Open-ended questions on each lesson will allow parents to share recommendation regarding each session's content and materials. The survey will take about 1-2 hours per participant.

Aim 2: We will track the number of EI providers and parents reached by the recruitment methods. We will monitor and document reasons for dropping out, and clearly indicate whether it was the provider or the parent who decide to drop out. Completion rates of assessments at all data collection time points, training sessions, and lesson and booster lesson implementation will be tracked and recorded.

Training session materials include a 90-minute presentation prior to the intervention implementation and a 90-minute mid-training session in-between lesson 4 and 8. Both training sessions have been developed and pilot-tested in our preliminary feasibility study, and all enrolled EI providers participated in those sessions without attrition. On-going EI provider support will be provided by offering co-coaching the sessions when the EI providers need assistance on nutrition-specific activities. Randomly selected sessions (20%) will be observed and check whether all lesson components are consistently implemented as designed across EI providers, adapting the 5-point scale from a previous clinical trial. We will examine whether our intervention sessions fit the context of the EI services as well as the needs, expectations, and values of the EI providers, using an exit survey. Using those selected sessions, compatibility of the intervention content and activities for different levels of children's autism features and symptoms will also be examined from the observation or video-recorded sessions. EI providers and parents will be invited for a semi-structured interview at 5-month follow-up. The interviews will be audio/video recorded for transcriptions.

Three-day food record is a gold-standard assessment for dietary intake of individuals. Three 24-hour food records will be completed by parents using the NCI's Automated Self-administered 24-Hour Dietary Recall. Research assistants (RA) will provide guidance as needed. We focus on average daily dietary intakes by food groups (i.e., fruit, vegetables, grain, protein, and dairy) and daily food variety. For all children aged 2 years or older, diet quality will be determined by the Healthy Eating Index's total and sub-component scores (adequacy vs. moderation food categories). The Brief Autism Mealtime Behavior Inventory (BAMBI) will be used to assess children's mealtime behaviors. The BAMBI is a validated assessment tool that contains 18 questions and uses a 5-point Likert scale. A trained RA (single-blinded) will assess children's height and weight with a professional stadiometer and a weight scale following the standardized protocol used in previous studies. As a standard weight status assessment for birth to 36 months, weight-for-length based on the CDC growth chart will be calculated. Parent BMI will be calculated and used as a covariate in data analysis. If height and weight

information is available for the spouse of the participating parent or the other biological father/mother, it will be recorded. Questions on sex, race/ethnicity, family history of ASD, age, parental education, income, insurance status, and history of other illnesses and comorbid health conditions such as epilepsy, sleep disorders, and anxiety disorders will be asked at baseline. We will also administer the Child Feeding Questionnaire, a validated questionnaire used in our multi-site nutrition intervention clinical trial.

5.3 Our comparison group will receive an enhanced usual early intervention service. Enhanced Usual Care (EUC) Comparison. A one-time 25-minute session on nutrition (modified lesson 4 of the Autism Eats) will be embedded in the regular EI services. The EUC EI providers will receive one 30-minute training session on EUC content and activities. To maintain scientific control for attention threats and increase rigor, EUC families will also receive publicly available web-based information on healthy eating using We Can! materials weekly over 10-weeks by email to correspond with the number of Autism Eats sessions. We Can! is evidence-based nutrition and physical activity materials from the National Heart Lung and Blood Institute (https://www.nhlbi.nih.gov/health/educational/wecan/index.htm). We will also send out two monthly booster information by email.

5.4 Potential risks are minimal. Participants may experience psychological discomfort during intervention sessions or while answering survey questions or having their height and weight measured. To protect against risk, research procedures will be explained, and any questions will be answered. The risks and benefits of participation will be described before obtaining a signed IRB-approved informed consent from EI providers andparents, respectively. Children younger than 3 year old cannot complete assent form, so parents will sign the consent forms for their children and for themselves. No pressure will be exerted on the subjects to participate, and they have the right to withdraw from the study at any time. Research personnel will be told to report any untoward participant reactions directly to the research project coordinator and the PI. Minor concerns raised byproviders and parents (e.g. embarrassment about being weighed) will be addressed by the research staff. Participants will be carefully monitored using the resources of the University of South Florida, a researchinstitution. Dr. Gray and Dr. Stern each bring extensive experience working with the development and evaluation of behaviorally-focused interventions targeting dietary behaviors to children. The research team will be available to refer any participants to appropriate specialists as necessary. EI providers and parents will be told that they can terminate their participation in the study at any time with nopenalty.

5.5 N/A

5.6 N/A

5.7 There will be post intervention (2.5-3 months after baseline measurements) and 5-month follow-up assessment as described in Table 4 below.

Table 4. Efficacy Outcomes		
Outcomes	**Measures / Expected Outcomes**	**Time**
Dietary intake	3-day food records (ASA24™) / Food intakes (e.g., fruit and vegetables ↑), daily food variety ↑, diet quality (e.g., HEI fruit ↑, vegetables ↑, plant protein ↑)	T1, 2,3
Mealtime 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
Feeding behaviors	Child Feeding Questionnaire via REDCap	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 & 3

*T1: baseline; T2: post intervention; T3: 5-month follow-up

6.0 Data and Specimen Storage for Future Research

6.1 Data will be collected and maintained in accordance with legal and ethical standards and will be centrally stored in a master database. RedCap is a secure web application for research studies in HIPAA compliant environments, which will be used to collect data, except the dietary intake data that will be collected through the ASA24 online system. RedCap will allow for data to be entered and uploaded to a central, secure database, while prohibiting access outside USF. Providers and parents will be emailed a link to the RedCap-based surveys.

Only principal investigator and study staff members will have access to files containing identifiers such as contact information of study participants (providers and parent-child dyads). These files will be stored in an encrypted form in a password protected secure database. These files will be used only for data collection. The collected data will be deidentified. Participants' information that individuals can be identified with will be removed from the study data files. The deidentified data will be stored as study data files in a password protected USF computer in a locked USF office.

For data security and confidentiality of study data files, we will develop data management and security policy that all users of the study data should adhere to. Only authorized users can have access to and possess the data files to conduct data analyses. Authorized users include principal investigator, study data managers, study data analysts. Other internal users and external users should be given authorization by the principal investigator. All users must sign a data security agreement and send a copy of the agreement to the principal investigator. Users should not share a copy of study data files. All users must adhere to the data security and confidentiality procedures. All users other than principal investigator and study data managers must destroy study data files upon the completion of a study as specified in the agreement.

6.2 The final dataset will include self-reported demographic, dietary, and behavioral data from 3-day food records, a validated mealtime behavior questionnaire, and a survey. Obesity exploratory outcome data will be collected with children's and parents' height and weight. All datasets will be de-identified with numeric numbers.

6.3 We will make the data and associated documentation available to users under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes such as a review of similar intervention studies and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. Our aggregated data and results will be available through ClinicalTrial.gov following their requirement and guidelines.

7.0 Sharing of Results with Subjects

7.1 Because the proposed study is a preliminary efficacy study (Stage 1 clinical trial), without clear understanding of the intervention content and context, the data can be misinterpreted. Thus, results will not be shared with anyone outside the research team or without a data-sharing agreement.

8.0 Study Timelines

8.1 Activities for Aim 1 will start in October 2021 and Aim 2 is planned to be started in January 2022. The project will end in July 2023. Participants will be recruited in a rolling basis. For Aim 2 (RCT), each parent-child dyad will have three data collections: baseline (T1), post-intervention (T2), and 5-months follow-up from baseline (T3). The Enhanced Usual Care (EUC) comparison group will receive one intervention session and periodic written materials from We Can!.

9.0 Inclusion and Exclusion Criteria

9.1

Level 1 – Early Intervention (EI) service providers:
Inclusion criteria: Full-time employees of EI services who have children with ASD in their service at the time of recruitment are eligible to participate.

Level 2 – Parent-child dyads:
Inclusion criteria:

- Children should be enrolled in the EI service. Children who are determined as "at risk/monitored for ASD" at the time of screening or diagnosed with ASD determined by clinical assessment such as the Autism Diagnostic Observation Schedule (ADOS) or another validated evaluation tool such as Gilliam Autism Rating Scale (GARS-3). Children birth to 36 months are eligible for the EI

services, and therefore, age of our research participants will range from birth to 36 months.
- Parents should be 18 years or older and speak fluent English and/or Spanish

9.2
Level 1 – Early Intervention (EI) service providers:
Exclusion criteria: Non-EI service providers and who do not work with children with ASD.

Level 2 – Parent-child dyads:
Exclusion criteria:
- Children who are on exclusive breastfeeding, medicines that may interact with appetite and food consumption, having severe GI conditions such as irritable bowel syndrome, diagnosed with feeding disorders or severe food selectivity, or other serious medical comorbidities such as cancer.
- Parent and child with ASD who have previously participated in a similar nutrition intervention study will also be excluded.
- Parent's first language is not English or Spanish.

9.3 If participants are diagnosed with other serious illnesses or medication condition other than ASD, they will be excluded from the study. The intervention and EUC program will be implemented within the EI service schedules. EI providers and parent-child dyads work closely together within their regular EI programs regardless their participation status in our study. If either an EI provider or parent-dyad wish to withdraw from the study, it is likely that they will discuss and made a decision together.

9.4 The study will include employees from the USF Florida EI program, Early Steps, since the USF Early Steps EI providers will be recruited.

10.0 Vulnerable Populations

10.1 Children from birth to 36 months diagnosed with ASD. All efforts will be made to safeguard the children with ASD. Children's privacy and confidentiality will be protected, as will their rights, safety, and well-being. The intervention materials have been written to address mealtime and eating behaviors in children with ASD and a pilot study was conducted in this population. As mentioned, the possible risks of the study are minimal. The direct and potential benefits outweigh the risks of the intervention. Resources and specialists will be made available to parent-child dyads who experience any adverse reactions, e.g., discomfort answered questions about dietary behaviors or being weighed by the research staff.

11.0 Local Number of Subjects

11.1

For Aim 1, 10 EI providers and 10 parents will be enrolled.
For Aim 2, 30 EI providers and 48 parent-child dyads (48 parents and 48 children) will be enrolled.

12.0 Recruitment Methods

12.1

☒ Email	☐ Online/Social Media Advertisement
☒ Flyer	☐ Record Review
☐ Letter	☐ SONA
☐ News Advertisement	☐ Other

12.2
For aim 1, the EI providers and parents will be recruited through the county EI services. The research team members will send out emails to the EI directors and ask them to distribute the flyers to EI providers. The EI service directors/administrators/providers will distribute the parent flyer to potentially eligible parents. Anyone who is interested in participating in the study will be asked to contact the research team.

For aim 2, EI providers and parent-child dyads will be recruited through email and flyer as described below.
Early Intervention (EI) service providers: Providers will be first recruited through the EI program that covers Hillsborough and Polk Counties in Florida. There are approximately 180 EI providers in these two counties. The director of the EI services in these counties is a Co-I of this study. A recruitment flyer emphasizing the importance of early nutrition intervention and common mealtime behavioral problems among children with or at risk/monitored for ASD will be distributed by email and through appropriate social media platforms (e.g., Facebook). Trained research staff and/or the PI will conduct a brief introductory session at one of the regular provider meetings to introduce the study and use a sign-up sheet to recruit potential providers who are willing to participate in the study. Recruitment materials will be distributed repeatedly until the target participant number is met.

Parent-child dyads: EI providers who agree to participate will inform potentially eligible parents about the study and recruit them to contact the research team for study participation. A parent recruitment flyer will be distributed through the EI services and/or directly by the EI providers to eligible parents.

12.3 For vulnerable population described in section 10, at the intake and then subsequently at the time of each follow-up assessment, participants are reminded that they may discontinue any procedure at any time, or withdraw from the study altogether, without

prejudice, and afforded opportunities to ask questions about any facet of the study. We take great care to assure that neither participants nor their families feel any coercion to take part in the project, and that participation in the study is a positive and affirming experience for those who do take part. Study participants are assured that they are free to withdraw at any time without prejudice and will still receive the same quality of services.

13.0 Withdrawal of Subjects

13.1 Withdrawals without participants' consent are not anticipated.

13.2 We will contact participants who withdraw by email to ask the reason for withdrawal and conduct an interview if possible. To manage dropout, we will first assess whether dropout was related to certain baseline measures and demographic variables. We will report dropout rate and compare distributions of baseline measures and demographic variables.

14.0 Risks to Subjects

14.1 Potential risks are minimal. Participants may experience psychological discomfort during intervention sessions or while answering survey questions or having their height and weight measured. All survey measures are online, and a virtual session will be available for participants' height and weight measurement, considering the risks associated with COVID-19. For program implementation, EI providers will adhere to their organizational recommendations and procedures for COVID-19 safety measures. Our program can be implemented in person or through telehealth with the manual that include detailed instructions for both modalities. Therefore, participants won't have an increased risk for getting COVID-19 based on their status of study participation. Participants will still be informed that, there is a risk of transmission of the novel coronavirus if they participate in any research activities in person, and that while precautions will be taken, we cannot guarantee that the participant will not be exposed to the virus.

14.2 N/A

14.3 N/A

15.0 Potential Benefits to Subjects or Others

15.1 Autism Eats may prevent problematic mealtime behaviors and promote development of healthy eating habits among children with ASD. Participants may benefit from increased awareness of health factors related to foods that might improve their ability to manage their health in the future. Thus, it is possible that the proposed study will advance the well-being of the participants. Professional

development sessions for EI providers can benefit the providers by training them about the Autism Eats nutrition intervention and healthy eating behaviors in general.

15.2 This novel and timely study may establish potential feasibility and preliminary efficacy of an EI-integrated nutrition intervention that if proven effective could substantially reduce lifetime risk for diet-related chronic conditions among children with ASD. The findings may benefit the field of health promotion, especially promoting health eating habits among children with ASD, by identifying whether an innovative nutrition intervention through the Part C EI services can improve participants' dietary behaviors, problematic mealtime behaviors, and potentially weight status. The benefits of the study to the children with ASD, and to society at large appear to justify the minimal risks. Findings from this study will provide relevant information to determine appropriate nutrition intervention to promote healthy eating behaviors for birth to 36 months children with ASD, a developmentally critical period. In addition, if we found any positive trends/outcomes related to obesity as tested in our exploratory aim, this can inform the field of obesity and chronic disease prevention research, significantly relevant to public health.

16.0 Data Management and Confidentiality

16.1

Aim 1: Descriptive statistics for quantitative data (i.e., mean, standard deviation, frequency and percentages) and content analyses for qualitative data (i.e., theme coding) will be performed based on information collected from the questionnaires.

Aim 2: 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.

Aim 2a. Test the feasibility of enrollment, implementation, and evaluation of Autism Eats. 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.

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

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.

16.2 Data will be collected and maintained in accordance with legal and ethical standards and will be centrally stored in a master database. RedCap is a secure web application for research studies in HIPAA compliant environments, which will be used to collect data, except the dietary intake data that will be collected through the ASA24 online system. RedCap will allow for data to be entered and uploaded to a central, secure database, while prohibiting access outside USF. Providers and parents will be emailed a link to the RedCap-based surveys.

Only principal investigator and study staff members will have access to files containing identifiers such as contact information of study participants (providers and parent-child dyads). These files will be stored in an encrypted form in a password protected secure database. These files will be used only for data collection.

The collected data will be deidentified. Participants' information that individuals can be identified with will be removed from the study data files. The deidentified data will be stored as study data files in a password protected USF computer in a locked USF office.

For data security and confidentiality of study data files, we will develop data management and security policy that all users of the study data should adhere to. Only authorized users can have access to and possess the data files to conduct data analyses. Authorized users include principal investigator, study data managers, study data analysts. Other internal users and external users should be given authorization by the principal investigator. All users must sign a data security agreement and send a copy of the agreement to the principal investigator. Users should not share a copy of study data files. All users must adhere to the data security and confidentiality procedures. All users other than principal investigator and study data managers must destroy study data files upon the completion of a study as specified in the agreement.

The study statistician (Kim) will work closely with the PI (Gray) to ensure that the research team adhere to the data management procedures and security plan.

The Aim 2 study parent-child data will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH) as required for all NIH funded research studies collecting data from individuals with ASD. NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing deidentified study data helps researchers learn new and important things about brain science more quickly than before. During and after the study, the study researchers will send deidentified study data about participants' health and behavior to the NDA. Other researchers across the world can then request the deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests the deidentified study data must promise to keep the data safe and promise not to try to learn participant identity. Experts at the NIH who know how to keep the data safe will review each request carefully to reduce risks to the participant privacy. Sharing the study data does have some risks, although these risks are rare. The study data could be accidentally shared with an unauthorized person who may attempt to learn participant's identity. The study researchers will make every attempt to protect the participant identity. NIMH will also report to Congress and on its website about the different studies using NDA data. The study participants will not be contacted directly about the study data submitted to NDA.

The study participants may decide that they do not want their study data to be added to NDA. They can still participate in this research study even if they decide that they do not want the data to be added to NDA. If any participants decide any time that they do not want the data to be added to NDA, we will let them call or email the study staff, and we will inform NDA to stop sharing the study data. Once the data is part of NDA, the study researchers cannot take back the study data that were shared before they were notified. The participants are informed about NDA on the consent form and the research staff will be explained through the informed consent process. Detailed NDA information is available on-line at http://nda.nih.gov.

16.3 Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur monthly during the recruitment period. This will assure that participants will meet eligibility criteria and ethnic diversity goals outlined in the grant application.

Data type	Frequency of review
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	Monthly
Adverse events	As they happen
Adverse events rates	Bimonthly

Compliance to intervention	Bimonthly
Stopping rules regarding statistical power, implications of dropouts, and missing data	Semiannually

16.4

All datasets will be de-identified with numeric numbers. The PI will have ultimate responsibility for ensuring participant well-being and for the integrity of data collection in the proposed study. The confidentiality of information provided by participants will be safeguarded by the use of participants' code numbers. In addition, all data will be stored in a locked file cabinet, and project staff will be instructed to maintain the participants' anonymity. All measurement protocols are well established in our research center and pose minimal risk. The data safety monitoring plan (DSMP) involves monitoring by the PI in conjunction with a safety officer from University of South Florida Institutional Review Board. There will be periodic reports by the project coordinator and Dr. Gray on data collected by the research team.

Only principal investigator and study staff members will have access to files containing identifiers such as contact information of study participants (providers and parent-child dyads). These files will be stored in an encrypted form in a password protected secure database. These files will be used only for data collection.

The collected data will be deidentified. Participants' information that individuals can be identified with will be removed from the study data files. The deidentified data will be stored as study data files in a password protected USF computer in a locked USF office.

For data security and confidentiality of study data files, we will develop data management and security policy that all users of the study data should adhere to. Only authorized users can have access to and possess the data files to conduct data analyses. Authorized users include principal investigator, study data managers, study data analysts. Other internal users and external users should be given authorization by the principal investigator. All users must sign a data security agreement and send a copy of the agreement to the principal investigator. Users should not share a copy of study data files. All users must adhere to the data security and confidentiality procedures. The study records and data will be maintained for 5 years after completion of the research, and will be destroyed based on the USF data disposal procedure and regulations.

16.5

☒Obtaining Signed Authorization	☒Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only
☐Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization)	☐Waiver of HIPAA Authorization for Entire Study
☒Data Use Agreement	☐Business Associate Agreement

- For Aim 1 of the study, we will not collect any PHI from participants. For Aim 2 of our study, children's clinical diagnosis of ASD or at risk/monitored for ASD is considered as a PHI because we will need to collect the ASD diagnosis or at risk/monitored for ASD status from the USF Epic. All USF Early Steps members have access to USF Epic and a liaison person to our research will verify the ASD diagnosis or at risk/monitored for ASD status under supervision of the director and co-investigator Dr. Shaffer-Hudkins. If the ASD diagnosis was performed outside the USF clinics or Early Steps program, the Early Steps usually have the information in file. We will ask the Early Steps to provide us with the ASD diagnosis or at risk/monitored for ASD status information for each child to confirm the eligibility before we obtain informed consent from the parents. We will not collect any PHI from the EI providers. Our parent consent/permission form for Aim 2 includes HIPAA language to indicate that such information is obtained for the purpose of the study.
- **Inclusion criteria:** The recruitment letters and flyers have the eligibility criteria about children's ASD diagnosis or at risk/monitored for ASD status. Children aged 0-36 months who are clinically diagnosed with ASD or at risk/monitored for ASD status within the Early Steps and their parents are eligible to participate in this study. After the EI providers shared the parent recruitment letter with the parents who are potentially eligible, parents who are interested in the study will contact the project coordinator or the principal investigator. Then, to determine children's eligibility before USF research staff obtain signed consent from parents, we will obtain a PHI (ASD diagnosis or at risk/monitored for ASD status) from the Early Steps program as described above. Therefore, we need to request a waiver of HIPAA authorization for recruitment/screening purposes only.
- **Time interval:** ASD diagnosis and at risk/monitored for ASD status verification process will be done twice: (1) one at the beginning of the enrollment process, prior to obtaining parent's informed consent; and (2) the other at the 5-month follow up assessment to capture any changes in ASD diagnosis or at risk/monitored for ASD status. The time interval between the ASD diagnosis verification and parent consent will be approximately 1-7 days. The second verification will be done around the time when the dyads complete the 5-month follow up assessment.
- **Plan to protect identifiers**: We will obtain the ASD diagnosis or at risk/monitored for ASD status PHI with de-identified numeric numbers. Study IDs and matched parent names will be separately provided to the Early Steps (see "ID and parent name tracking sheet.xlsx"). The Early Steps liaison staff will confirm the ASD diagnosis by looking up their USF Epic records and complete the ASD diagnosis tracking sheet using only the ID numbers without participants' names. The liaison staff will record ASD diagnosis or at risk/monitored for ASD status including who diagnosed ASD and determined at risk/monitored for ASD status, date of the evaluation, level of ASD (if reported), autism diagnostic observation schedule (ADOS) or alternative scale score (if reported), and child's age at diagnosis or evaluation date on "Early Steps ASD diagnosis tracking sheet.xlsx"). This ASD diagnosis tracking sheet does not include identifiable information. Only principal investigator and study staff members will have access

to the file containing identifiers (the ID and parent name tracking sheet), which will be stored separately from other data in a password protected secure database. They will be kept in a secure in Box that is HIPAA compliant.

- **Plan to destroy:** For individuals who agree to participate, their information will be kept as part of their research file and will be signing an authorization allowing for this information to be included in the research. Any PHI from those who are not eligible to participate or refuse to participate will be destroyed immediately.
- **Written assurance:** The PHI (ASD diagnosis or at risk/monitored for ASD status) will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclose of PHI would be permitted by the HIPAA privacy regulations. Only de-identified data may be used for other research.
- **Why is not practicable to obtain signed HIPAA Authorization:** For Aim 2 of our study, the HIPAA waiver for screening and recruitment is needed to verify ASD diagnosis or at risk/monitored for ASD status prior to obtaining signed consent. After screening, signed authorization will be obtained through the parent consent/permission.
- **Why study cannot be conducted without access to PHI (ASD diagnosis or at risk/monitored for ASD status):** By collecting information from USF Epic regarding child's ASD diagnosis or at risk/monitored for ASD status, level of autism, and date of diagnosis/evaluation, we will obtain the most accurate information about clinical ASD assessment and diagnosis. The HIPAA waiver for screening and recruitment is needed to verify ASD diagnosis or at risk/monitored for ASD status prior to obtaining signed consent. There are cases with other developmental delays or disabilities such as down syndrome within the Early Steps programs. Because children with or at risk/monitored for ASD status experience specific mealtime and eating challenges and our intervention is designed to address those specific challenges, we need to know that children are diagnosed or at risk/monitored for ASD status prior to obtaining signed consent.

- **For Aim 2 of study, parent-child study data will be submitted to NDA as described in section 16.2. with Data Use Agreement completed by the PI and USF:** NIH-funded studies with human subjects who are diagnosed with ASD are required to submit deidentified data about health and behaviors of participants. Complying with this requirement, we have submitted the Data Use Agreement (DUA) and signed the Data Submission Agreement (DSA) on the NDA system. Any identifiable information will not be submitted to the NDA system.

17.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

17.1 An adverse event (AE) is any untoward medical occurrence that is temporally associated with participation in the clinical study. A serious adverse event (SAE) is any adverse event that results in one or more of the following outcomes: death, life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, congenital anomaly or birth defect, significant medical event based on clinical judgment.

AE severity will be graded by severity (mild, moderate, or severe) depending on the intensity of the event for the participant. An AE will be termed 'mild' if it does not have a major impact on the participant, 'moderate' if it causes the participant some minor inconvenience and 'severe' if it causes a substantial disruption to the participant's well-being. A participant can have a severe event that is not a SAE and a moderate event that meets the SAE definition. AE's will also be categorized according to the likelihood that they are related to the study intervention as: definitely, probably, possibly, or unrelated to the study intervention. SAEs that are unanticipated or possibly related to the study intervention will be reported to the Safety Officer at IRB and PI as they happen, and to the IRB, Clinical Research Center (CRC) and NIH within two weeks. Anticipated SAEs or those unrelated to the study intervention will be reported to the Safety Officer and PI as they happen, and to the IRB, CRC and NIH on a monthly basis.

There are multiple health professionals within the early intervention services. We will refer the subject to an appropriate professional counselor to address any adverse effect(s).

17.2 N/A

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 All research activities will be conducted in private setting/platform with EI providers or research staff.

18.2 Subjects will provide informed consent.

19.0 Compensation for Research-Related Injury

19.1 N/A

20.0 Subject Costs and Compensation

20.1 There will be no cost incurred because of study participation that are over and above the costs that would be incurred from standard care or services.

20.2

☐No Compensation	☐Tokens (pens, food items, etc.)
☒Financial Compensation (cash, gift cards)	☐Other
☐Course Credit (i.e. extra credit, SONA points)	

- Aim 1: Each EI provider and parent will receive $50 for reviewing the intervention manual and materials.

- Aim 2: For both the Autism Eats intervention and We Can! EUC control groups,
    - Each EI provider will be compensated for the following activities,
        - First training session: a $50 gift card
        - Second training session in the mid-point: a $50 gift card
        - Completing intervention implementation: a $50 gift card
        - Exit interview: a $50 gift card.
        - Total amount: $200

    - Each parent-child dyad will be compensated for the following activities,
        - Baseline assessment: a $50 gift card
        - Post intervention assessment: a $60 gift card
        - 5-month follow-up assessment: a $70 gift card
        - Exit interview: a $50 gift card
        - Total amount: $230

- If any providers or parents participate in both Aim 1 and Aim 2 research activities, the maximum amount a provider can get from this study is $250, and the maximum amount a parent-child dyad can get from this study is $280. All participants (EI providers and parents), in both the intervention and EUC control group, will receive the same compensation schedule. There is no difference between the parent-child dyad intervention and control groups as it pertains to schedule.

21.0 Consent Process

21.1

☒Obtaining Signed Consent (Subject or Legally Authorized Representative)	☒Obtaining Consent Online (Waiver of Written Documentation of Consent)
☒Obtaining Signed Parental Permission	☐Obtaining Verbal Consent (Waiver of Written Documentation of Consent)
☐Obtaining Signed Assent for Children or Adults Unable to Consent	☐Waiving Consent and/or Parental Permission (Waiver of Consent Process)
☐Obtaining Verbal Assent for Children or Adults Unable to Consent	☒Waiving Assent/Assent is Not Appropriate

21.2

The signed consent will be used for Aim 2 for both EI providers and parents. The consent process will be completed remotely.

EI provider consent process: EI providers who are interested in the study will contact the PI or the project coordinator. The project coordinator or a trained research assistant

will schedule a phone or virtual Teams meeting to explain detailed research activities and go over the consent form together. The consent document will be emailed to each participant in advance and for them to keep. Once the project coordinator or the research assistant answer or clarify any questions that the provider has, the project coordinator/research assistant will send an electronic signature form to the provider via DocuSign.

Parent consent process: Parents will provide consent for study participation. Once EI providers indicate that one of their parents who have a child with or at risk/monitored for ASD and enrolled in the EI program is interested in participating in the study, the parent will contact the PI or the project coordinator to schedule a phone call or virtual Teams meeting. The project coordinator or a trained research assistant will explain detailed research activities and go over the combined parental consent and permission with the parents. The consent document will be emailed to each participant in advance and for them to keep. Once the project coordinator or the research assistant answer or clarify any questions that the parent has, the project coordinator/research assistant will send an electronic signature form to the parent via DocuSign.

Aim 2 research activities explained in the consent form:

- EI providers: signed consent form
    - Attending training sessions
    - Implementing intervention
    - Completing fidelity checklist
    - Exit interview virtually through Microsoft Teams
- Parents: signed consent form
    - Dietary intake assessment virtually through Microsoft Teams
    - Mealtime behavior, demographic, and health conditions questionnaires through online survey platform (REDCap)
    - Height and weight measurement
    - Exit interview virtually through Microsoft Teams

21.3

The consent online (waiver of written documentation of consent) will be used for aim 1 for both EI providers and parents.

EI providers and parents who are interested in the study will contact the PI or the project coordinator. The project coordinator or a trained research assistant will assess the eligibility and explain the study procedure via a preferred method by the participant (e.g., email, phone call, virtual meeting), and send the REDCap survey link to the participant including the consent document. Participants will be asked to proceed with the survey by clicking the “next” button on the page if they agree to participate, or they will be asked to

leave the survey page. All participants will have access to the copy of consent document via email, REDCap, or file attachment in the virtual meeting.

Aim 1 research activities explained in the consent form:

- EI provider/parent manual review. Feedback from the EI providers and parents will be collected through online survey platform (REDCap)

21.4 N/A

21.5 Once the English consent document is approved by the IRB, the study team will submit an amendment to obtain approval for the Spanish consent document. The Spanish-speaking research staff will be responsible for translating the consent from English to Spanish. A separate independent translator who has no knowledge of or contact with the original text will translate the consent back from Spanish to English. The project coordinator or trained research assistant will then assess the two versions to see if they are consistent. Approved translated consent form will be used by the Spanish-speaking research staff to obtain consent from all Spanish-speaking participants.

21.6 The children to be enrolled are from birth to 36 months diagnosed with or at risk/monitored for ASD status and cannot provide consent. Parental permission will be obtained from parent participants.

22.0 Setting

22.1 The study will be conducted at the USF College of Public Health (single site). The Florida EI service is called Early Steps. There are 15 Early Steps programs in Florida and the USF Early Steps program covers two counties (Hillsborough and Polk Counties). EI providers and parents from the USF Early Steps program in these two counties will be recruited for both Aim 1 and 2 of the study. For Aim 2, participants will be involved in weekly Autism Eats sessions or one EUC session through their regular EI services. The EI providers from the USF Early Steps program will be recruited on a rolling basis and parent-child dyads will be recruited through those EI providers. The director of the USF Early Steps program is a Co-investigator of the project (Dr. Emily Shaffer-Hudkins) and there will be a project liaison staff person who will be paid to assist with the study recruitment and communication. Dr. Shaffer-Hudkins participated in protocol writing and has attended monthly project meetings since August 2021. All decisions regarding recruitment and participant engagement have been discussed with Dr. Shaffer-Hudkins and approved by her. Any further changes will be discussed with Dr. Shaffer-Hudkins at regular research team meetings.