Study Protocol

Title: The Food Allergy Superheroes Training (FAST) Program: Increasing Adherence to Food Allergy Safety Guidelines

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Study Goal:
The goal of this study was to develop, conduct feasibility testing, and refine a developmentally tailored, skills training intervention designed to promote adherence to food allergy (FA) safety guidelines. the Food Allergy Superheroes Training (FAST) Program - in low-income, young children with a FA. Consistent with the Rounsaville stage-model of treatment development, the study sought to provide initial feasibility and acceptability data based on feedback from a joint advisory board (JAB; parent-child), pilot trial, and preliminary randomized trial comparing the FAST intervention to a food allergy knowledge (FAK) intervention.

Due to pandemic-related challenges regarding recruitment and retention, the study protocol (e.g., inclusion criteria, exclusion criteria, modality of intervention, etc.), in consultation with our program official, was changed throughout the course of this project. The overview provided below provides a summary of the modified protocol used for this study.

Study Methods:
In Phase 1a (i.e., JAB and FAST Program pilot trial) young children with a FA from low-income backgrounds were recruited. In Phase 1b (i.e., preliminary randomized trial), young children with a FA were randomly assigned to either the Food Allergy Superheroes Training (FAST) Program or a Food Allergy Knowledge (FAK) Intervention. All facets to the pilot and randomized controlled trial portions of this study were conducted virtually.

Assessment Schedule:
In Phase 1a (pilot trial only) and Phase 1b (preliminary randomized trial), pre-and post-intervention assessments were conducted virtually. In Phase 1b, assessors blinded to intervention condition (FAST vs. FAK) conducted the assessments. Treatment satisfaction was evaluated at the end of the pilot trial. Our aim in conducting the randomized trial was to examine changes in a child's adherence to food allergy safety behaviors, as assessed via a virtual, in situ food allergy assessment. Secondary outcomes including changes in food allergy knowledge and quality of life were also of interest.

DETERMINATION OF ELIGIBILITY

The parent/caregiver of potential young child participants will first complete a phone screen to determine potential eligibility (e.g., household income, child age, FA status, etc.). Because our team has chosen to include parent-report of a FA, as opposed to documented skin testing or IgE-level, as one of our core inclusion criterion, it is highly unlikely that participants deemed to meet eligibility criterion at the time of the phone screen will be determine ineligibile upon completion of the pre-intervention assessment.

Eligibility criteria. Inclusion for young children in the present study will be based on the following: 1) 6-8 years old; 2) parent-report of a FA; 3) from a low-income family (income-to-needs ratio < 200% of DHHS Federal Poverty Threshold); 4) English speaking; and 5) One English-speaking parent/caregiver. Exclusion criteria include parent-reported neurodevelopmental disorder (i.e., autism spectrum disorder), cognitive delays, or major psychiatric disorder. As noted above (see inclusion criterion #5), one English-speaking parent/guardian per young child will participate.

A. DELIVERY OF INTERVENTIONS

Phase 1a (i.e., JAB and FAST intervention pilot trial) will be carried out at the young child?s home. All intervention content (i.e., education module, behavioral skills training content) will be delivered by the PI or an advanced clinical psychology graduate student closely supervised by the PI. The PI has extensive experience in the implementation of behavioral skills training for young children.

Phase 1b (i.e., preliminary randomized trial of FAST v. FAK) will be carried out at the child?s home. All intervention content (i.e., education and skills training content of the FAST intervention, educational content of FAK intervention) will be delivered by the PI or an advanced clinical psychology graduate student closely supervised by the PI. The PI has extensive experience in the implementation of behavioral skills training for young children.

B. DESCRIPTION OF INTERVENTIONS

1. Food Allergy Knowledge (FAK) Intervention:

The primary aim of the FAK intervention is to increase the young child?s understanding of FAs including prevalence, symptoms, and management strategies among other topics. We will achieve this aim through the use of educational materials targeting knowledge acquisition through a variety of didactic materials made freely available through the Food Allergy Research Education (FARE) website (www.foodallergy.org). More specifically, we will employ information embedded within the ?Food Allergy 101? segment of the FARE website. The FAK intervention is designed to be administered over the course of 5 days. Each session will take approximately 15-20 minutes to complete. The young child and their parent/caregiver will be present for the entirety of all sessions; however, all intervention materials are designed with the young child as the primary focal point of interest. All children will be rewarded with a small toy (<$5 value) at the end of each successfully completed session. All FAK sessions will occur within the child?s home and will include informational handouts relevant to the day?s session. What follows is a detailed description of the session-by-session content pertaining to the FAK intervention:

Session 1: What is a Food Allergy?

The young child and parent/caregiver will be introduced to foundational information relating to FAs, including: What causes a FA? FAs are serious, and FA have no cure. Additional data and statistics available via the FARE website will

also be provided regarding the prevalence of FA among children and adults. The session will end with a brief, 6-min video entitled, ?Kids and Parents Talk About Living with Food Allergies.? Session-related content is designed to be interactive, rather than presented in a lecture-type format; thus, young children and their parent/caregiver will be allotted time/opportunity to ask questions.

Session 2: Diagnosis and Testing

This session will begin with a review of Session 1 content and continue with a discussion about the potential problems that self-diagnosis of a FA can cause. Given empirical evidence to suggest that low-income families may be more likely to self-diagnosis FAs, this topic will be covered with caution; however, we also believe that it is important content for young children and their parent/caregiver to understand. Next, the young child will be introduced to the four primary methods doctors use to determine whether someone has a FA: 1) skin prick test; 2) blood test; 3) oral food challenge; and 4) elimination diet. Session content will be interactive and ample opportunity will be left for participants to ask questions.

Session 3: Symptoms of Allergic Reactions to Food

This session will begin with a review of Session 2 content. This session?s focus will center upon 1) aiding the young child in understanding that allergic reactions can range from mild to severe, 2) developing a better understanding of the most typical symptoms associated with an allergic reaction (i.e., redness on skin, tingling throat), and 3) management strategies for dealing with allergic reactions. Session content will be interactive and ample opportunity will be left for participants to ask questions.

Sessions 4: Food Allergy Myths and Misconceptions

Session 4 will begin with a review of session 3 content. This session will focus upon materials developed by FARE to dispel myths many youths and families hold about FAs, including: FAs aren?t serious, peanut is the most ?dangerous? FA, peanut is the most common FA, all allergy-inducing ingredients must be placed on food labels, and each allergic reaction will get worse among others. Consequently, this session both helps to provide important facts and statistics about FAs as well as providing an opportunity for discussion as to commonly held beliefs that may lack empirical evidence. Session content will be interactive and ample opportunity will be left for participants to ask questions.

Session 5: Epinephrine

Session 5 will begin with a review of Session 4 content. This final session will focus solely upon the role of epinephrine in the lives of young children with FAs. A developmentally-tailored explantion of epinephrine will be provided. This description will include when it can and should be used as well as dispelling myths about epinephrine auto-injectors (epi-pens; i.e., they do more harm than good if the reaction isn?t severe, they never expire, can be stored anywhere). The session will conclude with a practice demonstration utilizing an ?epi-pen trainer? (i.e., a prototype epi-pen lacking medication or a needle but mimicing an epi-pen in all other ways). After the educator demonstrates the correct implementation of the epi-pen, the young child?s parent/caregiver will be asked to demonstrate correct administration. At the end of session 5, the young child will be congratulated for completing the intervention and receive a certicate of completion.

2. Food Allergy Superheroes Training (FAST) Intervention:

The primary aim of the FAST intervention is to 1) increase the young child?s understanding of FAs and 2) promote-adherence to FA safety guidelines through active skills training. We will achieve this aim through the use of educational materials (session 1) and a developmentally-tailored skills training intervention (session 2-5). The FAST and FAK interventions are designed to be equivalent in regards to number and duration of sessions; thus, the FAST intervention is administered over the course of 5 days, 15-20 minutes sessions. The young child and their parent/caregiver will be present for the entirety of all sessions; however, all intervention materials (i.e., educational content, skills training components) are designed with the young child as the primary focal point of interest. All children will be rewarded with a small toy (<$5 value) at the end of each successfully completed session. What follows is a description of the session-by-session content pertaining to the FAST intervention and a more detailed description of the individual components within each session (i.e., instruction, modeling, rehearsal, reinforcement/corrective feedback):

Session 1: Education

Session content will represent an abbreviated version of information provided throughout the FAK intervention. To achieve this aim, session 1 of the FAST intervention will de-emphasize discussion and focus to a greater extent on providing an engaging presentation of FA information and knowledge.

Sessions 2-5: Behavioral Skills Traning

Within session content for Sessions 2-5 will be identical (i.e., skills training implemented in identical order for each session) and is based upon PI Flessner?s prior work within the area of child injury prevention. Each session will last approximately 15-20 minutes. Four core components to BST exist and will be administered during each session in identical order: Instruction, Modeling, Rehearsal, and Praise/Corrective Feedback. A list of potentially relevant practice scenarious (see Modeling and Rehearsal below) will be developed through the course of Phase 1a?s joint advisory board. What follows is a brief overview of these components:

1. Instruction. With Session 1 content as a foundation, trainers will review basic FA safety guidelines (i.e., food avoidance) and introduce the specific skills a young child can use to promote adherence (i.e., ?stick to to what keeps you safe?).

SAMPLE DIALOGUE:
TRAINER. Ok. Now, to be a FA Superhero, you are going to need some special powers. Aquaman can talk to sea creatures and breathes underwater. Batman/Batgirl is a super crime fighter. The Flash has superspeed. Superman/ Supergirl is superstrong, can fly, and can use his/her eyes to cut through metal. Superman/Supergirl has one really important weakness though. Do you know what that is?

CHILD. Kryptonite!

TRAINER: You got it! Superman/Supergirl can?t touch kryptonite or they get really, really sick. That means they also have to be really careful. In fact, they have to be SUPER SAFE!!! I am going to work with you on developing your own special power - just like Superman/Supergirl. We are going to work on your? Super Safety!!! To earn your special power, we are going to need to work on 3 different skills. We need to STOP!?..when we see food that an adult has not said is ok?.DON?T TOUCH!.... even though we might want to check it out and - ASK AN ADULT??if the food is safe to eat. Do you think you can do those 3 things?

CHILD. Uh-huh.

TRAINER. Great! Let?s get started!

2. Modeling. Within this component to the FAST intervention, the trainer will create realistic scenarios in which the trainer ?acts out? the individual skill(s) to be learned. The trainer may make use of ?props? (e.g., plastic food) to make this portion more realistic. Each facet to the adherence-skills are modeled. First, the trainer models STOP! Next, he/she models STOP! DON?T TOUCH!. Finally, the trainer models STOP! DON?T TOUCH! ASK AN ADULT! With each new skill, the trainer develops a different and realistic scenario. The trainer uses loud and energetic physical demonstrations of the skills (e.g., throwing hands up in the air and stating ?STOP!?). As part of each successive scenario, the trainer will probe with questions to ensure the child is engaged and that they understand what they need to do to earn their Super Safety power (e.g., ?Ok. I see a cookie on the ground. What should I do??). Finally, the trainer ?checks? to make sure the child understands the step(s) by, for example, modeling incorrect behavior (e.g., ?STOP! TOUCH!) to see whether the child catches the mistake. If not, corrective feedback is provided and the example is reviewed. If yes, the trainer moves to rehearsal of skills.

3. Rehearsal. A child may be able to verbally describe what is to be done in a particular situation, but they may not yet posses the skills necessary to demonsrate this in the ?real world.? The trainer will develop at least 5, novel practice scenarios for the child to complete. These practice scenarios will be taken from a list developed by our research team and refined through input provided by the joint advisory board during Phase 1a. For each situation, the trainer will pretend that he/she is the child?s teacher, relative, friend?s parent, etc. The young child?s parent, if willing, will also be incorporated into practice scenarios as appropriate. The trainer will present the scenario to the child, observe the child? s compliance with the skills trained earlier in the session (i.e., STOP! DON?T? TOUCH! ASK AN ADULT!), and provide praise/corrective feedback (see below) as appropriate. Below is an example:

SAMPLE DIALOGUE:
TRAINER: Ok. Let?s practice. I want you to pretend that I am your teacher and this (shows the child a prop) is a candybar. Let?s pretend this (shows the child a flat surface) is your desk. I am passing out a birthday treat, and I put this candybar on your desk. Show me what you?d do.

[CHILD PICKS UP THE CANDYBAR AND ASKS IF IT IS OK TO EAT]

TRAINER: That is a really good first try. We definitely want you to ask your teacher if it is ok, but we don?t want to touch the candybar, right? So, we?d STOP! DON?T? TOUCH! and then ASK IF IT OK TO EAT! (trainer acts out the behavior in dramatic fashion)

In the above example, the child?s response would be considered incorrect. The child demonstrated only part of the sequence of behaviors. Asking an adult is important; however, it is equally important that a young child gains practice in not touching the candybar as well ? as food will not always be wrapped in plastic or cellophane. In this instance, the trainer would develop a new scenario and repeat the process. The rehearsal phase is completed upon the young child obtaining 5 consecutive correct responses or reaching the day?s session time limit (i.e., 20 minutes).

4. Praise/Corrective Feedback. This facet to the FAST intervention is provided throughout training (see above for an example); however, praise will also be provided throughout the course of the intervention and non-contingent on the exhibition of a correct skill. For example, a trainer may state ?Wow! You are going to do a great job today. I just know it.? Non-contigent praise is designed to increase the young child?s esteem regarding the skills being trained. This fits well within both basic principle of human behavior that facilitate more positive outcomes (i.e., child engagement) as well as the pediatric adherence-promotion model guiding this proposal (see Research Strategy).

At the end of the day?s session (with the exception of the final day), the young child will be reminded that they have 5 levels to compete before they earn their Super Safety power (i.e., Sessions 1-5). The trainer will explain that he/ she will be back tomorrow to continue/finish their superhero training. At the end of session 5, the young child will be congratulated for completing the intervention and receive a certicate of completion (i.e., Superhero certificate).

3. Common Process Issues Related to Protocol Implementation (both intervention groups) These are issues that are commonly encountered in interventions with young children. The goal is to recognize these concerns and address them as relevant each session. In practice, a particular concern would be addressed as it relates to follow up or teaching of content or a particular skill ? e.g. a young child refuses to participate in the session on that day or conflict arises between the young child and parent, etc. For some young children (and their parent/caregiver), there may be a recurrent theme across several sessions, while for others it may vary. Examples of themes include:

a. Child refusal to participate in session activities (e.g., work with family to develop a behavioral reward program to increase motivation to participate).

b. Inattention during instructional materials (e.g., break-up session into smaller segments, increase child?s engagement in session?s activity)

c. Parental anxiety about food allergy (e.g., social support, normalization of fears).

4.1.b. Primary Purpose Other

Promoting adherence