PROTOCOL TITLE: Food Allergy Symptom Self-management with Technology (FASST) for Caregivers: An mHealth Intervention to Address Psychosocial Outcomes in Caregivers of Children with Food Allergy

NCT04512924

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Document Date: 5/7/2021

Specific Aims

Overview: *Caregivers of children with life threatening severe food allergic reactions are more likely to experience fatigue, depression and anxiety. These distressing psychosocial conditions, in turn, may impact child and family functioning. Unfortunately, there is a paucity of self-management tools for caregivers to address these consequences. This proposal leverages advances in mHealth to develop and test such a tool.*

Approximately 6 million US children suffer from food allergy [1], an immune response that occurs reproducibly upon exposure to a given food. Food allergy is one of the fastest growing national public health concerns with incidence at 8% of children and prevalence increasing by 50% between 1997 and 2011.[2] Severe allergic reactions may include food-induced anaphylaxis (FIA), an acute life-threatening event affecting more than 40% of children diagnosed with food allergies.[3] FIA can result in a rapid reaction that leads to circulatory collapse, coma, and death. Once a child experiences a food-induced reaction, of any severity, it is not possible to predict the severity of subsequent reactions but raises the risk of future fatal reactions.[3] Between 2007 and 2016, FIA increased by 377% in the US, underscoring the need for better prevention and treatment [2] and for **interventions to address significant distress experienced by caregivers of children with food allergies**.[4]

Our recent preliminary research [4] corroborates findings in the literature [3; 5-11] suggesting that 32% of caregivers with a child who is newly diagnosed with food allergy(ies) experience clinically significant psychological distress.[12] Symptoms and related factors include fatigue, anxiety, depressed mood, social isolation, stress, and substantially reduced quality of life. Despite recognition that family caregivers of children with severe food allergies experience fatigue, adverse psychosocial conditions and decreased quality of life, there is a lack of caregiver-centered self-management interventions to address these outcomes. Moreover, a lack of self-management interventions for these caregivers means that these distressing symptoms will likely persist.

To address this gap, we propose to develop an intervention that specifically targets fatigue and associated psychosocial symptoms. Bounce Back Now (BBN)[13], an existing technology-enhanced, self-management mHealth intervention designed to address disaster survivors' psychosocial health needs using a smartphone-formatted approach, will be tailored and adapted for caregivers of children with food allergy(ies), hence the renaming to **Food Allergy Symptom Self-Management with Technology (FASST)** for caregivers. Over the course of 6-months, we will conduct preliminary feasibility testing of FASST in a 4-week small randomized trial of 30 caregivers of children ≤18 years-of-age who are newly diagnosed (≤90 days from diagnosis) with food allergy(ies).

Aim 1a: Perform key informant interviews (n = 10) and analyze via conventional content analysis to determine ways to improve app acceptability.
Aim 1b: Adapt FASST using data collected during key informant interviews.
Aim 2: Conduct preliminary testing of implementation processes including feasibility, acceptability, adherence and satisfaction using the RE-AIM framework with process measures, surveys, and key informant interviews in 30 caregivers randomized to receive FASST (n = 20) or the control condition (i.e., basic app with resource links) (n = 10).
Aim 3: Obtain estimates of variability and measure caregiver experienced fatigue, anxiety, depression, sleep, self-efficacy, and quality of life at baseline, 4-week intervention completion and 3-months post intervention.

B. Significance

B1. Food allergy is a highly complex condition and is growing in frequency and severity among children, negatively affecting quality of life.

Approximately 6 million children in the U.S. suffer from food allergy [1], and incidence is increasing.[2] Food-induced anaphylaxis (FIA) is a health risk associated with food allergy affecting more than 40% of children diagnosed with food allergies.[3] FIA can result as a rapid reaction that leads to circulatory collapse, coma, and death. Once a child experiences a food-induced reaction, of any severity, it is not possible to predict the severity of subsequent reactions but raises the possibility of future fatal reactions. [3] Although FIA reactions in children are rare, they are responsible for over 200 deaths and 30,000 emergency room visits annually in the United States.[14] There is no cure for food allergies and treatment involves avoidance of food allergens and emergency treatment of symptoms caused by accidental exposure.[15] A caregiver's ability to adhere to this standard of care may be challenged by a whole host of new factors that accompany the diagnosis, the most salient being the potential for a fatal reaction from ingestion of ubiquitous substances which are often invisible.

This creates an ever-present element of hypervigilance and stress-related fatigue as caregivers learn to manage food allergies as a chronic condition and as they learn to respond to food-induced reactions as an acute illness or event. Caregivers with newly diagnosed children are particularly challenged to balance appropriate vigilance and management strategies while tempering the effects of food allergy on quality of life.[16]

B2. Caregivers experience symptoms that may reduce caregiving effectiveness.

The PI's research, and that of others, highlights that caregivers of children with food allergy describe the physical challenges of care as overwhelming and constant. The perpetual hypervigilance and ensuing exhaustion associated with time-consuming and persistent condition-management activities – such as monitoring a child's food consumption at school or when with friends, shopping for, and preparing special food – have the greatest impact on caregiver quality of life and are associated with fatigue, uncertainty, constant stress, social isolation, reduced spontaneity, and persistent anxiety, fear, and depression. [4-11] Following diagnosis, caregivers experience a period of psychosocial adjustment where these symptoms are most pronounced.[17] As caregivers begin to understand the necessary precautions and potential consequences of accidental ingestion associated with FIA and the required condition-management activities, fear and anxiety emerge as the predominant emotions. While a certain level of anxiety is essential for adequate management, high levels of sustained anxiety in caregivers of children with food allergy may be maladaptive, increasing the overall burden of caring for a child with FIA and negatively impacting the caregiver's ability to provide care to self, child, and family.[18]

B3. Self-management strategies for caregiver stress and fatigue are lacking.

Despite recognition that family caregivers of children with severe food allergies are at risk for adverse consequences, decreased quality of life, and diminished caregiving effectiveness, there are a lack of caregiver-centered self-management interventions to address stress-related fatigue, depression and anxiety symptoms. However, symptom self-management is exceedingly relevant to the caregiver of a child with newly diagnosed food allergy(ies) as management is complex and compounded by factors outside of the caregiver's control which are further intensified by the lack of definitive treatment or cure. The short-term goal of this technology-enhanced, self-management mHealth intervention is to enhance and promote effective self-management behaviors to improve the psychosocial well-being of the caregiver that in the long-term will lead to improved outcomes for the child, namely prevention of potentially fatal food induced reactions.

C. Innovation

This proposal is innovative because it is the first to address psychosocial manifestations of caregiving to children with newly diagnosed food allergy(ies) using a technology-based self-management scalable strategy that has the potential to be translated to other populations of caregivers of children with complex medical conditions. This proposal:

- Targets caregivers who are new to the disease process and management requirements and therefore have unique needs that will be addressed using a smartphone-formatted approach. This demonstrates an innovative approach that is both cost effective and sustainable over time (fewer personnel required).
- Focuses the intervention on psychosocial symptoms such as fatigue, addressing an unmet need recognized within the literature but neglected by providers.
- Uses a scalable strategy to engage caregivers during a critical time-period in the caregiving/condition trajectory (≤ 90 days from diagnosis) when psychosocial functioning is most at risk.
- Addresses barriers to accessing care such as transportation, work schedules, and childcare through the application of technology. Addressing these barriers lends to the translatability of the intervention to other populations of caregivers of children with complex medical conditions.
- Uses a technology-based intervention that has been tailored based on caregiver-reported needs and desires and provider expertise which is expected to increase engagement and reach of self-management strategy.

D. Approach

D1. Overview

This feasibility study is designed to modify an existing technology-enhanced, self-management mHealth intervention (BBN) and evaluate its impact on reach, self-management behaviors, caregiver psychosocial symptoms and quality of life targeting caregivers of children with newly diagnosed food allergy during the first 90 days after diagnosis. Our clinical sample will be recruited from the Medical University of South Carolina

(MUSC) Health Allergy and Immunology Clinic within the MUSC West Ashley Primary Care office. A sample of (n=10) caregivers of children with established food allergy (≥ 1 year from diagnosis) will be recruited for key informant interviews that will inform tailoring and adapting FASST. Feasibility (rate of recruitment, attrition, rate of missing data, adoption, implementation, satisfaction, acceptability) will be tested in a randomized sample (n=30) of caregivers of children newly diagnosed with food allergy (≤ 90 days from diagnosis). Participants (n=20) will be randomized to the experimental condition (FASST) or (n=10) to a control condition (i.e., basic app with resource links).

Participants randomized to the intervention arm (n=20) will receive the modified mHealth application (FASST) that contains elements of condition specific education and information, symptom self-monitoring, and symptom self-management. Participants in the control arm (n=10) will receive the modified mHealth application (FASST) that contains only the element of condition specific education and information.

D2. Investigative Team and Preliminary Work

This interdisciplinary team provides extensive, complementary expertise that will facilitate successful conduct of the proposed project. The primary mentor, Dr. Kelechi, a nurse scientist, has vast experience with developing rigorous feasibility and clinical trial management structure. Dr. Kelechi adds nursing expertise, theory-driven models, self-management/self-care, and expertise in intervention development and testing. Co-mentor Dr. Ruggiero has a background in clinical psychology and is the Director of Technology Applications Center for Healthful Lifestyles (TACHL) and is PI on multiple NIH-funded grants. Fifteen of the federally funded grants that he has led as PI (including 5 NIH awards) have incorporated technology-based strategies and/or telehealth platforms to deliver interventions. Dr. Ruggiero brings experience with technology, telehealth, user centered design, intervention adaptation, as well as intervention development and testing. This includes development of web-based self-help interventions,[19] as well as an iPad based intervention.[20] Our clinical partner, Dr. Kelli Williams, is a board-certified pediatric allergy and immunologist with MUSC Health Allergy and Immunology, completed her residency in Pediatrics at MUSC and her fellowship in Allergy and Immunology at the National Institutes of Health, National Institute of Allergy and Infectious Diseases. While in fellowship, her research focused on rare immunologic and allergic diseases in both children and adults. Dr. Williams' clinical interests include anaphylaxis and food allergy. Finally, Dr. Mueller, biostatistician, and co-investigator on several NIH-funded projects, including several with Dr. Kelechi, will provide expertise in measurement strategies and statistical analyses.

D3. Method

D3.1. Setting, Sample and Recruitment. Prior to participant recruitment, we will tailor and adapt BBN to FASST based on existing literature and expertise of the study team. We will then recruit 10 caregivers of children with established food allergy (≥ 1 year from diagnosis) to participate in key informant interviews that will inform the most practical changes needed when tailoring and adapting FASST prior to the intervention. We consider these key informant interviewees as co-designers of FASST as they possess a level of experience with and understanding of food allergy management and the psychosocial consequences of caring for a child during the critical period following a child's food allergy diagnosis that caregivers of newly diagnosed children have yet to experience. Caregivers will be recruited via the Medical University of South Carolina (MUSC) Health Allergy and Immunology Clinic within the MUSC West Ashley Primary Care office. Caregivers will be recruited who have at least one child with an established food allergy(ies) diagnosis (≥1 year from diagnosis) and are familiar with the disease process and management as determined by: child has been seen at least every 12 months for one or more years. Dr. Williams will identify potentially eligible caregiver participants and will contact the caregiver, briefly describe the study, and ask permission for the principal investigator (Dr. Broome) or research assistant (RA) to contact the caregiver for screening. Once permission is granted, the PI or RA will contact the caregiver and assess for eligibility. Prior to consenting, all questions will be resolved to the patient's satisfaction. If a participant does not appear to understand the information contained within the consent document or of what is expected of them as a study subject, then a member of the study team will review the consent document again with the participant. If after this second review, the subject does not demonstrate an understanding, they will not be enrolled in the study. Only participants, with no observed cognitive impairment, will be consented and enrolled into the study.

Feasibility testing. Thirty caregivers of children with newly diagnosed (≤ 90 days from diagnosis) will be recruited into the feasibility Aim 2 of the study. Eligible caregivers will again be identified through the MUSC Health Allergy and Immunology Clinic. Inclusion criteria are as follows: caregivers of children ≤18 years-of-age who are newly diagnosed (≤ 90 days from diagnosis) with food allergy(ies). Only participants, with no observed

cognitive impairment, will be consented and enrolled into the study. To recruit participants for feasibility testing, Dr. Williams at the MUSC Health Allergy and Immunology Clinic will identify potentially eligible participants, explain study procedures, and if caregivers express interest, then will ask permission for the PI or RA to contact the potential participant. If permission is granted, the PI or RA will contact the potential participant to determine eligibility.

D3.2. Intervention

The intervention will be a multicomponent (3-part) technology-based package delivered via a mobile device and used over a 4-week period. The intervention will target influences and processes informed by the Caregiving Process Model. **Component 1** (education and support) will consist of continuous access to directed educational resources about food allergy and its management. These materials will be easily accessible via a mobile device and will include embedded PDFs and links to websites developed and tested by authoritative sources. An example includes education materials provided by the Food Allergy Education and Research (FARE), the leading national organization and most trusted source of food allergy information, programs and resources, such as the Food Allergy & Anaphylaxis Emergency Care Plan. To address potential literacy barriers, all resources will be provided in a web compatible format and compliant with current accessibility guidelines. **Component 2** (symptom monitoring and tracking) will consist of a mobile-device based application for daily tracking and monitoring of fatigue, anxiety and other psychosocial symptoms in caregivers of children with newly diagnosed food allergy(ies) that also permits upload of physical and emotional symptom logs to study personnel. The PI or RA will send a daily text reminder to participants randomized to the intervention arm of the study reminding them to complete their daily physical and emotional symptom log. Logged symptom trends will be graphically illustrated by the application for participant viewing. Based on feedback from component 2, participants will be given directed guidance related to component 3 (symptom self-management). **Component 3** will consist of symptom-based interventions participants can utilize real-time. For example, if a participant logs symptoms related to anxiety, the application will recommend a brief guided intervention for relaxation, such as meditation, or deep breathing. If a participant logs symptoms related to fatigue, the application will recommend the participant listen to a short audio clip that offers ideas for achieving better sleep or suggestions for good sleep hygiene. We will collect data via the app on the frequency and patterns of usage and will also collect measures data for Aim 3 at baseline, 4-weeks intervention completion and 3-months post-intervention completion. As well, the RA will send caregivers a weekly text message using a semi-structured protocol to “check in” with participants and promote engagement.

D3.3. Control group

The control group will receive Component 1 of the intervention.

D3.4. Primary Aim 1a and 1b: Key informant interviews and intervention tailoring and adaptation

We will use a purposive sampling strategy to identify caregivers of children with established (≥ 1 year from diagnosis) food allergy(ies) familiar with the disease process and management. Data obtained through key informant interviews using a semi-structured protocol and a qualitative descriptive approach[21] will inform tailoring and adaptation of FASST. The purpose of interviews will be to obtain feedback from caregivers of children with established food allergy(ies) who have been managing the condition for one year or more. Participants will be asked about their experience in the first year of managing their child’s food allergy, with specific questions regarding the first 4 weeks of management and the perceived impact on their psychosocial well-being and overall quality of life. Participants will be shown a mocked-up application on a mobile device and asked to provide feedback related to the content. At the beginning of the session, the PI will deliver detailed verbal instructions regarding use of the device and intervention components. Participants will be provided with mobile devices that have been prepared for the feasibility testing (Aim 2) with access to the FASST application and text messaging. After allowing time for participants to explore the intervention (with direct observation), the PI will ask 8-10 open-ended questions with probes using an interview guide. Questions will be designed to assess the acceptability, feasibility, and usability of the intervention. The interview will conclude with questions regarding suggested improvements to the intervention. The hands-on, observational session is expected to last 45 to 60 minutes and the interview is expected to last an additional 45 to 60 minutes. The PI will video record observations to inform adaptation of the intervention. The interview will be audio recorded and transcribed. Following data analysis (described in **D3.7.**) the results from the interviews will be used to adapt the intervention to meet the specific needs of caregivers of children ≤18 years-of-age with a newly diagnosed food allergy(ies).

D3.5. Primary Aim 2: Feasibility Testing

To determine feasibility, we will apply the RE-AIM framework to assess the Reach, Efficacy, Adoption, Implementation, and Maintenance of the intervention with 30 caregivers.[22] The domains are further explicated in Table 1. Participants will be asked to download the FASST app onto their mobile device with intervention components 1, 2, and 3 if randomized to the intervention arm and only component 1 if randomized to the control arm. The PI or RA will deliver detailed verbal instructions to the participants in both arms of the study on the use of the application and the respective intervention components. Participants will also receive written instructions and a contact number for technical assistance if needed. Baseline measures (Table 1) will be collected during the same meeting. Participants will participate in the intervention over a 4-week-period. At the end of the 4-week period, the PI will attend a post-intervention meeting with each individual caregiver participant during which measures data for Aim 3 will be collected. The PI will also collect frequency and patterns of usage data 3 months post-intervention to assess implementation and preliminary evidence of maintenance (Table 1).The PI will meet with the RA weekly during the intervention.

Post-intervention interviews. Five participants from each study arm will be randomly selected and asked to participate in post-intervention key informant interviews with the PI to obtain more in-depth data on accessibility, usability, and adherence to intervention guided by the RE-AIM framework (Table 1). Semi-structured interviews will be conducted in-person or via phone (participant's choice) using a qualitative descriptive approach,[21] will last approximately 45-60 minutes, and will be conducted according to an interview guide with open-ended questions and probes.

Reimbursement for participants will be a $50 gift card provided at each of the 3 data collection points, with participants in key informant interviews (pre- and post-intervention) receiving an additional $50 gift card.

Measures. Caregivers will complete self-report measures at baseline, 4-week intervention completion, and 3 months post-intervention. Self-report measures will be collected during meetings between the PI and the participant. Participants will complete measures using a mobile tablet device. Data will be captured using REDCap data management system. The PI will be present to answer questions but will be unobtrusive while measures are completed.

Table 1: Intervention Domains and Measures

Major tasks and domains	Measures/instruments/ questions and Cronbach's alpha ( )	Data sources and time points
Demographics/clinical characteristics	Caregiver demographics including age, marital status, employment status, race/ethnicity, highest education level, and income; child age, health history, race/ethnicity, medications, health care utilization, rural/urban residence, insurance, family characteristics	Caregiver interview; baseline
Reach: Sample Recruitment	Monitoring of sample representativeness; types of recruitment activities; rates of recruitment; % eligible, consented, provided with informational session	Recruitment tracking forms; quality checks by PI; weekly meetings with mentor, clinic staff, and research team
Efficacy: Fatigue Emotional distress: anxiety Emotional distress: depressive symptoms Quality of Life Sleep Disturbance Self-Efficacy	 PROMIS Fatigue SF 6a(>0.9)[23] PROMIS Emotional Distress: Anxiety 6a (0.97)[24] PROMIS Emotional Distress: Depressive symptoms SF 6a (0.97)[25] Food Allergy Quality of Life-Parental Burden (>0.85)[26] PROMIS Sleep Disturbance SF 6a (0.9)[27] Food Allergy Self-Efficacy Scale for Parents (0.63-0.89)[28]	Tracking forms; fidelity checklist; transmissions from web-based application to PI/RA; post-intervention interviews; weekly meeting with mentor, clinic staff, and research team; baseline, 4-weeks post-intervention, 3-months post-intervention
Measures of self-management behaviors:	# days recorded symptoms; # days and types of recorded treatments/interventions	

Monitoring and tracking symptoms		
Adoption: Adherence Acceptability Education Symptom monitoring and tracking	# days symptoms recorded; # times problem-based intervention accessed; length of time in minutes problem-based intervention accessed; # times educational component accessed; length of time in minutes educational component accessed Caregiver satisfaction; # problems reported; types of problems reported # times accessed educational materials; length of time in minutes educational materials accessed # days recorded symptoms	Tracking forms; data transmitted from web-based application; fidelity checklist; weekly meetings with mentor and research team; caregiver interview at end of study
Implementation: Technology Consistency of intervention	 # problems encountered with mobile device, # problems reported to research staff; types of problems reported instructional session conducted as planned; fidelity to protocol maintained	 Tracking forms; weekly meeting with mentor and research team; caregiver interview at end of study
Maintenance: Projection of future adoption	 # caregivers who would continue intervention; caregiver perception of the intervention	Caregiver interview at end of study; weekly meetings with mentor and team

Sample size considerations

The purpose of this study is to establish feasibility of implementing the integrated intervention and obtain estimates of variability for efficacy outcomes, rather than to confirm or refute hypotheses. The proposed pilot study will recruit N=30 subjects for participation. Because this is a pilot study and thus will not be testing hypotheses or proposing use of inferential statistics, a target sample size of 30 is appropriate.[29]

D3.7. Data Analysis

Qualitative analyses (Aim 1): Data from observational sessions and key informant interviews with caregivers and providers will be analyzed using conventional content analysis[30] and nVivo qualitative data analysis software version 10[31] to code data into common themes. These themes will be compared to the intervention and the components of the intervention will be adapted based on the thematic findings. A tree diagram may be used to identify the hierarchical structure of themes.

Feasibility processes (Aim 2): For the feasibility trial, we will collect multiple measures informed by the RE-AIM framework to assess feasibility and inform future efficacy and effectiveness trials. Variables will include those pertaining to the study procedures as well as participant variables. Data to be collected are described in Table 1. Specifically, 95% confidence intervals for proportions will be used to estimate dichotomous outcomes including the proportion of caregivers who agree to participate out of the number approached, the proportion adherent to the intervention protocol, i.e. providing daily symptom monitoring/tracking, using the education component, etc. For the continuous feasibility measures (e.g., patient satisfaction scores from patient surveys and end-of-study interview), frequency distributions and the median and mean responses (with 95% confidence intervals) will be obtained.

Outcome measures and estimates of variability (Aim 3): Demographic and clinical variables obtained at baseline will be described via measures of central tendency (mean, median), variability and frequency distributions as appropriate. Additionally, demographic and clinical characteristics for those who adhered to the study protocol (study completers) versus those who did not adhere (non-adherers and drop-outs) will be compared to better describe the population for this study. For continuous measures for the caregiver (fatigue, anxiety, depression, quality of life, sleep disturbance, pain and self-efficacy), the difference between pre and post intervention measurements will be estimated via 95% confidence intervals.

Post-intervention qualitative analyses (Aim 2): Data collected from post-intervention key informant interviews will be analyzed using directed content analysis[30] and nVivo qualitative data analysis software version 10.[31] Consistent with the directed content analysis approach, initial coding categories are identified according to the guiding theoretical model, and for this study, will reflect the RE-AIM domains.

D3.8. Timeline

Activity	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2
Organization, IRB approval						
Adaptation of BBN to FASST						
Interviews with caregivers and providers						
Analysis of interview data						
Tailoring of FASST						
Recruitment						
Intervention delivery (with assessments)						
3-month follow up assessments						
Data analysis, manuscript preparation, grant submission						

Provisions to Monitor the Data to Ensure the Safety of Subjects
There is a well-developed and NIH/NINR prepared DSMP that involves the use of a Safety Monitoring Committee (SMC) that shall meet semi-annually post initial study enrollment. The Committee is comprised of key individuals that include: a safety monitoring committee chair (SMCC), a biostatistician (BS), and the Program Manager (PM). Post initial study enrollment, the SMC will convene semi-annually and all reports will be forwarded to the IRB and Sponsor in accordance with institutional policies and sponsor requirements.

SECTION A. Safety Monitoring Committee (SMC)
The study's SMC will be comprised of the following individuals, who will perform data safety management and monitoring of the study:
Susan Newman, PhD, RN, CRRN Safety Monitoring Committee Chair (SMCC)
Martina Mueller, PhD Biostatistician (BS)
Mohan Madisetti, MSc. Program Manager (PM)

Individual Roles and Responsibilities
Principal Investigator, (PI). Although not part of the SMC, as PI, Dr. Broome will overall be responsible for the immediate protection of all human participant study participants enrolled in the study.

Safety Monitoring Committee Chair (SMCC). **Dr. Newman** is an Associate Professor and the Director of the Ph.D. in Nursing Science program in the College of Nursing. Dr. Newman is a Certified Rehabilitation Registered Nurse currently researching the role of peer mentoring in the process of adapting to life with a spinal cord injury. Her work has been supported by the National Institutes of Disability, Independent Living and Rehabilitation Research, National Institutes of Health, and the Agency on Healthcare Research and Quality. Dr. Newman will act as the study's Safety Monitoring Committee Chair (SMCC). Dr. Newman has no real or apparent conflict of interest that would affect her performance in this role on the study. Dr. Newman will correspond semi-annually with the SMC to review de-identified cumulative AE study data to assess any impact on the safety of participants or on the ethics of the study. As the SMCC she will be responsible for reviewing all cumulative reported SAE related to study treatment and data safety monitoring reports generated by the BS to provide study recommendations to the PI, MUSC's IRB and NINR. Dr. Newman will be immediately notified of the occurrence of any SAE by the PI or PM and will be provided with the necessary study information to provide an informed recommendation in real-time regarding the protocol and human participant safety.

Martina Mueller PhD, Biostatiscian (BS). Dr. Mueller is a Professor in the College of Nursing with a joint appointment in the Department of Biostatistics, Bioinformatics and Epidemiology (DBBE) at MUSC. Dr. Mueller has served and is currently serving as a member of several NIH/NINR R01/R21 DSM Boards, and Committees. Dr. Mueller will be responsible for conducting semi-annual interim analyses, generating semi-annual AE safety reports from the electronic study research database and disseminating de-identified information to the SMC. The interim data analyses will only include safety related results; analyses in regards to study outcome will not be performed. The interim AE reports will provide typology, frequency data and outcomes of all reported and documented AE in the electronic study database. With no patient contact, Dr. Mueller has no apparent conflict of interests to serve in this capacity.

Mohan Madisetti MSc, Program Manager (PM). Mr. Madisetti is the P20 Progam Manager at the College of Nursing and a member of MUSC Institute of Human Values with Fellowship certification in Research Ethics. Mr. Madisetti has served and is currently serving as a member of several NIH/NINR R01/R21 DSM Boards and Committees, and FDA Industry Sponsored Clinical Trials. With no patient contact, Mr. Madisetti has no apparent conflict of interests to serve in this capacity. Mr. Madisetti will be responsible for the classification of all reported adverse events (AE) and for ensuring that all serious adverse events (SAE) are forwarded to the PI and SMC in real time and in compliance with MUSC IRB policies and procedures. In addition, and in conjunction with the PI, Mr. Madisetti will be responsible for amending the protocol in accordance with the SMC recommendations, submitting reportable SAEs and protocol deviations to MUSC IRB, and, submitting annual Progress Reports to the NIH/NINR through MUSC's OSRP. He will also be responsible for maintaining the regulatory binder, ensuring data management validation and verification of the electronic study research database, conducting monthly internal quality control audits on all participant records, notifying the PI of any deficiencies, and the

forwarding of reportable SAE to the NIH/NINR Program Official through MUSC's OSRP within 72hrs of IRB review and acknowledgement.

SECTION B. Procedures for Safety, Risk and Confidentiality

1. Monitoring Study Safety

From the initial screening of participant by inclusion and exclusion criteria to the informed consent process to the provision of participant study instruction to staff training in Good Clinical Practices (GCP) and regulations pertaining to the Conduct of Human Participant Research to study contact with participants to internal monthly quality control audits and protocol fidelity monitoring to the real-time review of AE by the SMC to the oversight of MUSC's IRB, procedures for monitoring study safety are consistently afforded throughout study. Specific study safety procedures include:

- Participants will be screened for inclusion and exclusion per the protocol; the PI or RA shall verify 100% of participants' eligibility prior to study enrollment through review of inclusion and exclusion criteria with potential participants.
- Participants will be fully informed as to all know risks and the possibility of risk from study participation in the informed consent process. **These risks are minimal.**
- Participants will be instructed to notify the researchers of any/all suspected or experienced adverse events whether they believe them to be related or not to the intervention.
- All reported participant AEs will be tracked through to resolution.
- All investigators and researchers will maintain active CITI Human Subject Research and Good Clinical Practice training.
- The PM will conduct a monthly internal quality control audit of all participant records to ensure compliance with MUSC IRB regulations; the PI and Program Coordinator (PC) will work together to correct any errors.
- The PI and/or designee will observe and evaluate ten (10%) percent of eligibility screening visits, informed consents and study instructions performed by IRB approved study personnel and provide feedback and/or retraining of study personnel if fidelity to both applicable federal regulations and the protocol is not observed.
- The BS willl generate semi-annual AE reports for the PI and SMC to review.
- The SMC will have access to real-time study data and will be able to provide immediate recommendations to the PI.
- Investigator performance and compliance will be provided for through MUSC IRB and ORI study oversight.

2. Minimizing Research-Associated Risk

Diligent study safety monitoring will be conducted by all member of the research team and the SMC throughout the conduct of this study in compliance with the following required elements of MUSC IRB's continuing review process:

- Tracking and follow-up of participant accrual (inc. withdrawn consents) will minimize risk by identifying, disclosing, and mitigating any potentially unknown risk(s) of harm to study participants.
- Timely and appropriate reporting of informed consent process deficiencies, protocol deviations, privacy breaches, conflicts of interest, and/or changes in personnel.
- Ongoing soliciting, monitoring and appropriate reporting of adverse event activities.
- Timely and appropriate IRB submission of safety-related documents such as audit reports, sponsor progress reports, SMC reports, and other materials or communications that might impact the safe conduct of this study.
- Active cooperation with the IRB, ACO, sponsor, and other applicable entities in the event of a random or for-cause internal or external audit.

Institution-Wide Assurances

This protocol will be conducted fully in keeping with the signed MUSC IRB Principal Investigator Statement of Assurance and Department Chair's Statement of Assurance, when submitted to the IRB as a required component of the MUSC IRB Human Research Review Application.

3. Protecting Confidentiality of Participant Data
Certificate of Confidentiality. This study will be conducted in accordance with recently enacted policy regarding the automatic granting of Certificates of Confidentiality to NIH/NINR federally funded research. Participants will be made aware of their rights and the limitations of the release of Protected Health Information during the Informed Consent process.

Participant Screening and Enrollment. All data from participants screened for the study will be entered into an electronic study database. Designated research staff will collect, gather, and enter required data (written informed consent, HIPAA Authorization, and demographics) onto study data forms. Screened patients who do not meet study eligibility will have specific screening data entered into the study database. The collected data will be helpful in examining the patient population and feasibility of enrollment criteria and will include reason for exclusion. All dates will be shifted and other Personal Health Information (PHI) will be removed from the study database upon study completion. All data obtained from this study will be used for research purposes only and will comply with Federal HIPAA regulations. Master Screening and Enrollment Logs will used by the PM to prepare reports on accrual and attrition for the PI and SMC.

Case Report Forms (CRF). All proposed study specific case report forms (source documents) for data collection will be designed by the PI, and, when possible, transferred into electronic Case Report Forms (eCRFs) for use in the study's REDCap database. These study specific eCRFs source documents (study logs for correspondence, compensation and other forms such as pre-eligibility screens) will be coded by the participant's unique study ID# for all data collected including study instruments will be maintained in the participant research record. Completed instruments that require signature on a paper CRF will be scanned and uploaded into the study database to all for remote electronic safety monitoring as well as maintained on file in accordance with MUSC policies and applicable Federal Regulations for the Conduct of Human Participant Research.

Binders. The PC will prepare and maintain a participant-specific CRF binder for each participant containing all non-eCRFs records. A regulatory file will be maintainedby the PM to include the IRB-approved Protocol, original Informed Consent documents, HIPAA forms and other required study-related regulatory documents. All paper research records and CRFs will be maintained in a locked file cabinet, stored in a room for research files that is accessible only via a password protected entry system that features security cameras, within the College of Nursing. Access to the research records, study database and PHI's will be restricted to study personnel as approved by the PI and MUSC IRB. As with all studies conducted at MUSC, this study is also eligible for a random audit by MUSC Office of Compliance.

Data Processing. This study will use Research Electronic Data Capture (REDCap) for data capture and management. REDCap is a software toolset and workflow methodology for the electronic collection and management of research and clinical trials data. REDCap provides secure, web-based, flexible applications, including real-time validation rules with automated data type and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, SATA, R and Microsoft Excel. The study-specific REDCap electronic database will be designed and developed by the PI, CI, or PC. The provision of REDCap is made available through the South Carolina Clinical & Translational Research (SCTR) Institute at MUSC with NIH Grant awards UL1RR029882 and UL1TR000062.

Data Security. Ensuring data security, compliance with 45 CFR 46 and maintaining the integrity of PHI is a top priority. MUSC has Standard Operating Procedures (SOP) to ensure a high level of data security while coordinating electronic and paper data management activities for clinical research trials. The REDCap study database will be hosted in the Biomedical Informatics secure data center at MUSC, a secure environment for data systems and servers on campus, and includes firewall, redundancy, failover capability, backups and extensive security checks. The secure data center has strict access control; only authorized core personnel may access the facility un-escorted. Only authorized users are allowed to connect to the network, and the security of the network is actively monitored. Power and environmental controls have several layers of backups, from interruptible power supplies to alternate and redundant feeds to the local utility company. The

REDCap system administrator contributes to the maintenance of institutional disaster recovery and business continuity plans. Load balancers and a highly fault tolerant SAN infrastructure contribute to high availability.

The REDCap system itself has several additional layers of protection including password protection. Access to the data and its security is managed institutionally by sponsored login IDs through a Shibboleth login with an MUSC issued NetID and features a user account management filter that controls who can access the data and to what degree. All personnel must pass an employment background check before being issued an ID. Password complexity, history and expiration standards are implemented at the institutional level. Access to individual REDCap projects and their data is managed by the owner of the project. All transactions are securely delivered to the application using Secure Sockets Layer (SSL – SHA-1 with RSA Encryption; 2048-bits). It is then transmitted internally (behind the firewall) to the database server. All transactions are logged at the server layer (httpd logging), application layers (REDCap logs activity to a database table), and the database layer, using both query and binary logging. This feature provides audit trails for all changes, queries, data exports and reports. MUSC Information security policies are available at: https://mainweb-v.musc.edu/security/policy/

Data Entry. Only MUSC IRB approved study personnel that are authorized to have access to the REDCap study database will be granted password access. Study personnel using computers that are connected to the Internet will directly enter data into the remotely housed database. As such, no electronic study data will be stored on hard drives and/or any portable electronic devices. Additionally, all personnel with access to the database will have current University of Miami CITI training in the Conduct of Human Subject Protections, and HIPAA and Information Security trainings that are completed annually. Each participant will be assigned a unique study identifier, all PHIs will be masked, and data exports will be limited to the PI or the PC for generating reports and the conduct of statistical data analysis.

Data Monitoring. Ongoing quality control procedures will be implemented for data collection, storage and processing. The PM will conduct routine monitoring of the study database and generate a monthly report for review at study team meetings. Standing agenda items for these meetings will include participant recruitment and retention, AE's, protocol deviations, data integrity and overall study conduct. The PI and PC will work to resolve and validate discrepant data. Discrepancies that warrant clarification will be sent to appropriate parties for review and resolution. All data entry and changes made in the study database by authorized study personnel will be automatically logged by REDCap, and provide a transparent visible audit trail for reviewers.

SECTION C. Procedures for Identifying, Reviewing and Reporting Adverse Events

1. **Identifying.** Potential minimum risks identified for participants are outlined in the Protection of Human Participants and will also be outlined in the IRB-approved informed consent document. Additional unknown risks may occur and, if so, will be identified through diligent monitoring by the PI or PC throughout the conduct of this study. During the informed consent process, participants will be advised of the potential risks of participation as identified in the IRB-approved informed consent document and reminded throughout the study that the researchers should be promptly informed about any concerns regarding potential side effects, adverse events, or clinical deterioration. Participants will also be instructed to notify the PI, PC, and/or designee of any suspected adverse events immediately if possible. The PI or PC will maintain an electronic record of all reported adverse events and notify the SMC of all reportable events as they occur. The SMC will have real-time access to the study database to review and monitor all reported SAE that were reported as related to the intervention. Additionally, the BS will generate and provide de-identified cumulative administrative human participant semi-annual safety reports for the SMC to review.

2. **Reviewing.** Adverse events will be initially be assessed and graded by PM and then reviewed by the members of the SMC according to the following MUSC's IRB Adverse Event Reporting Policy http://academicdepartments.musc.edu/research/ori/irb/HRPP/HRPP Guide Section 4.7
   - **Expected/Anticipated**—Identified in nature, severity, or frequency in the current protocol, informed consent, investigator brochure, or with other current risk information.
   - **Unexpected/Unanticipated**—Not identified in nature, severity, or frequency in the current protocol, informed consent, investigator brochure, or with other current risk information.

- **More Prevalent**—Occurs more frequently than anticipated or at a higher prevalence than expected.
- **Serious**—Results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, cancer, overdose, or causes a congenital anomaly/birth defect.

The relationship of adverse events to study participation will be determined by the SMC according to the MUSC IRB Adverse Event Reporting Policy:

- **Unrelated**—There is not a reasonable possibility that the adverse event may have been caused by the drug, device or intervention.
- **Possibly Related**—The adverse event may have been caused by the drug, device, or intervention, however there is insufficient information to determine the likelihood of this possibility.
- **Related**—There is a reasonable possibility that the adverse event may have been caused by the drug, device or intervention.

3. **AE and UPIRSOS Reporting.** All reportable AE and unanticipated problems (UPIRSOS) experienced by participants will be reported to the NIH/NINR and MUSC IRB in compliance with their Adverse Event Reporting Policy requirements, using the IRB's password protected on-line secure server adverse event reporting system. Within 24 hours after a reportable AE, SAE or unanticipated problem has been reported by the participant, it will be graded by the PM, forwarded to the study's SMC for review, and then will be submitted by the PI to MUSC IRB. The Institutional Official(s) will review the event and discuss the report with the IRB Chair and the Director of the Office of Research Integrity. After IRB review and acknowledgement, the PI will further review, and the PI or PM will forward a copy of the reportable AE, SAE or unanticipated problem and IRB acknowledgement letter to the NIH/NINR Program Officer through MUSC's OSRP. The activities will be reported to the NIH/NINR within 72hrs. In addition, all cumulative reportable AE, SAE and unanticipated problems included in the SMC reports will be submitted to the NIH/NINR in the PI's Annual Progress Reports.
4. **Examples of Potential Reportable Adverse Events:** In accordance with MUSC IRB Adverse Event Reporting Policy, an AE is reportable is it meets all of the following criteria: 1) is unexpected 2) is related and/or possibly related, and 3) is serious and/or suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. Additionally, per MUSC's policy all participant deaths, protocol deviations, complaints about the research, and breaches of confidentiality are reportable events. An example of an AE would be physical pain (symptom) that could potentially be associated with caregiving activities. The steps to be taken may include withdrawing the subject from the study and inviting him or her to restart the study after symptoms subside. An example of an SAE would be the death of a participant from acute chest syndrome, which although would be viewed as unexpected and unrelated to the intervention is nonetheless a reportable serious event. No further steps would be taken except to review, grade and report the event. An example of an unanticipated problem would be the participant trips and falls while retrieving their phone to read a text message reminder. The steps in this case would be to report the event as per the IRB and NINR policy, and to discuss appropriate actions regarding whether the participant should remain in the study with the SMC. These events and problems will be reported in accordance with the IRB and NIH/NINR policy as noted in Section C.3.

SECTION D. Multi-site Monitoring and Compliance

This is not a multi-site study.

SECTION E. Assessment of External Factors

The PI will conduct a semi-annual assessment of external factors through a review of literature related to new developments in the areas of food allergy caregiver self-management, symptom management (including anxiety and fatigue), symptom reporting and other approaches that may have an impact on the safety of participants or on the ethics of the study. To determine whether any changes are necessitated to the study protocol, the SMC will review any identified literature or product safety data that may pose as a potential impact to the risk benefit ratio study and/or safety of study participants.

SECTION F. Interim Analysis

This study aims to test the feasibility of a multi-component, technology-based intervention to promote self-management and symptom management among caregivers of children newly diagnosed with food allergy. To our knowledge, there are no similar interventions specifically designed for this population and purpose. As such, the PI and BS will generate semi-annual qualitative interim analysis reports on a) adverse events; and b) data obtained during phone end-of-study interviews to understand issues related to the uptake, usability, and adoption of this platform among this population. We will evaluate the screening and enrollment procedures, barriers to participation and retention, including, safety, adherence, acceptability, technology problems encountered if any, and user feedback from the participants and providers. This information gained from this structured process will be used to both guide the refinement of the current protocol and to inform the design of a larger efficacy trial. Interim analysis of outcome variables (fatigue, anxiety, and quality of life) was not considered to avoid inexact inferences and increased chance of error due to few data points, as well as potential for bias if interim results were known to the investigators. Therefore, there are no planned stopping rules for this study.

Withdrawal of Subjects

Participants may voluntarily elect to withdraw their consent at any time for any or no given reason while enrolled in the study. The PI may withdraw participants from the study at any time if they decide it is in the participant's best interest, if they do not follow the investigator's instructions, and/or if they fail to maintain to contact with the researchers or attend study visits. Withdrawals of participants may also occur if there is a protocol violation or early study closure. All data gathered from withdrawn participants will be used in the analysis plan under an Intention-to-Treat (ITT) model.

Risks to Subjects

The risks associated with this intervention are not considered greater than those that patients would otherwise be exposed to when receiving normal standard of care (SOC). However, as with all studies, there are inherent risks involved with the conduct of human subject research that gathers Protected Health Information (PHI). Participants will be made aware of these risks during the Informed Consent process. Identified study risks include: Loss of privacy, emotional distress, physical discomfort, and randomization.

Loss of privacy: PHI from participants will be gathered and stored electronically on secure and encrypted servers and there are risks associated for the loss of privacy and confidentiality. We will further minimize the potential for loss of confidentiality through the physical separation of participant names from their research record according to the process described above. Audio recordings of participants interviews will be uploaded for transcription within 48 hours to an outside agency with which MUSC has established a Business Associates Agreement (BAA). Once uploaded, all audio recordings will be deleted from the portable storage device.

Emotional distress: Some of the questions asked may be upsetting to participants or make them feel uncomfortable answering them. Participants will be instructed that if they do not wish to answer a question, they can skip it and go to the next question.

Physical fatigue: Completion of the questionnaire and interview may be tiring to some participants. Participants will be given ample time to complete the questionnaire and may take breaks as necessary throughout the process.

Randomization: Participants are being assigned to a study group by chance. The intervention included in the first study arm may prove to be less or more effective or have more or less or unknown side effects than the second study arm or other available treatments.

Potential Benefits to Subjects or Others

Because this proposal focuses symptom self-management for caregivers of children newly diagnosed with food allergy, it does represent a potential immediate benefit to the caregiver due to the potential for improved psychosocial well-being. Furthermore, it is hoped that this proposal will contribute to generalizable scientific

knowledge and may change the management of food allergy in the future. A product developed with patient/provider engagement could be adopted en-masse and improve outcomes for caregivers, children, and families impacted by food allergy on a larger scale. Accordingly, the researchers view the anticipated risk benefit of study participation is favorable.

Drugs or Devices

This study does not involve the use or storage of any drug product. All investigational materials are readily commercially available and are not industry regulated.

Dissemination Plan

Purpose: This plan will ensure that all regulatory requirements are met in accordance with: 4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information designed to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov.

Consistent with the expectations of this policy:

1. Our clinical trial under the award will be registered and results information will be submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy.
2. The informed consent documents for our clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.
3. The College of Nursing at the Medical University of South Carolina has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements. Specifically, the PI contacts the University's Research Regulatory Coordinator who will assist with ClinicalTrials.gov registration as needed. Registration to ClinicalTrial.gov will be no later than 21 calendar days after the enrollment of the first study participants.

The Research Regulatory Coordinator will also assist with posting result information that is not later than one year after the trial's primary completion date.

The Associate Dean for Research is also involved in this process as follows: reviews registrations, receives reports on clinical trials registration and compliance updates.

The Medical University of South Carolina is committed to the open and timely dissemination of research outcomes. The Investigators involved in the proposed study recognize that promising new methods, technologies, data, software programs, and insights may arise during the course of their research. We are aware of and agree to abide by the principles for sharing research resources, as described by NIH in "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Programs".

During the course of the study, we plan to make presentations of interim results at national scientific meetings. Final research results will be published in a timely manner in scientific journals. Manuscripts to be submitted for publication will be accessible through the digital archive PubMed Central in compliance with the NIH Public Access Policy. Final non-restricted research data will be shared upon request following publication of the main findings. Final research data are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. Datasets resulting from the proposed study will be redacted of any identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of individual participants. We will make the data and associated documentation available to users under a data-sharing agreement that provides for a commitment to using the data only for research purposes and not to identify any individual participant; a commitment to securing the data using appropriate computer technology; and a commitment to destroying or returning the data after analyses are completed.

Sharing research results with study participants is a major priority at the Medical University of South Carolina. However, because this is a small pilot feasibility study, results from this project will not be shared with study participants. We anticipate results from future projects stemming from this current work will be made available to study participants.

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Intervention Components and Content related to Caregiving Process Model

Intervention Component	**Targeted Processes**	**App Content**
1. Education and Resources	Background and Context • Socioeconomic Status Caregiver Strain/Stress • Caregiving Demands • Perception of Formal Care	Intervention provided using an accessible technology-based package delivered via a mobile device **What is a Food Allergy?:** https://www.foodallergy.org/life-with-food-allergies/food-allergy-101/what-is-a-food-allergy **Recognize and Respond to Anaphylaxis:** https://www.foodallergy.org/sites/default/files/2017-12/common-symptoms-poster_2017.pdf **Symptoms of an Allergic Reaction to Food:** https://www.foodallergy.org/life-with-food-

		allergies/food-allergy-101/symptoms-of-an-allergic-reaction-to-food **Medic Alert Bracelet**: https://medicalalert.com **Video clips reviewing the proper usage of auto-injectable epinephrine** Epi-pen: https://www.youtube.com/watch?v=FXlqSuzzrws AuviQ: https://www.youtube.com/watch?v=BhModQKXMTo **How To Read Food Labels:** https://www.foodallergy.org/life-with-food-allergies/living-well-everyday/how-to-read-food-labels https://www.kidswithfoodallergies.org/page/choosing-safe-foods.aspx **Food Allergy and Anaphylaxis Emergency Care Plan: (**English and Spanish) https://www.foodallergy.org/life-with-food-allergies/food-allergy-anaphylaxis-emergency-care-plan **Talking with Your Child about their Food Allergy**:https://www.foodallergy.org/life-with-food-allergies/newly-diagnosed/talking-to-children-about-their-food-allergy
	Coping Factors • Social Support	**Find a Support Group:** https://www.foodallergy.org/education-awareness/find-a-support-group **Laws and Regulations:** https://www.foodallergy.org/life-with-food-allergies/newly-diagnosed/laws-and-regulations **Reliable Websites:** www.foodallergy.org www.kidswithfoodallergy.org http://www.aaaai.org/conditions-and-treatments/allergies/food-allergies www.allergyhome.org
2. Symptom Monitoring and Tracking	Caregiver Strain/Stress • Caregiving Demands Intrapsychic Factors • Self-perception	Daily text message will be sent to caregiver to remind him/her to log physical symptoms including: Fatigue/Trouble Sleeping Anxiety/Stress Pain/Body Aches/Headache Emotional/mood symptoms including: Depressed mood Overwhelm

		Frustrated Worry All symptoms will be pictorially represented by emoticons in the app to aid with participant discrimination. Logged symptom trends will be graphically illustrated by the app for participant viewing. The app will permit upload of physical and emotional symptom logs to study personnel.
3. Symptom Self-management	Coping Factors • Social Support • Stress Management • Family Function	Based on feedback from component 2, participants will be given directed guidance related to component 3. To address fatigue/trouble sleeping, participants will be directed to watch several short videos that focus on how to achieve better sleep; participate in guided imagery exercise; guided meditation. Anxiety and stress will be addressed through deep breathing exercises; guided relaxation; exercises to increase mindfulness. Altered emotional/mood states will be addressed through focused writing exercises within the app. For example, if a participant endorses negative emotions, they will be encouraged to log positive events/experiences and emotions to raise mood and esteem. If a caregiver endorses “worry”, they will have the option to create a worry tree to help decide what worries are controllable and what to do about them. https://www.getselfhelp.co.uk/docs/worrytree.pdf

Food Allergy and Anaphylaxis Emergency Care Plan

FARE Food Allergy Research & Education — FOOD ALLERGY & ANAPHYLAXIS EMERGENCY CARE PLAN

Name: _____ D.O.B.: _____

Allergy to: _____

Weight: _____ lbs. Asthma: ☐ **Yes (higher risk for a severe reaction)** ☐ **No**

NOTE: Do not depend on antihistamines or inhalers (bronchodilators) to treat a severe reaction. USE EPINEPHRINE.

Extremely reactive to the following allergens: _____

THEREFORE:

☐ If checked, give epinephrine immediately if the allergen was LIKELY eaten, for ANY symptoms.

☐ If checked, give epinephrine immediately if the allergen was DEFINITELY eaten, even if no symptoms are apparent.

FOR **ANY** OF THE FOLLOWING:

SEVERE SYMPTOMS

LUNG
Shortness of breath, wheezing, repetitive cough

HEART
Pale or bluish skin, faintness, weak pulse, dizziness

THROAT
Tight or hoarse throat, trouble breathing or swallowing

MOUTH
Significant swelling of the tongue or lips

SKIN
Many hives over body, widespread redness

GUT
Repetitive vomiting, severe diarrhea

OTHER
Feeling something bad is about to happen, anxiety, confusion

OR A COMBINATION of symptoms from different body areas.

1. **INJECT EPINEPHRINE IMMEDIATELY.**
2. **Call 911.** Tell emergency dispatcher the person is having anaphylaxis and may need epinephrine when emergency responders arrive.

- Consider giving additional medications following epinephrine:
  - » Antihistamine
  - » Inhaler (bronchodilator) if wheezing
- Lay the person flat, raise legs and keep warm. If breathing is difficult or they are vomiting, let them sit up or lie on their side.
- If symptoms do not improve, or symptoms return, more doses of epinephrine can be given about 5 minutes or more after the last dose.
- Alert emergency contacts.
- Transport patient to ER, even if symptoms resolve. Patient should remain in ER for at least 4 hours because symptoms may return.

MILD SYMPTOMS

NOSE
Itchy or runny nose, sneezing

MOUTH
Itchy mouth

SKIN
A few hives, mild itch

GUT
Mild nausea or discomfort

FOR **MILD SYMPTOMS** FROM **MORE THAN ONE** SYSTEM AREA, GIVE EPINEPHRINE.

FOR **MILD SYMPTOMS** FROM **A SINGLE SYSTEM** AREA, FOLLOW THE DIRECTIONS BELOW:

1. Antihistamines may be given, if ordered by a healthcare provider.
2. Stay with the person; alert emergency contacts.
3. Watch closely for changes. If symptoms worsen, give epinephrine.

MEDICATIONS/DOSES

Epinephrine Brand or Generic: _____

Epinephrine Dose: ☐ 0.1 mg IM ☐ 0.15 mg IM ☐ 0.3 mg IM

Antihistamine Brand or Generic: _____

Antihistamine Dose: _____

Other (e.g., inhaler-bronchodilator if wheezing): _____

_____

PATIENT OR PARENT/GUARDIAN AUTHORIZATION SIGNATURE DATE PHYSICIAN/HCP AUTHORIZATION SIGNATURE DATE

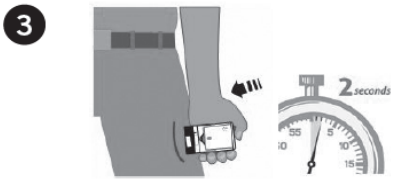
FORM PROVIDED COURTESY OF FOOD ALLERGY RESEARCH & EDUCATION (FARE) (FOODALLERGY.ORG) 5/2018

FOOD ALLERGY & ANAPHYLAXIS EMERGENCY CARE PLAN

FARE Food Allergy Research & Education

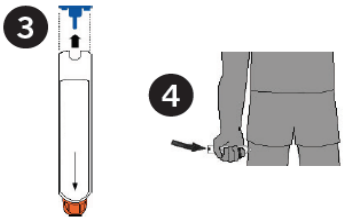
HOW TO USE AUVI-Q® (EPINEPRHINE INJECTION, USP), KALEO

1. Remove Auvi-Q from the outer case.
2. Pull off red safety guard.
3. Place black end of Auvi-Q against the middle of the outer thigh.
4. Press firmly until you hear a click and hiss sound, and hold in place for 2 seconds.
5. Call 911 and get emergency medical help right away.



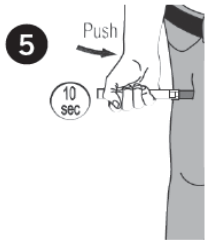
HOW TO USE EPIPEN® AND EPIPEN JR® (EPINEPHRINE) AUTO-INJECTOR AND EPINEPHRINE INJECTION (AUTHORIZED GENERIC OF EPIPEN®), USP AUTO-INJECTOR, MYLAN AUTO-INJECTOR, MYLAN

1. Remove the EpiPen® or EpiPen Jr® Auto-Injector from the clear carrier tube.
2. Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward.
3. With your other hand, remove the blue safety release by pulling straight up.
4. Swing and push the auto-injector firmly into the middle of the outer thigh until it 'clicks'.
5. Hold firmly in place for 3 seconds (count slowly 1, 2, 3).
6. Remove and massage the injection area for 10 seconds.
7. Call 911 and get emergency medical help right away.



HOW TO USE IMPAX EPINEPHRINE INJECTION (AUTHORIZED GENERIC OF ADRENACLICK®), USP AUTO-INJECTOR, IMPAX LABORATORIES

1. Remove epinephrine auto-injector from its protective carrying case.
2. Pull off both blue end caps: you will now see a red tip.
3. Grasp the auto-injector in your fist with the red tip pointing downward.
4. Put the red tip against the middle of the outer thigh at a 90-degree angle, perpendicular to the thigh.
5. Press down hard and hold firmly against the thigh for approximately 10 seconds.
6. Remove and massage the area for 10 seconds.
7. Call 911 and get emergency medical help right away.



HOW TO USE TEVA'S GENERIC EPIPEN® (EPINEPHRINE INJECTION, USP) AUTO-INJECTOR, TEVA PHARMACEUTICAL INDUSTRIES

1. Quickly twist the yellow or green cap off of the auto-injector in the direction of the "twist arrow" to remove it.
2. Grasp the auto-injector in your fist with the orange tip (needle end) pointing downward.
3. With your other hand, pull off the blue safety release.
4. Place the orange tip against the middle of the outer thigh (upper leg) at a right angle (perpendicular) to the thigh.
5. Swing and push the auto-injector firmly into the middle of the outer thigh until it 'clicks'.
6. Hold firmly in place for 3 seconds (count slowly 1, 2, 3).
7. Remove and massage the injection area for 10 seconds.
8. Call 911 and get emergency medical help right away.

ADMINISTRATION AND SAFETY INFORMATION FOR ALL AUTO-INJECTORS:

1. Do not put your thumb, fingers or hand over the tip of the auto-injector or inject into any body part other than mid-outer thigh. In case of accidental injection, go immediately to the nearest emergency room.
2. If administering to a young child, hold their leg firmly in place before and during injection to prevent injuries.
3. Epinephrine can be injected through clothing if needed.
4. Call 911 immediately after injection.

OTHER DIRECTIONS/INFORMATION (may self-carry epinephrine, may self-administer epinephrine, etc.):

Treat the person before calling emergency contacts. The first signs of a reaction can be mild, but symptoms can worsen quickly.

EMERGENCY CONTACTS — CALL 911

RESCUE SQUAD: _____

DOCTOR: _____ PHONE: _____

PARENT/GUARDIAN: _____ PHONE: _____

OTHER EMERGENCY CONTACTS

NAME/RELATIONSHIP: _____ PHONE: _____

NAME/RELATIONSHIP: _____ PHONE: _____

NAME/RELATIONSHIP: _____ PHONE: _____

FORM PROVIDED COURTESY OF FOOD ALLERGY RESEARCH & EDUCATION (FARE) (FOODALLERGY.ORG) 1/2019

Interview Guide for Caregivers of Children with Food Allergy(ies)

"Thanks for agreeing to help us with our study. We'd like to ask you a few questions about our program so we can continue to improve what we're doing."

Parent/Caregiver Questions

1. Have you used a tablet computer, iPad, the internet, or a smartphone before?

    1.1 [If so] How often do you use one?

    1.2 [If so] When you use a tablet, iPad, the internet, or a smartphone, what types of things do you use it for?

2. Have you ever used technology such as a tablet, iPad, the internet, or a smartphone to help you manage your health or your child's health?
[if **No,** skip to 3.] If **yes,** ask:

    2.1 What types of activities did you do on the tablet, iPad, internet or smartphone?

    2.2 How helpful was it / were they? What did you like about these activities? Is there anything you didn't like?

    2.3 What would make them better?

3. "Great. Thanks. Now I'd like to ask you some questions about the activities we have for our program. Remember, there are no right or wrong answers. The things that you tell us will help us improve the activities for other parents and caregivers. There are three main parts to the program."

"The first part uses educational materials. They are located here [show them on tablet]. Experts in food allergy created them for caregivers. You can move from one page to the next, like this [show them on tablet]. Please take a few minutes to look them over. If you notice something you like or don't like, or if something confuses you or catches your attention we would like to know about that." [allow time for review]

    3.1 What do you like about them?

    3.2 What would make them better?

    3.3 Do you think these materials would be helpful to you? [if yes, How? If no, Why not?] [if needed: How could you see yourself using them to manage your child's health?]

4. "Thank you. The second part of the tablet activities is an app that helps keep track of how caring for a child with a food allergy may impact you. The app is located here [show them on tablet]. The app allows you to track any symptoms you may experience as someone caring for a child with a food allergy. Please take a few minutes to look over this part of the app. If you notice something you like or don't like, or if something confuses you or catches your attention we would like to know about that." [allow time for review]

    4.1 What did you like about this part of the app?

4.2 What would make this part of the app better?

5. “Wonderful, thank you. The app also allows you to see on a graph how your symptoms may change over time [show them on tablet]. Please take a few minutes to look over this part of the app.” [allow time for review]

5.1 What did you like about this part of the app?

5.2 What would make this part of the app better?

6. “Great, thanks. Now, let’s look at the last part of the app. This portion allows you to receive directed guidance on ways to address the symptoms you reported in the second part of the app. For example, if you reported that you felt fatigued, the application will provide you with a brief audio clip that offers ideas to help you sleep better. Please take a few minutes to look over this part of the app.” [allow time for review] As with the other parts of the app, if you notice something you like or don’t like, or if something confuses you or catches your attention we would like to know about that.” [allow time for review]

6.1 What did you like about this part of the app?

6.2 What would make this part of the app better?

7. “Thank you again for reviewing each part of the app. The final piece of the program is communication with the study team. This will include receiving a daily text from the study team that will remind you to log your symptoms every day. The texting feature can be found here [show them on tablet]. We’ve sent some examples of what the daily texts will look like.”

7.1 What did you like about the text messaging?

7.2 What would make the text messaging better?

8. If you had the choice of using this program to help you better care for yourself and ultimately your child, would you want to use it? Why or why not? [if needed: How do you think you would use it? [e.g., how often, under what circumstances, etc.?]

9. “Thank you so much for your help today. Is there anything else you can think of that you would like to share with us?”
End interview, collect tablet, provide compensation.