Evaluation of an Interdisciplinary Decision Guide for Infant Feeding Assessment

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Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Evaluation of an Interdisciplinary Decision Guide for Infant Feeding Assessment
Study Description:	This study will determine if a decision support tool changes clinical practice recommendations when used by speech language pathologists and occupational therapists. We hypothesize the support tool will change whether providers will recommend specialist referral.
Objectives:	Primary objectives are the degree of concordance in feeding therapy, referral, and specific specialist referral recommendations between therapists using and not using the tool. Secondary objectives include degree of concordance between feeding therapy frequency and therapy target recommendations as well as acceptability, appropriateness, and feasibility of the tool.
Endpoints:	The endpoint is when the provider has finished reading the case study.
Study Population:	56 speech language pathologists and occupational therapists with at least two years of feeding experience and currently practicing in North Carolina
Phase:	N/A
Description of Sites/Facilities Enrolling Participants:	This study will occur through an online survey. Survey recruitment will be based out of UNC-Chapel Hill.
Description of Study Intervention:	The study intervention is a decision support tool, which is a checklist of signs and symptoms of feeding problems.
Study Duration:	The estimated duration is 6 months.

Participant Duration: Participants will take about 20 minutes to complete an initial interest survey and then the full survey.

1.2 SCHEMA

Ongoing Screening

- Total n=70
- Screen potential participants by inclusion and exclusion criteria through an online survey

Ongoing Randomization

- Case A, then Case B group (n=28)
- Case B, then Case A group (n=28)

Ongoing Study Intervention

- Participants complete informed consent
- Participants complete survey and demographic information

1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	Screening Day -7 to -1	Enrollment/Baseline Day 1	Survey Day 1 – Day 14
Screening	X		
Randomization		X	
Informed Consent			X
Administer study intervention			X
Demographic Information			X

2 INTRODUCTION

2.1 STUDY RATIONALE

While it is now recognized that pediatric feeding disorder (PFD) involves medical, nutritional ,feeding skill, and/or psychosocial domains [1], in early intervention (EI) in North Carolina, individual providers (speech language pathologists (SLPs) or occupational therapists (OTs), are tasked with individually assessing and treating infants with PFD. While trained in feeding skills and sensory processing, these professionals are also expected to screen the medical, nutritional, and psychosocial domains, and make appropriate external referrals, despite these areas being outside of their scope of practice. The importance of a thorough, systematic evaluation and referral process is particularly important at the transition to solid foods, a critical developmental juncture as feeding demands increase and nutritional needs shift [15,16]. SLPs and OTs in EI need a tool that facilitates timely referrals and communication with multidisciplinary feeding teams, or individual specialists, when assessing infants with PFD.

2.2 BACKGROUND

Pediatric feeding problems fall within the scope of many professionals; speech-language pathologists (SLPs), occupational therapists (OTs), nurses, dietitians, gastroenterologists, pediatricians, and psychologists/behavior analysts may be involved in evaluation and treatment. In 2019, a consensus definition of pediatric feeding disorder (PFD) was published, providing these professionals with common diagnostic criteria [1]. Preterm infants (1 in 10 live births in North Carolina), are particularly at risk for long-term PFD, representing up to 40% of children seen at feeding disorder clinics [2,3]. Th resulting economic impact is significant; even insured families report an average loss of $125,645 in income caring for their child with PFD [4].

While it is now recognized that PFD involves medical, nutritional, feeding skill, and/or psychosocial domains, in early intervention (EI) in NC, individual SLP or OT providers assess and treat infants with PFD. While trained in feeding skills and sensory processing, these providers are also expected to screen the medical, nutritional, and psychosocial domains and make appropriate referrals, despite these areas being outside of their scope of practice. The importance of a multi-domain, systematic evaluation and referral process is particularly important for preterm infants. Preterm infants are likely to present symptoms relevant to multiple professionals including gastroesophageal disorders, physiologic

instability, nutritional deficits, and behavior problems into early childhood [5–12]. This is particularly true at the transition to solid foods, a critical developmental juncture as feeding demands and nutritional needs shift [13,14]. EI SLPs and OTs need a tool to facilitate timely referrals and communication with other specialists when assessing preterm infants with PFD.

We propose the development of a decision-making tool for the evaluation of preterm infants with PFD by SLPs and OTs in EI to facilitate appropriate external referrals. This tool is specific to children at the solid food level (6mo-3years) and is called the Clinical Feeding Guide (CFG). We have developed a list of observational items through examination of existing tools and a literature review. To achieve our goal of developing a feasible clinical tool, we will pursue the following specific aims. Aim 1: Establish content validation using the Delphi Technique to generate a screening and decision-making tool. Aim 2: Complete pilot testing of the tool to determine feasibility, acceptability, and change from current standard practice.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

There are no known risks of using the intervention, as it is being used on mock case studies. There is the potential for participants to experience emotional distress or consequences of a breach of confidentiality. Although the likelihood of a breach of confidentiality is low, the data collected could yield information about participants' behaviors and demographics that could cause emotional distress if confidentiality were breached. Professionals may also experience fatigue, frustration, or stress will reading case studies. However mock case studies have been determined to yield the least stress over considering real cases or viewing videos of real children.

2.3.2 KNOWN POTENTIAL BENEFITS

This study does not have any potential for direct benefit to the individual subjects in this study. However, we do hope that the tool developed will benefit infants and professionals in the future by improving clinical practice and the accurate and timely diagnosis and treatment of feeding disorders in infants and children.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

This study will contribute to our understanding about how SLPs and OTs make appropriate external referrals during clinical feeding evaluations. It is necessary for SLPs and OTs to test this tool in order to understand its potential impact. Risks to participants have been minimized by de-identifying participant responses, reporting participant responses as an aggregate, and having participants read short, mock case studies while using the tool. These limited risks outweigh the value of the information to be gained, which would assist professionals in making better clinical decisions thereby improving the treatment of feeding problems in infants.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Degree of Concordance Between Therapists' Feeding Therapy Recommendations	After reading a feeding case study, early intervention professionals will answer the question "Would you recommend feeding therapy?" with two choices: yes or no. Difference in agreement between early intervention professionals using the decision support tool and those not will be calculated and compared for cases A and B.	To determine whether using the tool, which helps identify feeding problem symptoms, changes decisions therapists make around recommending therapy for a child.
Degree of Concordance Between Therapists' Referral Recommendations	After reading a feeding case study, early intervention professionals will answer the question "Would you refer this family to any other providers/specialists for evaluation/treatment?" with two answer choices: yes or no. Difference in agreement between early intervention professionals using the decision support tool and those not will be calculated and compared for cases A and B.	To determine whether using the tool, which helps identify feeding problem symptoms by discipline with the explicit purpose of facilitating referrals, changes decisions therapists make around recommending referral to a specialist.
Degree of Concordance Between Therapists' Specific Specialist Referral Recommendations	After reading the feeding case study, early intervention professionals will answer the question "What other professionals would you refer this child to? Check all that apply." with the following choices: nutritionist/dietician, gastroenterologist, otolaryngologist (ENT), aerodigestive clinic, pulmonologist, occupational therapist, speech language pathologist, psychologist/social worker, applied behavior analyst (ABA), or allergist. Difference in agreement between early intervention professionals using the decision support tool and those not will be calculated and compared for cases A and B.	To determine whether the tool, which lists feeding problem symptoms by specialist discipline, changes the specialists a therapist refers to.
Secondary		

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Degree of Concordance Between Therapists' Feeding Therapy Frequency Recommendations	After reading the feeding case study, early intervention professionals who recommended feeding therapy will answer the question "With what frequency would you recommend therapy?" with three choices: 2 times per week or more, 1 time per week, less than one time per week. Difference in agreement between early intervention professionals using the decision support tool and those not will be calculated and compared for cases A and B.	To determine whether using the tool, which helps identify feeding problem symptoms, changes decisions therapists make around recommending a specific frequency of therapy for a child.
Degree of Concordance Between Therapists' Intervention Target Choices	After reading the feeding case study, early intervention professionals who recommended feeding therapy will answer the question "What therapy targets might you include for this child?" and may check all that apply from the following choices: oral motor skills, sensory, behavioral, medication, modification of food/liquid, modification of equipment (seating, utensils, etc.), modification of environment (location, distractions, routine, etc.), parent coaching, or other. Difference in agreement between early intervention professionals using the decision support tool and those not will be calculated and compared for cases A and B.	To determine whether using the tool, which helps identify feeding problem symptoms by area of concern, changes decisions therapists make around recommending a specific intervention target for a child.
Decision Support Tool Acceptability Score	The Acceptability of Intervention Measure (AIM) will be used to measure acceptability of the decision support tool. This tool includes four items, rated on a five-point Likert scale from completely disagree to completely agree, and will be quantified with a score of 0 for completely disagree, 1 for disagree, 2 for neither agree nor disagree, 3 for agree, and 4 for completely agree. The average score across the four items will be calculated, with higher	To determine if this intervention is acceptable to practicing therapists.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	scores indicating higher acceptability of the decision making tool. The minimum score is 0 and the maximum score is 20. Items on this measure include: (Intervention) meets my approval; (Intervention) is appealing to me; I like (Intervention) and I welcome (Intervention).	
Decision Support Tool Appropriateness Score	The Intervention Appropriateness Measure (IAM) will be used to measure appropriateness of the decision support tool. This tool includes four items, rated on a five-point Likert scale from completely disagree to completely agree, and will be quantified with a score of 0 for completely disagree, 1 for disagree, 2 for neither agree nor disagree, 3 for agree, and 4 for completely agree. The average score across the four items will be calculated, with higher scores indicating higher acceptability of the decision making tool. The minimum score is 0 and the maximum score is 20. Items on this measure include: (Intervention) seems fitting; (Intervention) seems suitable; (Intervention) seems applicable; (Intervention) seems like a good match.	To determine if practicing therapists feel this intervention is appropriate for the preterm, early intervention population and to the therapists.
Decision Support Tool Feasibility Score	The Feasibility of Intervention Measure (FIM) will be used to measure feasibility of use of the decision support tool. This tool includes four items, rated on a five-point Likert scale from completely disagree to completely agree, and will be quantified with a score of 0 for completely disagree, 1 for disagree, 2 for neither agree nor disagree, 3 for agree, and 4 for completely agree. The average score across the four items will be calculated, with higher scores indicating higher acceptability of the	To determine if therapists feel this intervention is feasible to use in clinical practice.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	decision making tool. The minimum score is 0 and the maximum score is 20. Items on this measure include: (Intervention) seems implementable; (Intervention) seems possible; (Intervention) seems doable; (Intervention) seems easy to use.	
Tertiary/Exploratory		
N/A	N/A	N/A

4 STUDY DESIGN

4.1 OVERALL DESIGN

This is a randomized crossover pilot study. It will be conducted online through one site, UNC Chapel Hill. The study intervention is the 'Clinical Feeding Tool' also known as the decision support tool. Our hypothesis is that clinicians will change their recommendations for feeding therapy and specialist referral when using the tool compared to when they do not use the tool. Clinicians will be randomly assigned to respond to either Case A or Case B without using the tool (2 groups). Then, they will respond to the other case using the tool. Total participation time is estimated at 20 minutes.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We have selected a crossover design for this pilot study in order to directly compare use of the tool to no use of the tool among a small group of participants. Therefore, participants will serve as their own control group. This was chosen given the varying experience of the participants with feeding.

4.3 JUSTIFICATION FOR DOSE

All therapists will view the full tool in the survey in order to directly compare use of the tool to no use of the tool.

4.4 END OF STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the survey.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Male or female, aged 18 or older
4. Speech language pathologist or occupational therapist

5. At least 2 years of experience evaluating and treating pediatric feeding
6. Have worked in Early Intervention in the last 5 years
7. English proficiency
8. Currently reside in NC

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Less than 2 years of experience
2. Have not worked in Early Intervention in the last 5 years
3. Does not currently reside in NC

5.3 LIFESTYLE CONSIDERATIONS

Not applicable

5.4 SCREEN FAILURES

Screen failures are defined as participants who express interest in participating in the clinical trial but are not subsequently randomly assigned to the study intervention or entered in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes screen failure details, eligibility criteria, and any serious adverse event (SAE).

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

The target sample size is 56 participants with 28 SLPs and 28 OTs. We anticipate one site will be used – UNC Chapel Hill; although the study will be completed virtually by participants. Target enrollment will not be stratified for age, gender, or race/ethnicity for this pilot study, but future studies will control for these variables. Because participants are expected to be practicing in early intervention, participants will be recruited from private practices (which contract with early intervention) and from the early intervention system in North Carolina. Participants will be recruited through web search, the Child Developmental Services Agency, and word of mouth. Potential participants will be emailed through these groups and will be directed to an interest survey where they will complete a screening. If eligible and interested, they will provide their name and email. In the order of entry, the PI will email them a link to the survey.

Because the fields of occupational therapy and speech language pathology are majority female, specific female recruitment is not necessary. For this pilot study, participants will not be specifically selected for race/ethnicity, but this will be pursued in future, larger studies.

Participants who complete the full survey will receive a $25 gift card as an incentive.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

The study intervention is a checklist that was developed with feeding specialists at UNC Health through Delphi surveys. The checklist contains four headings: gastrointestinal, nutritional, behavioral, and aerodigestive. Under each heading there is a list of observable symptoms that may warrant referral to a specialist provider in that area.

The main heading says, “Feeding Assessment Referral Guide”. The main subheading says, “Use the following checklist during the feeding evaluation to observe symptoms that may warrant referral to specialists.”

Under gastrointestinal, the observable symptoms are:

- Frequent spitting up/vomiting during meal
- Fussiness, crying, or arching during meal
- Wheezing, stridor, cough, or hoarseness while eating
- Gagging during meal
- Burps frequently while eating
- Drools while eating
- Avoidance or prioritizing of certain food textures

Under aerodigestive, the observable symptoms are:

- Gets red in the face while eating
- Coughs during meal
- Food/liquid comes out nose while eating
- Gets tired and cannot finish eating
- Breathes harder/faster while eating
- Evidence of stridor v. stertor
- Needs to pause during meal to catch breath
- Watery eyes while eating

Under behavioral, the observable symptoms are:

- Refuses to eat
- Whines, cries, or tantrums during meal
- Insists on food being offered a specific way
- Throws or pushes food away
- Will not stay seated during meal
- Throws or spits food
- Parent has to do something special to get child to eat
- Parent and child have conflict during feeding
- The parent appears stressed and overwhelmed during feeding

Under nutrition, the observable symptoms are:

- Appears underweight
- Exclusion of entire food group
- Eating only one texture of food during evaluation

At the bottom, the checklist says, “If the child has demonstrated any of these signs/symptoms while eating, referral to a medical specialist, in addition to your treatment, may be warranted.”

6.1.2 DOSING AND ADMINISTRATION

Each provider will view the checklist to use during one case study.

6.2 PREPARATION/HANDLING/STORAGE/ACCOUNTABILITY

6.2.1 ACQUISITION AND ACCOUNTABILITY

The intervention is a checklist.

6.2.2 FORMULATION, APPEARANCE, PACKAGING, AND LABELING

The intervention is a checklist provided both within the body of a survey, and as a PDF.

6.2.3 PRODUCT STORAGE AND STABILITY

N/A

6.2.4 PREPARATION

N/A

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

14 OTs and 14 SLPs will receive case A first; 14 OTs and 14 SLPs will receive case B first. There are two versions of the survey – one where case A is presented first and one where case B is presented first. Providers will be sent the link to the version to which they are assigned.

Assignment will be based on the order of study entry. For example, the first SLP to enroll will receive case A first, the second SLP to enroll will receive case B first, etc. Similarly, the first OT to enroll will receive case A first, the second OT to enroll will receive case B first, etc.

The PI will complete all randomization computations. There will not be blinding. Blinding is considered unnecessary in this case because the researchers will not have direct interaction with participants, participants will complete the full survey and intervention independently without interaction with the researchers.

6.4 STUDY INTERVENTION COMPLIANCE

This study is a survey. Thus, as long as the participant completes the assigned survey, they will have adhered to the study protocol.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE MEDICINE

N/A

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Participant responses will be monitored for concerning responses. If there are repeated concerning responses about the survey or intervention, the study will be discontinued. Participants can also stop participating in the survey at any time.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Participant does not complete the intervention within the designated time frame

The reason for participant discontinuation or withdrawal from the study will be recorded on the Master Participant list. Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will be replaced.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to complete the survey within the specified time frame and is unable to be contacted by the study site staff.

The following actions must be taken if a participant fails to complete the survey:

- The site will attempt to contact the participant via email with a survey reminder and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make at least two emails to the participant. These contact attempts should be documented in the participant's medical record or study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 EFFICACY ASSESSMENTS

To test intervention efficacy, the participant will be asked to answer a set of clinical questions after reading the case study. They will first do this without the intervention and then read another case study using the intervention. This will be administered through Qualtrics in survey form.

The questions include:

- Would you recommend feeding therapy to this child? Yes/No
    - If yes, "With what frequency would you recommend therapy?"
        - 2 times per week, 1 time per week, Less than one time per week
    - If yes, "What therapy target areas might you include for this child?" (select all that apply)

        - Oral motor skills, sensory, behavioral, medication, modification of food/liquid, modification of equipment (seating, utensils, etc.), modification of environment (location, distractions, routine, etc), parent coaching, other (fill in)
    - If yes, "What would be the recommended length of treatment for this child?"
        - Less than 6 months, 6-12 months, More than 12 months
- What diagnosis would you give this child?
- Would you refer this family to any other providers/specialists for evaluation/treatment? Yes/No
    - If yes, "What other professionals would you refer this child to? Check all that apply."
        - Nutritionist/dietician, gastroenterologist, otolaryngologist (ENT), aerodigestive clinic, pulmonologist, occupational therapist, speech language pathologist, psychologist/social worker, applied behavior analyst (ABA), allergist, multidisciplinary feeding team, other (list)

In addition to the clinical questions, the following questions will be asked in order for the participant to evaluate the tool:

- With a likert scale of completely agree, agree, neither agree nor disagree, disagree, completely disagree
    - The Clinical Feeding Guide meets my approval
    - The Clinical Feeding Guide is appealing to me
    - I like the Clinical Feeding Guide
    - I welcome the Clinical Feeding Guide
    - The Clinical Feeding Guide seems fitting
    - The Clinical Feeding Guide seems suitable
    - The Clinical Feeding Guide seems applicable
    - The Clinical Feeding Guide seems like a good match
    - The Clinical Feeding Guide seems implementable
    - The Clinical Feeding Guide seems possible
    - The Clinical Feeding Guide seems doable
    - The Clinical Feeding Guide seems easy to use
- If you could make changes to the CFG you would (check all that apply):
    - Make it shorter, make it longer/more comprehensive, change the format, add items, remove items, I wouldn't make any changes, I wouldn't use it
- Please list 1-2 strengths of the CFG
- Please list 1-2 changes you would make to the CFG to make it more useful for clinical practice
- I would use the CFG in clinical practice (5pt likert scale from strongly agree to strongly disagree)
    - If Strongly, somewhat, or neither agree/disagree is selected: "Please describe why you would use the CFG in clinical practice"
    - If somewhat disagree, strongly disagree or neither agree/disagree is selected: "Please describe why you would not use the CFG in clinical practice"

8.2 SAFETY AND OTHER ASSESSMENTS

While no obvious safety concerns are expected, provider responses to the survey will be monitored weekly for any concerning responses.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".]

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the PI who communicates with the participant about the concerning survey response and evaluates its relationship with the intervention. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

The PI will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during weekly review of survey responses.

All AEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, date and time of survey response, PI's assessment of severity, and relationship to study product. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until study participation is complete. Events will be followed for outcome information until resolution.

8.3.5 ADVERSE EVENT REPORTING

AEs will be reported to the IRB and NCTraCS within 3 days of their identification.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

The study PI will immediately report to the sponsor any serious adverse event, whether or not considered study intervention related, including those listed in the protocol and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the study intervention and the event. In that case, the investigator must immediately report the event to the sponsor.

All serious adverse events (SAEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the IRB and study sponsor. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the study sponsor within 7 days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and to the study sponsor within 7 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) 7 days of the IRB's receipt of the report of the problem from the investigator.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s):
    - Degree of concordance between therapists' feeding therapy recommendations
        - Null Hypothesis: There is no difference in therapists' feeding therapy recommendations when using v. not using the tool

        - Alternative Hypothesis: There is a difference in therapists' feeding therapy recommendations when using v. not using the tool
        - Non-inferiority comparison
        - Time period: After reading the case study
    - Degree of concordance between therapists' referral recommendations
        - Null Hypothesis: There is no difference in therapists' referral recommendations when using v. not using the tool
        - Alternative Hypothesis: There is a difference in therapists' referral recommendations when using v. not using the tool
        - Non-inferiority comparison
        - Time period: After reading the case study
    - Degree of concordance between therapists' specific specialist referral recommendations
        - Null Hypothesis: There is no difference in who the therapists recommend referral to when using v. not using the tool
        - Alternative Hypothesis: There is a difference in who the therapists recommend referral to when using v. not using the tool
        - Non-inferiority comparison
        - Time period: After reading the case study

- Secondary Efficacy Endpoint(s):
    - Degree of concordance between therapists' feeding therapy frequency recommendations
        - Null Hypothesis: There is no difference in therapists' feeding therapy frequency recommendations when using v. not using the tool
        - Alternative Hypothesis: There is a difference in therapists' feeding therapy frequency recommendations when using v. not using the tool
        - Non-inferiority comparison
        - Time period: After reading the case study
    - Degree of concordance between therapists' intervention target choices
        - Null Hypothesis: There is no difference in therapists' feeding therapy intervention target choices when using v. not using the tool
        - Alternative Hypothesis: There is a difference in therapists' feeding therapy intervention target choices when using v. not using the tool
        - Non-inferiority comparison
        - Time period: After reading the case study
    - Decision Support Tool Appropriateness
        - Null Hypothesis: The decision support tool is not appropriate.
        - Alternative Hypothesis: The decision support tool is appropriate.
        - Superiority
        - Time period: After using the tool
    - Decision Support Tool Acceptability
        - Null Hypothesis: The decision support tool is not acceptable.
        - Alternative Hypothesis: The decision support tool is acceptable
        - Superiority
        - Time period: After using the tool
    - Decision Support Tool Feasibility
        - Null Hypothesis: The decision support tool is not feasible.
        - Alternative Hypothesis: The decision support tool is feasible.

- Superiority
- Time period: After using the tool

9.2 SAMPLE SIZE DETERMINATION

This is a pilot study. Sample size was selected based on available funding and to achieve equal numbers in each group (group 1: case A then case B; group 2: case B then case A) as well as equal numbers of SLPs and OTs per group (group 1: 14 SLP, 14 OT. Group 2: 14 SLP, 14 OT).

9.3 POPULATIONS FOR ANALYSES

All participants who completed the full survey will have their data included in analysis. Partial survey responses will not be included.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

For descriptive statistics, counts and percentages will be reported.
For inferential tests, two-tailed tests will be used. Test statistics, p-values, and effect sizes will be reported.
Covariates will be assessed to determine if they should be included in the statistical model. These will include years of experience and being an OT v SLP.
Due to the small sample size and categorical variables, only nonparametric tests will be used.

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

For the following primary outcomes: degree of concordance between therapists' feeding therapy recommendations and degree of concordance between therapists' referral recommendations we have categorical data (2 groups – using tool and not using tool; 2 answers – yes or no). This is a repeated measure (therapists answer once for case A and once for case B). Each case will be analyzed separately. Due to the categorical data and small sample, reporting will be descriptive. Chi square tests will also be run if determined to meet the required assumptions. For chi-square tests, p value and effect size will be reported. These will be independent and therefore, adjustment for multiple comparisons will not be pursued.

For the third primary endpoint, degree of concordance between therapists' specific specialist referral recommendations, descriptive statistics will be used due to the multiple categories, small counts, and small sample size. The percentage of therapists recommending a particular provider will be compared among therapists using and not using the tool.

Across all analyses, missing data will be reported but not corrected for due to the small sample size. Participants who did not complete all survey items will not be included in analysis. Adjustment for multiple comparisons is considered unnecessary due to the small sample size and minimal use of inferential statistics.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

For degree of concordance between therapists' feeding therapy frequency recommendations we have categorical data (2 groups – using and not using the tool; 3 response categories – 1xweek, 2xweek, less than 1 time per week). This is a repeated measure (therapists answer once for case A and once for case B). Each case will be analyzed separately. Due to the categorical data and small sample, reporting will be descriptive. Chi square tests will also be run if determined to meet the required assumptions. For chi-square tests, p value and effect size will be reported.

For degree of concordance between therapists' intervention target choices, descriptive statistics will be used due to the multiple categories (categorical data), small counts, and small sample size. The percentage of therapists recommending a particular provider will be compared among therapists using and not using the tool. This will be analyzed separately for case A and for case B.

For decision support tool acceptability, appropriateness, and feasibility, we have ordinal data (Likert scale). Additionally, each score (acceptability, appropriateness, feasibility) has 4 Likert scale items that form the score for that subscale. This is a single endpoint. The mean across the 4 items will be calculated for each participant to achieve a mean acceptability, appropriateness, and feasibility score. Then, the mean and standard deviation will be calculated across participants to result in an overall mean rating for acceptability, appropriateness, and feasibility.

Across all analyses, missing data will be reported but not corrected for due to the small sample size. Participants who did not complete all survey items will not be included in analysis. Adjustment for multiple comparisons is considered unnecessary due to the small sample size and minimal use of inferential statistics.

9.4.4 SAFETY ANALYSES

Survey responses will be monitored for any concerns responses and these will be reported.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Intervention groups will be compared on the basis of years of experience (in feeding, early intervention, and overall clinical practice), and years since graduation with their clinical degree. Due to the small sample size, inferential statistics will be trialed (i.e. Mann-Whitney U), but may not be used if assumptions are not met for their appropriate use.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

The primary and secondary endpoints will not be analyzed based on age, sex, or race/ethnicity for this pilot study due to the small sample size.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will not be listed.

9.4.9 EXPLORATORY ANALYSES

No exploratory analyses are planned.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are viewed by the participant and documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol Online Consent form.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. Interested participants will view an online version of the consent form via Qualtrics. They will be prompted to email the PI with any questions they have about the study. The professional will e-sign the consent form via Qualtrics to consent to participants.

The consent forms and processes will include information about the legal obligations of researchers that may, in rare instances, require a disclosure of confidential information. Professional participants will receive an emailed copy of their signed consent; original signed consent forms will be downloaded from Qualtrics and stored securely and separately from subject data on a secure UNC server.

Given the nature of the consent process, the research subjects will have time to read and think over the consent and whether they would like to participate, before signing. They will be offered the opportunity to ask the PI any questions before signing.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor, and/or IRB.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, study records for the participants in this study.

The study participant's contact information will be securely stored on OneDrive for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on UNC OneDrive. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected.

Certificate of Confidentiality

To further protect the privacy of study participants, a Certificate of Confidentiality will be issued by the National Institutes of Health (NIH). This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

This study does not involve storage of specimens for future unspecified research.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Faculty Advisor**
Kelsey Thompson, MS, CCC-SLP	Cara McComish, PhD
UNC Chapel Hill	UNC Chapel Hill
321 S Columbia Street Chapel Hill, NC	321 S Columbia Street Chapel Hill, NC
919-966-1007	919-966-1007

Kelsey_thompson@med.unc.edu	Cara_mccomish@med.unc.edu

10.1.6 SAFETY OVERSIGHT

Because this study does not have any obvious safety concerns, provider responses to the survey will be monitored weekly for any concerning responses. Additionally, providers will be informed they should not yet use this tool in clinical practice.

10.1.7 CLINICAL MONITORING

This study will be completed virtually and is low-risk (a survey). Clinical site monitoring will include monitoring of data entry. A random 20% of participant entries will be audited to ensure data is correctly transferred from the Qualtrics survey into data records for analysis.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The PI will manage all quality assurance and control. The survey will not be changed during the study unless approved by the IRB. Data will be downloaded and recorded by the PI and checked by a RA as necessary. QA and QC errors that are identified will be addressed by the PI.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Clinical data (including adverse events (AEs) will be saved in a file within the secure OneDrive system which is maintained by UNC. Data will also be stored within Qualtrics until the study is complete. Then this data will be downloaded to OneDrive and the surveys containing identifiable data in Qualtrics will be deleted.

10.1.9.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an International Conference on Harminosation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

10.1.10 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents, reported to NCTraCS Program Official. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 2 years after the completion of the primary endpoint by contacting Kelsey Thompson.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with NCTraCS and UNC have established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.]

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS

AE	Adverse Event
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
EI	Early Intervention
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IRB	Institutional Review Board
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
OT	Occupational Therapist
PFD	Pediatric Feeding Disorder
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure
SLP	Speech language pathologist
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

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