Implementation of an Outpatient Protocol for Children and Adolescents with Food Allergy Anxiety: A Quality Improvement Project

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Implementation of an Outpatient Protocol for Children and Adolescents with Food Allergy Anxiety: A Quality Improvement Project

A Doctor of Nursing Practice Project Presented to the Faculty of the Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice

By

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TABLE OF CONTENTS

Abstract .......................................................................................................................... 4

Introduction .................................................................................................................. 5

Background .................................................................................................................. 5

Problem Statement ...................................................................................................... 8

Problem Identification ............................................................................................... 9

Scope of the Problem ................................................................................................. 9

Consequences of the Problem ................................................................................... 10

Knowledge Gaps ....................................................................................................... 11

Literature Search ...................................................................................................... 13

Summary of the Literature ....................................................................................... 13

Anxiety Related to the Management of Food Allergies ......................................... 14

Food Allergy Anxiety Related to Bullying ............................................................... 15

The Need for Assessment of Food Allergy Anxiety ............................................. 16

Management of Food Allergy Anxiety ................................................................... 18

Purpose ...................................................................................................................... 19

PICO Question ......................................................................................................... 21

SMART Objectives ................................................................................................. 21

Definition of Terms ................................................................................................. 22

Conceptual Underpinning and Theoretical Framework ....................................... 22

Methodology ........................................................................................................... 24

Research Design, Settings, Participants, Description of Approach, and Procedures.... 24

SWOT Analysis ....................................................................................................... 27
Protection of Human Subjects……………………………………………………………30
Data Collection…………………………………………………………………………..30

**Results**……………………………………………………………………………………..31
Descriptive Statistics……………………………………………………………………..32

**Discussion**……………………………………………………………………………………35
Limitations…………………………………………………………………………………36
Next Steps for QI Project………………………………………………………………..36
Sustaining Practice Change……………………………………………………………..38

**Implications for Nursing Practice**…………………………………………………39
Nursing Education………………………………………………………………………39
Clinical Practice…………………………………………………………………………40
Nursing Administration………………………………………………………………..41
Nursing Leadership………………………………………………………………………42

**Conclusion**…………………………………………………………………………………42

**References**……………………………………………………………………………45

**Appendix A:** Support Letter…………………………………………………………..49
**Appendix B:** Consent Form…………………………………………………………….50
**Appendix C:** Pre-Implementation Questionnaire…………………………………….52
**Appendix D:** Post-Implementation Questionnaire………………………………….55
**Appendix E:** Survey of Food Allergy Anxiety Tools……………………………….58
**Appendix F:** Educational Presentation………………………………………………60
**Appendix G:** Florida International University Institutional Review Board Exemption Letter…64
**Appendix H:** University of Miami Institutional Review Board Exemption Letter………65
Abstract

Background: Food allergies are a growing health concern in the United States. Ige-mediated food allergy is an anxiety provoking diagnosis due to the possibility of anaphylactic reactions, epinephrine use and life limitations. Providers who do not use a validated, condition-specific food allergy anxiety assessment tool in their practice have difficulty identifying patients at risk for moderate-severe food allergy anxiety. The literature has shown that providers also lack the knowledge of when to refer patients exhibiting food allergy anxiety to mental health services. This quality improvement project focused on improving providers' identification and education of food allergy anxiety after implementing a food allergy anxiety protocol that consisted of an educational presentation and 4-week use of the Survey of Food Allergy Anxiety tool in their practice.

Methods: A literature search was conducted, and articles were accessed from CINAHL Plus with Full Text, PsycINFO, and MEDLINE (Web of Science). After reviewing those articles, a quasi-experimental research experiment was conducted using pre-implementation and post-implementation surveys to determine baseline food allergy anxiety provider confidence and knowledge and the impact of a food allergy anxiety protocol. A two-tailed paired samples t-test was used to analyze the data.

Results: The mean of the pre-total scores were significantly lower than the mean of the post-total scores showing a positive impact of the educational presentation and SOFFA tool.

Keywords: Food allergy anxiety, allergists, SOFAA tool, nursing, psychosocial needs
Introduction

Food allergies across the lifespan have become a substantial public health concern as their prevalence continues to rise (Gupta et al., 2018). In 2018 it was reported that 32 million people were living with food allergies in the United States (Gupta et al., 2019). The burden of food allergies experienced by individuals and their families includes the physical response, uncertainty, and the overall impact on one’s mental well-being. The body’s immune response to food allergens can vary from mild to life-threatening anaphylaxis, leading to heightened avoidance. Although many view food allergy-related anxiety at a certain level as a healthy mechanism, avoidance can fuel heightened anxiety that can result in psychosocial distress (Engel & Bunning, 2021). Individuals with food allergies may become preoccupied with the constant fear of developing a life-threatening reaction and adversely, develop ineffective coping mechanisms.

Food allergies affect approximately 8% of children in the United States, which places a significant financial and emotional burden on affected families (Gupta et al., 2018). The adaptive behaviors children, adolescents, and their families develop in response to a food allergy diagnosis may cause their heightened food allergy-related anxiety (Engel & Bunning, 2021). The difficulty differentiating between adaptive versus maladaptive anxiety can be decreased using condition-specific tools assessing severity (Herbert et al., 2016). The issues in question are do providers know how to identify patients at risk for food allergy-related anxiety and do providers know what to do when a patient exhibits moderate to severe food allergy-related anxiety.

Background
The rate at which children and adolescents are diagnosed with psychological disorders, such as depression and anxiety, continues to increase as its prevalence increases with age (Zsamboky et al., 2021). Globally, the World Health Organization reports approximately 1 in 7 (14%) adolescents having experienced an undiagnosed mental health disorder (2021). Failure to acknowledge and treat psychological distress during this vulnerable stage can lead to poor health outcomes. Anxiety is the most prevalent mental health disorder in childhood, with approximately 4.4 million children diagnosed in the U.S. (Zsamboky et al., 2021). The anxiety children exhibit after experiencing danger is expected. However, interventions are warranted when anxiety worsens to impaired functioning (Zsamboky et al., 2021). Ineffective coping mechanisms can harm the development of children and adolescents already at a vulnerable stage. In addition, caregivers may not adequately address distress symptoms at home and rely heavily on healthcare providers for education and guidance. With growing access to mental health services, approximately 59.3% of children and adolescents with an anxiety diagnosis receive treatment (Zsamboky et al., 2021). Anxiety disorders present with different symptoms depending on the setting, perceived threat, and stages of development. Children and adolescents may experience generalized anxiety, social anxiety, separation anxiety, selective mutism, or obsessive-compulsive disorder during their developmental stages, leading to impaired functioning if untreated (Zsamboky et al., 2021). Anxiety during childhood and adolescence manifests as helplessness, somatic complaints, avoidant behaviors, and social problems, which are seen across various anxiety disorders (Zsamboky et al., 2021).

A growing area of research is anxiety as it relates to chronic illness diagnoses. Healthcare providers focus on care’s physical and psychological aspects to provide the best possible patient outcomes. In doing so, patients may experience better disease trajectories than
they would from solely focusing on the physical symptoms of the disease. Unfortunately, adolescents and young adults with chronic illnesses such as cancer experience high levels of psychological distress throughout the disease process that have lasting effects even after attaining remission. Previous research has focused on the psychological aspect of care for adult patients with cancer. However, recent studies show that adolescents experience higher rates of moderate to severe depression and anxiety than adults (Smrke et al., 2020). Unfortunately, some healthcare providers are reluctant to address these patients’ psychological needs and are left unaddressed for quite some time. Addressing and educating healthcare providers, patients, and families on the benefits of early interventions promotes ending the stigma surrounding mental health diagnoses, allows for early engagement of all parties, and results in positive patient outcomes (Smrke et al., 2020).

Childhood food allergy is a common diagnosis that also affects the well-being of families socially, psychologically, and economically. A diagnosis of a food allergy is primarily given in early childhood, which places a large part of its burden on the parent (Herbert & DunnGalvin, 2021). The Centers for Disease Control defines immunoglobulin E (IgE) mediated food allergy as a heightened immune response that occurs when an individual is exposed to a specific food that causes the body to create an IgE protein antibody to the food (2013). Nine significant allergens that cause heightened immune responses include eggs, milk, shellfish, peanuts, tree nuts, wheat, soy, sesame, and fish (Gupta et al., 2018). With 8% of children affected by IgE-mediated food allergies, it is essential to consider the psychosocial impact of the limitations and constant stress from the diagnosis, which also adds to its extensive public health impact (Quach & John, 2018). During childhood and early adolescence, the parent must be equipped to adhere to emergency management properly and cope with the emotional, nutritional,
and behavioral deficits that accompany the diagnosis (Herbert & DunnGalvin, 2021). Approximately 40% of children diagnosed with food allergies have experienced severe allergic reactions, which illustrates how time-consuming food allergy management can be to prevent an anaphylactic reaction (Herbert et al., 2016). Thus, both parent and child are prone to developing constant fear surrounding a fatal allergic reaction and grow preoccupied with its prevention. As a result, hypervigilance can increase throughout the diagnoses and impact the overall psychosocial well-being of the parent and child.

Children and adolescents with food allergy experience similar patient presentations as those with generalized anxiety as they also report avoidance, somatic symptoms related to perceived threats, and social problems. Food allergy patients report avoidance of certain foods and social situations due to increased fear of exposure, frequently report headaches, irritability, and restlessness in unfamiliar settings, and experience social problems due to feelings of embarrassment with their diagnoses (Quach et al., 2018). The overlapping presentations of generalized anxiety and food allergy anxiety may be why some healthcare providers use generalized anxiety tools to assess for food allergy anxiety in their patients. However, studies have shown a more significant benefit of using a condition-specific assessment tool. Early assessment for food allergy-related anxiety and early interventions can provide access to necessary behavioral interventions to aid in decreasing distress. Although the anxiety related to a food allergy diagnosis may not meet the requirements for a diagnosable anxiety disorder listed in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5), assessing, and treating the amount of distress experienced is necessary to prevent further exacerbation (Feng & Kim, 2019).

**Problem Statement**
The psychological repercussions of food allergies can significantly affect an individual’s quality of life if left untreated. Children and adolescents with food allergy-related anxiety experience a complicated clinical picture when healthcare professionals fail to properly assess anxiety risk and provide the necessary interventions (Dahlsgaard et al., 2022). Food allergy-related anxiety remains challenging to manage when providers lack the knowledge, assessment tools, and behavioral interventions to do so (Dahlsgaard et al., 2022). A literature review highlights the need for early intervention and a condition-specific measure when assessing anxiety in this population to improve patient outcomes. As the prevalence of food allergies continues to rise, healthcare providers must prioritize the mental health of individuals with food allergies, just as they prioritize the physical health of these patients.

**Problem Identification**

Diagnosing food allergies in children and adolescents can be challenging. The fear of life-threatening reactions, the constant uncertainty, and the psychosocial stress accompanying the diagnosis can be overbearing for the patient and family. Although allergists and nurse practitioners do a phenomenal job in treating food allergy, many lack the necessary knowledge or experience to address the diagnosis’s psychosocial effects, leading to unmet psychosocial needs (Engel & Bunning, 2021). Allergists and other healthcare providers will benefit from guidance in identifying appropriate versus excessive or harmful anxiety and implementing the necessary behavioral interventions to address the patient’s distress (Engel & Bunning, 2021). Without the providers’ proper education, assessment, and interventions, patients and families may view the daily anxiety experienced as a normal adaptation and fail to seek effective interventions.

**Scope of the Problem**
Mental health and well-being in children and adolescents are growing issues impacting healthcare worldwide. Children and adolescents with unresolved mental health conditions are more susceptible to discrimination, isolation, physical health issues, increases in risky behaviors, and bullying (World Health Organization [WHO], 2021). With multiple factors affecting the mental health of this population, a child can easily have an increased risk for mental health conditions based on living situations, parenting styles, sexual backgrounds, and even chronic illness (WHO, 2021). Furthermore, chronic disease can exacerbate symptoms of depression and anxiety in children and adolescents, which should be appropriately assessed and treated early in the disease trajectory to promote positive patient outcomes. Thus, anxiety related to a food allergy diagnosis is worth exploring.

Nationally, approximately 8% of children in the United States are impacted by food allergies (Gupta et al., 2018). On average, a food allergy diagnosis may cost $4,184 per year for a child when considering physician visits, treatments, and the purchasing of allergy-free foods (Gupta et al., 2018). In addition, one must also consider the financial impact of being diagnosed with severe food allergy and requiring mental health services for anxiety relating to the diagnosis. Patients without private health insurance may lack the necessary funds to obtain mental health services and rely on other resources that take longer to obtain, such as mental health services at a community health clinic (Memauri et al., 2022). The assessment and treatment of food allergy anxiety should start at diagnosis and carry on through routine follow-up visits to ensure the psychosocial needs of everyone are monitored and addressed. Although allergists and mental health providers must collaborate in rare cases, doing so may help decrease the number of patients suffering from food allergy anxiety (Feng & Kim, 2019).

**Consequences of the Problem**
Failure to address the psychosocial needs of children and adolescents with chronic disorders or illnesses has lasting effects. For example, regarding food allergy patients, failure to address psychosocial needs can result in heightened anxiety and significantly impact social and economic outcomes. Socially, children and adolescents may isolate themselves and not participate in social events due to the heightened fear of having an anaphylactic reaction (Feng & Kim, 2019). Families of children with food allergies may also limit vacations and avoid public events or public transportation as a precautionary measure to decrease the possibility of exposure to allergens (Feng & Kim, 2019). Although these ineffective coping mechanisms may seem appropriate, they are viewed as over-compensatory mechanisms due to unmet psychosocial needs.

On the other hand, psychological distress related to a medical diagnosis can lead to non-compliance with treatment regimens and poor patient outcomes (Smrke et al., 2020). For example, in the food allergy population, non-compliance includes failure to maintain an up-to-date epi-pen, missed follow-up appointments, and failure to engage in treatment regimens. Economic consequences of food allergies include $1.7 billion for the special diets that are required to prevent anaphylaxis, $857 million for the unintentional exposures that individuals with food allergies avoid, and $650 million for changes in schools for those parents who want their child to attend a school that is food allergy safe (Feng & Kim, 2019).

Knowledge Gaps

Despite the evidence in the literature highlighting the unmet psychosocial needs of children and adolescents with food allergies, sufficient literature still lacks the best tools to assess food allergy anxiety. Some assessment tools are more thorough than others and require longer administration time, which may cause physicians to hesitate due to their limited time to
discuss psychosocial concerns during the clinic visit (Herbert et al., 2016). In addition, the range of broadness, the time needed to complete the measures, and ability to assess for anxiety related to food allergies can confuse the provider who is not fully aware of the many different measures. For example, the Screen for Child Anxiety Related Disorders is a generic anxiety measure that does not capture the condition-specific behaviors of food allergy patients and may give providers an incorrect reading (Dahlsgaard et al., 2022). On the other hand, a condition-specific measure such as the Scale for Food Allergy Anxiety only focuses on those measures directly related to food allergies and can better capture distress pertaining solely to the diagnoses (Dahlsgaard et al., 2022). In this case, providers must be knowledgeable about selecting the measure that best suits their assessment needs to ensure proper assessment and intervention are administered.

Unfortunately, some healthcare providers still fail to meet those needs due to their institutions’ lack of knowledge and infrastructure. The failure of healthcare providers to adequately address the psychosocial needs of these patients makes it more likely that mental health issues corresponding to food allergies will be underreported (Feng & Kim, 2019). For allergists, and primary physicians, mental health aspects of care may not be a strong point when considering assessment and developmental interventions. However, these physicians encounter patients frequently, which would be a disservice to the patient if that aspect of care was omitted.

Another knowledge gap is the lack of tested behavioral interventions to address food allergy anxiety post-assessment. Few articles suggest the implementation of interventions specific to food allergy anxiety. The literature states that although this is a topic for further research, using best practices, interventions from children with varying chronic conditions can be applied (Herbert et al., 2016). This guides one to search behavioral interventions for children diagnosed with anxiety post-cancer diagnosis, sickle-cell anemia diagnosis, or other chronic
pediatric conditions and apply them to pediatric patients with food allergies. Continuous research on this population, condition-specific assessment methods, and behavioral interventions will strengthen evidence-based practices, leading more providers to engage in its implementation.

**Literature Search**

To identify relevant articles regarding food allergy anxiety in children and adolescents, the following databases were searched between January 2016-October 2022 using Florida International University’s online library: CINAHL Plus with Full Text, PsycINFO, and MEDLINE (Web of Science).

For this research study, only peer-reviewed articles were considered. Articles were required to be written in English and include full text. Inclusion criteria for current articles that provided evidence-based information on food allergy anxiety were restricted to those published between 2016 and 2022. By having only those articles from the last six years, the most up-to-date information was reviewed for best practice considerations. Qualitative and quantitative articles were considered for this research study.

Excluded articles were those that consisted of literature reviews or systematic reviews. Studies conducted outside the United States and Canada were also excluded.

**Summary of the Literature**

Overall, the literature states that as food allergy cases continue to rise, so will the cases of food allergy anxiety and psychosocial distress related to the diagnosis. Therefore, healthcare professionals should engage in early identification and intervention of patients at risk for developing food allergy anxiety to help promote a better quality of life and patient outcomes. With increased food allergy anxiety seen at diagnosis, before a food challenge procedure, or after
an anaphylactic reaction, healthcare providers should implement interventions that support patients and families during those times to decrease psychosocial distress. Monitoring psychological well-being in the outpatient setting allows for assessment during initial and follow-up routine appointments to identify any changes in well-being. Cognitive behavioral therapy is the mainstay for children and adolescents experiencing moderate to severe food allergy anxiety; however, techniques to help decrease stress and anxiety are also beneficial to the patient and families. The overall goal for patients suffering from food allergy anxiety is to decrease the burden of unmet psychosocial needs to improve patient outcomes and overall quality of life. The articles discussed in this literature review have similar recurring views surrounding the topic of children and adolescents with food allergy anxiety. The main themes that appeared in the articles selected were the following: anxiety related to the management of food allergies, food allergy anxiety related to bullying, the need for assessment of food allergy anxiety, and management of food allergy anxiety. These themes address the gap in knowledge of healthcare providers who fail to address the psychosocial needs of their patients and how it can affect the psychosocial well-being of the patient and their families. To better serve this population, the literature review was conducted to bring awareness to current best practices and suggestions for addressing the knowledge gap.

Anxiety Related to the Management of Food Allergies

One theme identified in the review is the anxiety related to the management of food allergies (Petrovic-Dovat et al., 2016); (Goodwin et al., 2017); (Kanter et al., 2021); (Memauri et al., 2022). Food allergies in children and adolescents can lead to heightened anxiety and psychosocial distress levels stemming from the uncertainty of the disease and the constant fear of exposure to an allergen (Memauri et al., 2022; Goodwin et al., 2017). Depending on the
patient’s age, their knowledge of the diagnosis and their role in managing their food allergies may be limited. The uncertainty can be anxiety provoking as observed in transitional periods of development when the caregiver is absent and the child, although more knowledgeable of the diagnosis than in their previous developmental stage, may not be well equipped for self-protection (Kanter et al., 2021; Goodwin et al., 2017). The constant fear of exposure to food allergens also causes heightened anxiety because of the potential for a life-threatening anaphylactic reaction (Goodwin et al., 2017; Kanter et al., 2021; Memauri et al., 2022). Whether the child has previously experienced an anaphylactic reaction or has yet to experience one, the fear surrounding anaphylaxis increases dietary constraints and fear of administering emergency treatment (Goodwin et al., 2017; Kanter et al., 2021).

**Food Allergy Anxiety Related to Bullying**

The second theme identified is food allergy anxiety related to bullying. Studies have shown that teasing and bullying may be due to a lack of food allergy knowledge in children without food allergies (Kanter et al., 2021). The labeling and isolation of children and adolescents with food allergies have been linked to reports of being bullied by their peers (Goodwin et al., 2017; Kanter et al., 2021; Memauri et al., 2022). Peer bullying is common in both age groups and may be due to them sitting at isolated food allergy tables in the school cafeteria, eating different foods from their peers, or simply having the diagnosis (Goodwin et al., 2017; Kanter et al., 2021; Memauri et al., 2022). This is mainly seen in the school setting, where some schools make accommodations to prevent exposure to food allergens. Although the accommodations are viewed as practical measures of food allergy management within the school setting, the unwanted attention it creates can be a source of increased social anxiety for the child with food allergies (Goodwin et al., 2017; Kanter et al., 2021; Memauri et al., 2022).
The Need for Assessment of Food Allergy Anxiety

The third theme, the need for assessment of food allergy anxiety, focuses on the benefit of assessing for food allergy anxiety using validated tools. Allergists and other healthcare providers report the inability to address the psychosocial needs of children and adolescents with food allergies due to time constraints at their institution, lack of resources, and gaps in training (Dahlsgaard et al., 2021; Memauri et al., 2022). These factors contribute to food allergy anxiety going undiagnosed while patients and their families rely on ineffective coping mechanisms that complicate their overall clinical picture (Dahlsgaard et al., 2021; Memauri et al., 2022). The need for early assessment of those at risk for psychosocial distress and anxiety related to food allergy is at an all-time high as food allergy cases are rising. Incorporating mental health screening into initial and routine outpatient allergy visits is one-way healthcare providers can address the unmet psychosocial needs of this population (Petrovic-Dovat et al., 2016; Kanter et al., 2021; Memauri et al., 2022). Proper assessment of food allergy anxiety can help identify vulnerable patients at risk for developing excessive, maladaptive anxiety and help healthcare providers tailor interventions and resources to the patient’s needs (Petrovic-Dovat et al., 2016).

Previous literature suggested using a generalized anxiety measure to screen for food allergy anxiety, such as the Screen for Child Anxiety Related Disorders (SCARED). However, recent studies have shown that using a more condition-specific tool will account for anxiety as it solely relates to food allergy, rather than the use of generic measures that produce equivocal results (Dahlsgaard et al., 2021; Petrovic-Dovat et al., 2016).

The high volume of patients seen at outpatient pediatric allergy clinics requires an assessment tool that can be easily implemented to ensure all patients are screened promptly (Dahlsgaard et al., 2021). For this purpose, the complete and brief versions of the Scale of Food
Allergy Anxiety (SOFAA), a food allergy anxiety assessment tool for children and adolescents aged 8-18, are ideal for the outpatient setting and account for the viewpoints of the child and caregiver (Dahlsgaard et al., 2021). The Survey of Food Allergy Anxiety is used to assess food allergy anxiety and related anxious avoidance over the past week, and items are written at grade 6-8 reading level (Dahlsgaard et al., 2022). The reliability of the SOFAA was calculated using the test-retest method and resulted in the following: full SOFAA $r = 0.85$ and brief SOFFA $r = 0.79$, suggesting that this assessment tool accurately measures anxious avoidance behaviors as it aims to. In addition, this measure is beneficial to focus both on the child-report and parent-report measure of food allergy anxiety which can help strengthen assessment (Dahlsgaard et al., 2022). The convergent and discriminatory validity of the SOFAA measures produced a moderate correlation between the SOFAA and the SCARED and a moderate to strong correlation between the SOFAA and the Food Allergy Quality of Life Questionnaire (FAQLQ) (Dahlsgaard et al., 2022). This suggests that the SOFFA measures a similar construct as the SCARED tool does but is more condition-specific, and although it measures some of the anxious avoidance behaviors just as the FAQLQ does, it focuses more on the unnecessary anxious avoidance than the overly cautious avoidance (Dahlsgaard et al., 2022).

Another measure used to screen for food allergy anxiety in children and adolescents is the Screen for Child Anxiety Related Emotional Disorders (SCARED) tool. This 41-item self-report anxiety measure can be administered to children aged 8-18 years and assesses panic or somatic symptoms, generalized anxiety, separation anxiety, social phobia, and school phobia (Petrovic-Dovat et al., 2016; Kanter et al., 202). The SCARED tool also offers a child and parent report, just as the SOFAA measure does, however, the SCARED is more of a generic measure of child anxiety than a condition-specific measure (Dahlsgaard et al., 2022). This assessment tool has
demonstrated validity and reliability with a good overall internal consistency of $\alpha = .90$ (Petrovic-Dovat et al., 2016; Kanter et al., 2021).

The Multidimensional Anxiety Scale for Children (MASC) is also used to assess anxiety in children and adolescents aged 8-19. This 39-item self-report uses a 4-point Likert scale to assess somatic autonomic symptoms, humiliation rejection, tense restlessness, perfectionism, performance fears, and anxious coping, with higher total scores suggesting increased severity of anxiety symptoms (Goodwin et al., 2017). This scale has also demonstrated strong predictive validity in identifying youth with anxiety disorders and reliability with high test-retest reliability (Goodwin et al., 2017).

Other measures that can screen for anxiety but focus more on quality of life include The Food Allergy Quality of Life Questionnaire (FAQLQ and the Quality of Life (QOL) tool; however, these measures are not as specific as the SOFAA tool.

**Management of Food Allergy Anxiety**

The final theme Although a certain level of anxiety is optimal when managing food allergies, patients and families experiencing higher anxiety levels require immediate interventions to prevent exacerbation of psychosocial distress related to their food allergies diagnosis. Individuals scoring high on measures of food allergy anxiety may benefit from further mental health services (Petrovic-Dovat et al., 2016; Kanter et al., 2021). With limited research surrounding various behavioral interventions proven to alleviate food allergy-specific anxiety, one known intervention is cognitive behavioral therapy (CBT). CBT is the first-line treatment for childhood anxiety disorders and can include cognitive restructuring, exposure-based interventions, and relaxation techniques (Dahlsgaard et al., 2021). Therefore, it is imperative for allergists who screen for food allergy anxiety to refer patients who present with
moderate to severe debilitating anxiety to a mental healthcare provider who specializes in cognitive behavioral therapy (Herbert et al., 2022).

Although psychotherapy is the first treatment for anxiety, patients and families can also benefit from stress and anxiety management techniques to cope with the daily burden of food allergy (Herbert et al., 2022). For example, educating patients and families on deep breathing techniques, mindfulness, and meditation to decrease anxiety may allow for effective coping when faced with daily food allergy experiences or food challenges, as those are the moments that cause heightened anxiety responses. In addition, advocacy skill building, peer support groups that focus on alleviating embarrassment and isolation, education on the transition of care management, and executive functioning skill building are behavioral interventions that can help to build confidence and understanding of the food allergy diagnosis (Herbert et al., 2022).

Continuous psychoeducation is another intervention that can help to alleviate anxiety related to food allergies. Psychoeducation can inform patients and families in areas that bring about uncertainty to decrease feelings of anxiety stemming from a lack of knowledge. The lack of food allergy education and fear of misinformation from unreliable sources causes heightened anxiety in children and adolescents with food allergies (Kanter et al., 2021; Herbert et al., 2022). Misinformation from social media posts and unverified online sources can cause patients to avoid more foods than necessary or learn incorrect methods of food allergy management (Kanter et al., 2021). Children who report anxiety before a food challenge or with the emergency treatment epinephrine auto-injector can also benefit from psychoeducation on these topics to help alleviate feelings of unpreparedness (Herbert et al., 2022).

**Purpose**
This quality improvement project addresses the unmet psychosocial needs of children and adolescent patients at risk for food allergy-related anxiety by educating and guiding healthcare providers in identifying and treating children and adolescents at risk for food allergy-related anxiety. The protocol includes the use of a validated assessment tool for food allergy-related anxiety in patients with immunoglobulin E (IgE) mediated food allergies, followed by possible interventions to address the food allergy related anxiety. The literature states that there is a lack of proper assessment and interventions for children and adolescents with food allergy related anxiety and that many healthcare providers who treat this population are unaware of how to address the unmet psychosocial needs (Engel & Bunning, 2021).

During the organizational assessment, the clinical staff at the project site shared many reports of past and recent experiences where they witnessed patients and families experiencing what appeared to be food allergy-related anxiety and the negative impact it had on patient outcomes. They reported that due to excessive anxiety, some patients and families were less likely to implement certain foods when prompted by physicians, and other families refused to consider food challenges. According to the healthcare providers at the clinic, parents, and caregivers often give pushback to treatment plans and overcompensate for the diagnosis by restricting more foods than necessary and completely restricting social outings. In addition, the behavior of the parent and caregiver can impact that of the child, which providers also report is a growing issue at their clinic. Currently, the project site does not have a protocol or policy in place to address the psychosocial needs of pediatric patients with food allergies. Although the clinic staff has encountered many patients they suspect have food allergy anxiety, no assessment tool is used to identify whether it is truly that or assess severity. Providers also report being unaware of how to intervene if a patient reports moderate to severe food allergy-related anxiety.
The literature suggests that allergists should identify the individuals most vulnerable to the psychosocial consequences of food allergy to be able to provide them with the necessary support and interventions (Golding et al., 2022). Although some allergists have reported limited time and resources to address the psychosocial needs of their patients fully, articles suggest implementing mental screening tools into their practice to help identify at-risk patients, determine if appropriate referrals are needed, and foster reassessment as indicated, is essential (Memauri et al., 2022). With the increasing prevalence of food allergies, an intervention to address this gap in care is warranted.

**PICO Question**

The project seeks to answer the following PICO question:

- **P** - In children and adolescents ages 8-18 years with IgE-mediated food allergies
- **I** - Does the implementation of an outpatient protocol for food allergy-related anxiety
- **C** - Compared to current practice
- **O** - Increase the identification and treatment of those at risk for food allergy-related anxiety

**SMART Objectives**

For this quality improvement DNP project, the following SMART objectives were identified:

- Implement a protocol to aid healthcare professionals in addressing the psychosocial needs of children and adolescents with food allergies [within five months of starting the quality improvement project.}
• Provide resources for behavioral interventions for children and adolescents presenting with food allergy anxiety before completing the DNP project.

**Definition of Terms**

The definition of terms for this study include:

1. **Food allergy** - an adverse health effect that arises from a specific immune response that occurs reproducibly on exposure to a given food (Centers for Disease Control and Prevention [CDC], 2013)

2. **Immunoglobulin-E (IgE)-mediated food allergies** - a heightened immune response that occurs when an individual is exposed to a specific food allergen that causes the body to create an IgE protein antibody to the food, alerting cells to release histamine, affecting the respiratory system, cardiac system, skin, gastrointestinal tract, leading to anaphylaxis (CDC, 2013).

3. **Food Allergy Anxiety** - apprehensive uneasiness or nervousness related to a true or suspected food allergy that may not necessarily warrant a DSM-V diagnosis.

**Conceptual Underpinning and Theoretical Framework**

Kurt Lewin’s Theory of Change is the selected theoretical framework for the DNP project, focusing on the frequent changes occurring within the healthcare field and how organizations can adapt. The Theory of Change consists of four elements: Field Theory, Group Dynamics, Action Research, and the 3-step model.

Field theory focuses on understanding group behavior as it relates to forces that act on the group affecting the group structure and individual behaviors (Burnes, 2004). First, he discussed that changes seen in individual behavior stemmed from forces within the group environment or group field and understanding the forces in the field will help to identify why groups act as they
do and how to change the culture of the group by changing the forces (Burnes, 2004). The next element of Group Dynamics had a similar focus but stressed that group behavior should be the focus of change rather than individual behavior since the individual is most likely to conform to the group’s behavior (Burnes, 2004). Lewin then decided to create two processes that the group members could use to guide their change in behavior: Action Research and the 3-Step Model of Change.

Action Research consists of two parts; recognizing the change is necessary and requires one to act and recognizing that actions are successful only after careful analysis of the issue, identification of all possible solutions and selection of the best solution (Burnes, 2004). Lewin’s 3-Step Model of Change is the key contributor to organizational change and consists of three components: unfreezing, moving and refreezing (Peterson & Bredow, 2017). To begin with, the driving and restraining forces of the planned change must be identified. Once the organization agrees that there is a need for change, unfreezing of the old practice occurs. Driving forces will make the change easier to accept, while restraining forces may inhibit change (Peterson & Bredow, 2017). This is like acknowledging the internal and external strengths, weaknesses, opportunities, and threats during the organization need assessment that significantly impacts the DNP project outcomes. For the change process to succeed, the driving forces must outweigh the restraining ones. The next step in Lewin’s Theory of Change is the moving process. This is where change occurs because the driving forces overcome the restraining forces (Peterson & Bredow, 2017). The old practice is no longer in effect, and the organization is adapting to the new practice. Lastly, refreezing occurs with the new practice change as it becomes a part of the status quo (Peterson & Bredow, 2017).
The clinical fit of Kurt Lewin’s Theory of Change to the DNP project is perfect as it guides the practice change from initially failing to address the unmet psychosocial needs of the children and adolescent food allergy patients to recognizing the need for change and implementing a protocol to assess and intervene, ultimately seeking to improve patient outcomes. By educating the clinical staff and providing them with the resources and methods they need to make the practice change smoother, they may be more likely to accept the change instead of resisting. By analyzing and addressing the organizational strengths, weaknesses, opportunities, and threats, the project team can analyze the driving and restraining forces that significantly impact the change process to ensure the practice change is a success.

Lewin’s Action Research component of the Theory of Change highlights that for change to be successful, the group must recognize that change is necessary. The clinical staff in the DNP project agreed that a practice change was needed to provide the best possible care to the patients and families and ultimately improve patient outcomes. During the needs assessment, all possible solutions to the problem were considered and with completion of the literature review, a solution to the problem focus of the DNP project was selected.

Methodology

Research Design, Settings, Participants, Description of Approach, and Procedures

The DNP quality improvement project uses a quantitative quasi-experimental pre-test post-test design to seek to improve healthcare delivery in the outpatient setting. This approach allows for the gap in healthcare delivery to be addressed systematically to enhance the healthcare providers’ knowledge of assessing for food allergy anxiety in their outpatient clinic. The quality improvement project will be conducted at a South Florida pediatric allergy and immunology
outpatient clinic. Surveys will capture the healthcare provider’s knowledge and practices relating to food allergy anxiety. The outpatient pediatric allergy and immunology clinic are relevant to the DNP project in that it allows for a population-specific to the clinical question that can aid in the possibility of a sufficient sample size. The participants include healthcare providers serving the clinic, including medical doctors, advanced practice nurse practitioners, registered nurses, licensed practical nurses, physician assistants, and medical students specializing in pediatric allergy and immunology. The sample is relevant to the DNP project because it consists of participants specific to the project’s needs.

Following the recruitment of participants by email, each prospective participant will complete a consent form before implementing the intervention (see Appendix B). Other documentation tools used in this project include: a demographic questionnaire, a pre-implementation questionnaire, a post-implementation questionnaire, and the validated food allergy anxiety assessment tool, Survey of Food Allergy Anxiety.

The 9-item pre-implementation questionnaire (see Appendix C) and post-intervention questionnaire (see Appendix D) was created by the DNP student and consists of multiple choice, true or false and select all that apply questions. These questionnaires assess participant knowledge of food allergy anxiety, current clinical practice for identifying at-risk patients, and healthcare professionals’ confidence in addressing food allergy anxiety. The information used to develop the surveys was obtained from various reliable food allergy anxiety sources, including websites and scholarly evidence-based articles, which enforces the credibility of the surveys. The pre-implementation questionnaire will be given to participants prior to the education power point presentation to assess baseline knowledge. Following the initial questionnaire, all participants will attend a 60-minute educational presentation (see appendix F) to be instructed on
the outpatient food allergy anxiety protocol and how to use the validated food allergy anxiety assessment tools. This will include the cut-offs scores of when a patient should be referred to mental health services for excessive food allergy anxiety. The participants will receive copies of the SOFAA tools, and all supplemental materials needed to implement the tool into their practice for 4-6 weeks. Every patient aged 8-18 years with IgE-mediated food allergies will be given the SOFAA-C assessment tool. Their parent will be given the SOFAA-P at the beginning of their clinic appointment by any clinical staff member (medical assistant, licensed practical nurse, registered nurse, advanced practice registered nurse, medical doctor, medical student, or physician assistant). The healthcare provider will collect and evaluate both forms at the end of the appointment. Next, the tool will be scored; if warranted, the provider will refer the patient to mental health services. Finally, after the visit, the provider will give all patients and families with IgE-mediated food allergies a brochure with education and credible resources for dealing with food allergy anxiety.

The post-implementation questionnaire will be given after the 4-6 weeks of protocol implementation is completed to reassess provider’s knowledge, confidence, and how many patients were identified as at risk for food allergy anxiety using the validated SOFAA assessment tool. All participants will receive the same questionnaires to ensure reliability and the questionnaires only address food allergy anxiety which is valid for the participant population.

The assessment tool that will be implemented into the participants’ practice is the Scale of Food Allergy Anxiety (SOFAA) (see Appendix E). The Scale of Food Allergy Anxiety (SOFAA) is a condition-specific tool that assesses for food allergy-related anxiety and the degree of anxious avoidance in the past week of children and adolescents with IgE-mediated food allergies. This assessment tool was selected for the intervention because outpatient allergists and
other providers have reported time constraints for additional assessments in their current practice. In partnership with a cognitive-behavior therapist, medical professionals specializing in food allergies, and parents of children with food allergies, the Children’s Hospital of Philadelphia researchers developed the SOFAAs. This scale has a child (SOFAA-C) and parent (SOFAA-P) component to account for the child’s self-report and the parent’s corresponding perception of their child’s food allergy-related anxiety (Dahlsgaard et al., 2022). The full versions of the SOFFA are each 21-items long and have shown good-to-excellent validity (full SOFAAs: r = 0.85) when evaluated for convergent, construct and divergent effects and excellent reliability (SOFAA-C: P>.05) (SOFAA-P: P= .01) for test-retest and internal consistency suggesting that this assessment tool accurately measures anxious avoidance behaviors as it aims to (Dahlsgaard et al., 2021). Implementing this tool into current practice allows the providers to have a brief, yet reliable, condition-specific measure of food allergy anxiety available for routine use.

The project aims to improve healthcare provider knowledge of how to address food allergy anxiety in children and adolescents presenting with IgE-mediated food allergies and determine the efficacy of a PowerPoint educational intervention and outpatient protocol to meet this objective. As a result of this project, participants are expected to understand the benefit of having a protocol for food allergy-related anxiety at their institution. Furthermore, this study is expected to benefit children and adolescent patients with IgE-mediated food allergies.

**SWOT Analysis**

The strengths, weaknesses, opportunities, and threats (SWOT analysis) were evaluated to analyze contributing and aggravating factors that may influence the project. When translating
evidence into practice, a SWOT analysis is a beneficial tool that can highlight areas of strength that are essential to the project’s success, identify the weaknesses of the project that need to be addressed, uncover the possibility of opportunities within the project and discover threats to be aware of (Zaccagnini, 2015).

Strengths that were considered for this project included that the facility is a research and teaching hospital, the clinic was comprised of allergy providers and the staff being aware of the need for a change in their current practice. The literature states that more allergists should screen their patients for food allergy anxiety (Golding et al., 2022). If the study was conducted at a pediatric primary care clinic, the chances of obtaining a sample that specialized in pediatric allergy would be smaller. During the organizational assessment the clinical staff reported that they believed many of their patients suffer from food allergy anxiety and the need for an intervention. The mentor for this DNP project, the head pediatric allergist of the clinic, was in full support of this project and its ability to produce a practice change at the facility.

Time limitation is an organizational weakness as some allergists reported not having enough time to assess for food allergy anxiety during clinic visits because they have many other issues to address (Memauri et al., 2022). Shorter appointments are follow-ups while longer appointments are needed when conducting food challenges. Although that seems like enough time to administer an assessment, servicing approximately 800 allergy patients in addition to the immunology patients seen at the same clinic and having roughly 3-6 providers, makes it difficult to spend excess time with each patient to address psychosocial needs. Another weakness was that the institution lacked policies and procedures for addressing food allergy anxiety. Considering the social determinants of health, another organizational weakness is the clinic location. Although the clinic is located at a well-known academic hospital, the patients may not
have access to transportation for their appointments. Some caregivers may find it challenging to set appointments for their child during the allotted clinic time frames due to work schedules and not being able to get time off approved. This can affect their agreeing to seek mental health services if needed, which will add more appointments for the patient and family since the clinic does not have a psychologist or a social worker in-house, requiring outside referrals. This may result in some patients holding onto the referral and never following up with a mental health provider, exacerbating the unmet psychosocial needs.

A key opportunity for the organization is that this DNP student is dedicated and able to champion the implementation of this project to lessen the burden on staff. The clinic staff is aware of the need for intervention but currently lacks the time to pioneer a quality improvement project by themselves due to a high volume of patients and other projects in the works. By conducting the project for them, it allows clinic staff to give focus to other clinic needs while still being able to address the issue of food allergy anxiety in their patients. The identification of food allergy patients at risk for food allergy anxiety is another organizational opportunity. Using a validated assessment tool to screen for food allergy anxiety in children and adolescents allows allergists and clinical staff to increase awareness of food allergy anxiety, identify individuals most vulnerable to the psychosocial consequences of food allergy, and provide them with the necessary support and resources for interventions (Golding et al., 2022). This allows allergists to better assess the severity of food allergy anxiety in their patients than in their current practice.

A possible threat to the DNP project is the insurance coverage for mental health services and establishing a referral network of mental health providers knowledgeable about food allergies. Patients who lack adequate insurance coverage but present with severe food allergy
anxiety may have to wait long periods due to the high volume of patients currently seeking mental health services and the inadequate number of providers (Memauri et al., 2022).

**Protection of Human Subjects**

The Institutional Review Board (IRB) is federally mandated to review any research that prior to the enrollment of human subjects to ensure ethics are enforced. The IRB completed a thorough review of the use of human subjects and deemed the project exempt via the Exempt Review process. Potential participants were identified via an email list supplied by the pediatric allergy and immunology department. All email correspondence was encrypted, and password protected. Email lists were only used for the recruitment purpose to protect privacy and were not shared. Prior to the collection of any data, participants completed the consenting process and were given ample time to consider their participation in the study. The consent process informed participants about the project, their voluntary role if agreeing to participate, privacy and confidentiality, no compensation given, and the risks and benefits associated with participation. After participants completed the consent form, each participant was given a code to use throughout the project on the pre and post implementation surveys.

All surveys regarding participant knowledge, perceptions, and practices regarding food allergy anxiety in children and adolescents with IgE-mediated food allergies were coded solely to compare pre and post answers. Due to the use of work email, in person informed consent, coded surveys and in-person data collection and educational presentation, there was a possibility to associate a participant with the study. To ensure privacy and confidentiality was maintained throughout the duration of the project, only investigators had access to the master key and all in person data collection was stored in a locked folder and locked file cabinet.

**Data Collection**
Following IRB approval, the data collection for this project was obtained from the Pre-Implementation Survey, and Post-Implementation Survey. After the consent process, participants completed an in-person pre-implementation survey to assess their knowledge, perceptions, confidence, and current clinical practices regarding food allergy anxiety in children and adolescents with IgE-mediated food allergies. After completing the pre-implementation survey, the participants were given a 60-minute in-person educational PowerPoint, based on the results of a related systematic, on food allergy-related anxiety and a protocol to address the identification and treatment of at-risk patients. After participants implemented the validated SOFAA-C and SOFAA-P assessment tools discussed in the 60-minute presentation into their practice for four weeks, they completed a post-implementation survey. The post-implementation survey assessed the provider’s knowledge and confidence in assessing for food allergy anxiety and included a self-report of the number of patients identified with food allergy anxiety and requiring referral to mental health services.

**Results**

Anxious avoidance can significantly affect a child’s life by increasing stress and affecting social activities resulting in psychological problems if unaddressed (Quach, 2018). The literature highlighted the knowledge deficit of providers caring for patients with food allergy anxiety and the need for education and guidance to assist those providers. The data collected during the DNP project was analyzed to determine the significance of implementing an outpatient protocol for children and adolescents with food allergy anxiety to increase provider knowledge and confidence in identifying patients at risk for food allergy anxiety.

A two-tailed paired samples t-test was conducted to examine whether the mean difference was significant. The total scores of the participant's pre-implementation and post-
implementation surveys were compared. The mean of pre-total was significantly lower than the mean of post-total. The results are presented in Table 1. A bar plot of the means is presented in Figure 1.

**Table 1**

*Two-Tailed Paired Samples t-Test for the Difference Between pre-total and post-total*

<table>
<thead>
<tr>
<th></th>
<th>Pre-total</th>
<th>Post-total</th>
<th>t</th>
<th>p</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>5.14</td>
<td>13.57</td>
<td>-8.08</td>
<td>&lt; .001</td>
<td>3.05</td>
</tr>
<tr>
<td>SD</td>
<td>2.61</td>
<td>0.53</td>
<td></td>
<td></td>
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</tbody>
</table>

*Note.* N = 7. Degrees of Freedom for the t-statistic = 6. d represents Cohen's d.

**Figure 1**

*The means of pre_total and post_total with 95.00% CI Error Bars*

*Descriptive Statistics*
The pre-implementation survey included a demographic section revealing that n = 7 (57.14%) of participants were 25-45 years of age, and 42.86% of patients were 46 or older. Regarding licensure, 57.14% of participants identified as medical doctors (MD), 14.29% of participants identified as advance practice registered nurses (APRN), and 28.57% of participants identified as registered nurses (RN). Of the 7 participants in the study, 57.14 reported having a certification in pediatric allergy and immunology. The participants’ years of experience in pediatric allergy and immunology included 42% reporting 0-2 years, 14.295 reporting 3-5 years, 14.29% reporting 6-9 years, and 28.57% reporting 10+ years. The number of food allergy anxiety trainings also varied across participants with 57.14% reporting 0 trainings, 14.29% reporting 1 training, 14.29% reporting 3 trainings, and 14.29% reporting 3+ trainings. These statistics are shown in table 2.

Table 2

Demographic Data of Participants (n=7)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-45 years</td>
<td>4</td>
<td>(57.14%)</td>
</tr>
<tr>
<td>46+ years</td>
<td>3</td>
<td>(42.86%)</td>
</tr>
<tr>
<td><strong>Licensure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MD</td>
<td>4</td>
<td>(57.14%)</td>
</tr>
<tr>
<td>APRN</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
<tr>
<td>RN</td>
<td>2</td>
<td>(28.57%)</td>
</tr>
<tr>
<td><strong>Certification in specialty</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>No</th>
<th>3</th>
<th>(42.86%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>(57.14%)</td>
</tr>
</tbody>
</table>

**Years of experience in pediatric allergy**

<table>
<thead>
<tr>
<th>0-2 years</th>
<th>3</th>
<th>(42.86%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-5 years</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
<tr>
<td>6-9 years</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
<tr>
<td>10+ years</td>
<td>2</td>
<td>(28.57%)</td>
</tr>
</tbody>
</table>

**Food allergy anxiety trainings attended**

<table>
<thead>
<tr>
<th>I do not know</th>
<th>0</th>
<th>(0.00%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4</td>
<td>(57.14%)</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>(0.00%)</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
<tr>
<td>3+</td>
<td>1</td>
<td>(14.29%)</td>
</tr>
</tbody>
</table>

*Note:* Due to rounding errors, percentages may not equal 100%.

Frequencies and percentages were calculated for question 2 on the pre-implementation (Pre2) and post-implementation (Post2) survey to analyze the frequency and percentage of participants reporting confidence in identifying patients at risk for food allergy anxiety before and after the use of a validated screening tool. The most frequently observed category of Pre2 was Somewhat confident \( n = 4, 57.14\% \). The most frequently observed category of Post2 was Very confident \( n = 7, 100.00\% \). Frequencies and percentages are presented in Table 3.
Table 3

*Frequency Table for Ordinal Variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>3</td>
<td>42.86</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>4</td>
<td>57.14</td>
</tr>
<tr>
<td>Very Confident</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Post2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not confident</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Very confident</td>
<td>7</td>
<td>100.00</td>
</tr>
</tbody>
</table>

*Note.* Due to rounding errors, percentages may not equal 100%.

**Discussion**

Although there was a small sample size, as predicted, participants reported an increase in confidence and knowledge after the educational presentation and implementing the SOFAA tool into practice for 4 weeks. As shown, there were various licensure, years of experience and training levels amongst participants and the food allergy anxiety knowledge and confidence reported were independent of those factors. Post-implementation of the food allergy anxiety screening tool 100% of participants reported that the tool helped identify patients at risk for food allergy anxiety. Participants also reported in the post-implementation that there was an increase in the number of patients they referred to mental health services using the SOFAA tool. The SOFAA tool can be used by busy clinical practices to quickly screen for food allergy anxiety in all food allergy patients. This is essential for clinical practices whose healthcare providers report
time constraints that do not allow them to use lengthier assessment tools such as the Food Allergy Quality of Life measure. Providers who implement the food allergy assessment tool can address the unmet psychosocial needs of patients growing up with food allergies. The SOFAAs ability to quantify the severity of the patient's food allergy anxiety allows clinicians to monitor improvement or decline and suggest appropriate behavioral interventions or referral for cognitive behavioral therapy.

**Limitations**

Limitations of the DNP project included the delayed timing in obtaining approval from the IRB and the small sample size. Ideally the participants were expected to have at least 8 weeks to implement the SOFAA tool into their current practice, however this was reduced to 4 weeks due to a delay in IRB protocol review. Obtaining IRB from both institutions took roughly 2 months instead of 1 month, in which the student originally accounted for. Even though there was a delay, participants were still given at least one week for recruitment and an additional week to confirm their participation in the project. During the 4 weeks of project implementation the DNP student remained readily available to address questions, comments, and concerns. In this manner, the project team increased the QI project's productivity during the decreased implementation phase. Another limitation was the small sample size of 7 participants. Although the sample size was rather small for generalizability of the results; a convenience sample of providers at a pediatric food allergy clinic accounted for a setting specific to the DNP project. For this reason, further research can expand on implementing the QI project in food allergy clinics at different institutions to see if it yields the same results.

**Next Steps for QI Project**
The increase in knowledge and confidence that the participants experienced, and the increase in patients identified as at risk for food allergy anxiety suggests the need for incorporating a food allergy anxiety assessment tool into the providers' everyday practice. Food allergy anxiety tools can help providers quantify the experienced anxiety and direct them to the best interventions to address the patient's anxiety. Adding a clinical decision-making tool into the electronic health record will guide providers on when to provide further education on diagnosis versus when to refer to mental health services. During the organizational assessment, stakeholders offered their support for implementing a food allergy anxiety assessment protocol to strive for better patient outcomes in the child and adolescent food allergy population. The project mentor and clinical staff will continue efforts to further the quality improvement project.

After presenting the final project findings to stakeholders, they expressed interest in furthering the QI project. The mentor agreed to attend the organization’s monthly policy meetings to further develop the protocol and ideally have it entered in the policy and procedures database within the next 3-6 months. In the early stages of the project, the project team obtained permission from the SOFAA tool's developers to build an electronic version of the tool into the electronic health record to make it easier for providers to collect and review if considering implementation into practice. The mentor’s goal is to communicate with IT personnel, immediately after the policy is adopted organization-wide, to create an electronic version of the SOFAA tool that provides a clinical decision-making tool for providers to know when to consider referral to mental health services. This can help decrease the time spent completing the tool during the clinic visit as patients and caregivers will be able to complete the tool prior to the scheduled appointment. For patients who cannot read the English language, the form will have to be translated at the clinic visit with a certified interpreter since currently, the tool is only
provided in English. The educational presentation, pre and post surveys and food allergy anxiety resources were adopted by the mentor and his clinic to help educate new staff members and provide patient food allergy anxiety resources. The mentor’s goal is to have quarterly check-ins with staff members after the SOFAA tool is adopted to address any further issues with implementation and reassess the confidence level and provider knowledge. The educational department also received the educational presentation to disseminate organization-wide and incorporate into annual nursing competencies to help increase food allergy anxiety knowledge in nursing staff. By furthering the implementation of the food allergy anxiety QI project, the mentor can continue to address the psychosocial needs of the patients and decrease discrimination, social isolation, avoidance of non-allergic foods, and bullying (World Health Organization [WHO], 2021).

**Sustaining Practice Change**

Sustaining the practice change requires continued efforts regarding organizational change and support, health policy, and fiscal factors. Changes that are beneficial to patients and staff and do not greatly disrupt the workflow, are easier to sustain long-term. As mentioned before, the clinic staff supported the need for change, the proposed model of change, and the continued efforts in implementing the change project. Having a supportive team makes it easier to identify change leaders or champions of change that can help reinforce the need to sustain the practice change. For employees less receptive to change, it is imperative to have anticipated mitigation tactics to help further gear them toward acceptance of the change project. During the process of change, it is important to keep an open line of communication with all team members to address any questions or concerns along the way. Setting time aside for private and group meetings to discuss issues that arise during the change project help mitigate feelings of uncertainty or
disturbances in routine. Employee involvement in the change project is another mitigation technique that allows for employees who may be less receptive to change to give input on the process, ultimately increasing their chances of better adapting to the change. Another important aspect for sustaining change requires the organization to identify the long-term benefits of adopting the change project to determine its longevity. Quality improvement projects, such as this one that aim to increase provider knowledge and ultimately improve patient outcomes and patient satisfaction can quickly gain support from stakeholders who prioritize improvement in the overall business' performance.

**Implications for Advanced Nursing Practice**

The ever-changing healthcare field demands advanced practitioners to be more integral team members as their roles continue to expand and evolve. As practitioners at the forefront of change, APRNS are equipped to provide advanced levels of designing, delivering, and evaluating evidence-based changes in practice. The advanced practice nursing community is driven by evidence-based research that drives change and seeks to provide quality care resulting in optimal patient outcomes. Nursing education, clinical practice, administration, and leadership influence APRNs' ability to promote practice changes and influence health care delivery.

**Nursing Education**

Although the initial knowledge gap displayed by each healthcare provider in this project can be attributed to different factors, education is key. Nursing education, just as doctoral education, introduces the topic of psychosocial aspects of care and their overall impact on patient outcomes; however, it is up to the providers to stay up to date with evidence-based research to remain knowledgeable of best practices. The next step is for practitioners to disseminate the
knowledge gained to their colleagues to improve their practice and provide the best possible care for their patients. Ultimately, advanced practitioners educate registered nurses, licensed practical nurses, nursing assistants, and medical assistants. By fostering a relationship that educates, guides, mentors, and supports other nurses, the APRN can work towards achieving nursing excellence.

**Clinical Practice**

Advanced practice registered nurses (APRNs) play a significant role in identifying patients and families dealing with food allergies who are at risk for psychosocial issues. In clinics where mental health screening may be omitted for various reasons, the APRN can advocate for patients by proposing the benefits of early screening of psychosocial issues and early interventions. Recognizing how food allergies influence a patient's overall health allows the APRN to address all aspects of care, ultimately decreasing the impact of the food allergy diagnosis while promoting better patient outcomes (Quach, 2018). APRNs can provide psychosocial support by working with patients and families to brainstorm coping strategies to decrease anxiety, recommending support groups to help increase knowledge and confidence in managing the condition, and promoting open expression of their feelings (Quach, 2018). The information gathered during this quality improvement project can

APRNs are in an ideal position to promote the collaboration of healthcare providers, school personnel and patient's families to ensure optimal care of food allergy patients in various settings. Including school, personnel can help decrease anxiety felt in the school setting by increasing education for staff and parents. The collaboration of healthcare providers from various specialties, including primary care, psychology, and allergy specialists, can decrease the overall
impact of food allergies on a child's physical, emotional, and psychological health (Quach, 2018). The inclusion of food allergy patients and families into the collaborating team allows for shared decision-making to promote autonomy and healthy self-care behaviors while decreasing the risks of anxiety and social isolation (Quach, 2018). APRNs can assist in collaborative efforts by providing education from reliable sources, keeping an open line of communication between all team members, and providing patients and families with the necessary resources to manage food allergies and comorbid anxiety (Quach, 2018).

**Nursing Administration**

The supportive culture that nursing administration creates for nursing practice at the institution allows advanced practitioners to create and implement evidence-based research projects to guide practice-level or institution-wide policy changes. Without the supportive forces from nursing administration, quality improvement projects would be difficult to conduct. Nursing administration needs to keep staff motivated by promoting nurses and other healthcare professionals to work together to increase patient satisfaction, employee satisfaction and patient outcomes. Nursing administrators serve as liaisons for interpersonal team collaborations, which are beneficial to quality improvement implementation, and dissemination because it creates a space for nurses to share their project ideas or project findings. Offering bonus monetary incentives for nurses who participate in evidence-based research is one way nursing administrators can increase QI project engagement while indirectly enhancing patient experiences and outcomes. To ensure nursing staff is performing at optimal levels, educational seminars, professional development opportunities, and incentives for furthering education can be presented to motivate and support nurses.
Nursing Leadership

APRNs play a supportive role in the care of their patients and can further impact the profession as they continuously seek out leadership roles. Participation in leadership positions allow advanced practice nurses to positively impact healthcare in many ways. Childhood and adolescent anxiety that is heightened to the point where it impairs normal everyday functioning requires interventions (Zsamboky et al., 2021). Thus, as leaders of change, APRNs are in a prime position to advocate for food allergy anxiety patients. Although addressing the unmet psychosocial needs takes precedence for the healthcare provider, it must be done strategically (Engel & Bunning, 2021). APRNs have the leadership skills to influence food allergy health policy at practice, institutional, state, and nationwide levels. Leaders can advocate for assessing food allergy anxiety with condition-specific tools and early psychosocial treatment. Participation in activities, such as, speaking at seminars within the hospital, presenting at a food allergy conference, or attending nationwide health policy meetings to address food allergy anxiety are just a few possibilities for nursing leaders to help further the profession by active engagement while positively impacting healthcare delivery. Nurse leaders are healthcare role models who exhibit the necessary skill set to promote increased productivity and higher staff and patient satisfaction.

Conclusion

Children and adolescents with food allergies suffer from a chronic condition that can be life-threatening at any given moment, thus, affecting their overall psychological well-being. The uncertainty that stems from the condition has been shown to cause anxious avoidance, increased stress, and social isolation (Quach, 2018). Unfortunately, the psychosocial needs of children and adolescents with food allergies are often unaddressed due to allergists and primary care
providers, who see the patients most frequently, lacking the knowledge and resources to properly address these needs (Memauri et al., 2022).

This project implemented a protocol at an outpatient pediatric allergy and immunology clinic to address the unmet psychosocial needs of children and adolescents with food allergies. The protocol promotes food allergy anxiety screening of all IgE-mediated food allergy patients aged 8-18 years with the use of the validate Survey of Food Allergy Anxiety tool. The SOFAA tool quantifies the severity of the food allergy anxiety so that the provider can identify possible excessive food allergy anxiety and refer to mental health services. This tool was selected above other anxiety screening tools because it is condition-specific to anxiety related solely to the food allergy condition and allows patients to be quickly screened, unlike other lengthier tools.

The quality improvement project required an in-depth literature search to better understand food allergy anxiety, available screening measures, and evidence-based benefits of screening for food allergy anxiety before developing the outpatient protocol. Ultimately, the QI project helped providers recognize patients at risk for food allergy anxiety with proper use of a screening tool that also guided behavioral interventions. Providers also reported increased confidence in the identification of food allergy anxiety patients with the use of the condition specific SOFAA tool.

This project highlights the benefits of APRNS participating in evidence-based research projects to advocate for changes in practice that promote better patient outcomes and increased patient satisfactions. Although this project focused on the providers' knowledge and confidence, patient outcomes are indirectly affected. Promoting food allergy anxiety awareness and educating providers on when to refer those patients exhibiting moderate to severe food allergy
anxiety to mental health services can help patients receive a better disease trajectory and quality of life.
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Appendix A

Support Letter

Date: 01/19/2023  
Michael Sanchez, DNP, APRN, FNP-BC  
Clinical Associate Professor  
Nicole Wertheim College of Nursing & Health Sciences  
Florida International University

Dear Dr. Sanchez,

Thank you for inviting UHealth to participate in the DNP Project of Rochelle Bradley. It is to my understanding that Ms. Bradley will be conducting this project as part of the requirements for the Doctor of Nursing Practice program at Florida International University (FIU). After reviewing the project’s proposal titled “Implementation of an outpatient protocol for children and adolescents with food allergy-related anxiety: A quality improvement project,” I have warranted Ms. Bradley permission to conduct the project in the pediatric allergy and immunology clinic.

We understand that the project will be developed in our setting and will occur over 2 months and possibly be implemented afterward. We are also aware of our staff participation in supporting the student to complete this project, granting the student access to our facilities, giving consent, and implementing the protocol into our practice. We will provide a peaceful and safe environment to safeguard our participants’ privacy and adequate area to conduct the quality improvement project. The screening tool that will be implemented is the Scale of Food Allergy Anxiety and it will be administered by the providers to the parent and child. A pamphlet will be given to the parent and child at the end of the appointment with helpful information regarding managing anxiety. Any data collected for the project will be kept confidential.

This project intends to evaluate if an outpatient protocol for children and adolescents with food allergies will enhance the identification and intervention for those at risk for food allergy-related anxiety. Before implementing this project, the Florida International University Institutional Review Board will evaluate and approve the procedures to conduct the project. Evidence suggests that outpatient allergists should screen for food allergy anxiety in patients with IgE-mediated food allergies in order to properly assess and address their psychosocial needs.

We expect that Rochelle Bradley will not interfere with the normal office performance. Furthermore, Ms. Bradley will behave professionally and follow the office standards of care. As the Director of the Pediatric Allergy and Immunology Center of UHealth, I support the staff’s participation in this project and look forward to working with you.

Regards,

Gary Kleiner MD PhD  
University of Miami Miller School of Medicine  
Director, Pediatric Allergy and Immunology  
Batchelor 141 (D4-4)  
1580 NW 10th Ave  
Miami FL 33136  
305-243-4863  
305-243-7409 fax

Pediatric Allergy and Immunology  
P.O. Box 018950 (D4-4)  
Miami, FL 33136  
Ph: 305-243-6676 Fax: 305-243-5562
Appendix B

Consent Form

CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT
“Implementation of an outpatient protocol for children and adolescents with food allergy-related anxiety: A quality improvement project.”

PURPOSE OF THE PROJECT
You are being asked to be in a quality improvement project. The goal of this project is to improve healthcare provider knowledge of how to address food allergy anxiety in children and adolescents presenting with IgE-mediated food allergies through a structured intervention which identifies tools and guidelines that could be implemented in the outpatient care setting to improve patient’s outcomes.

NUMBER OF PROJECT PARTICIPANTS
If you decide to be in this project, you will be one of ten people participating in this research project.

DURATION OF THE PROJECT
Participation is expected to span a total of approximately 2 months. The pre-test and post-test assessments are expected to take approximately 5 minutes each to complete. The educational session is expected to last approximately 60 minutes, total amount of time will be 70 minutes of the educational module.

PROCEDURES
If you agree to be in the project, we will ask you to do the following things:
1. At your first session, you will complete a demographic questionnaire, which includes general information such as age, licensure, certifications; and a pre-test survey with current practice and knowledge of food allergy anxiety.
2. In the first session, you will receive a 60 minute educational program about food allergy anxiety in children and adolescents with IgE-mediated food allergies
3. Next, you will implement the food allergy anxiety protocol into your current practice for 6-8 weeks.
4. Then you will be asked to complete the food allergy anxiety post-test survey.

RISKS AND/OR DISCOMFORTS
There are no foreseeable risks with you for participating in this project.

BENEFITS
The following benefits may be associated with your participation in this project: An increase in food allergy-related anxiety knowledge, which will help you to better assess food allergy anxiety in children and adolescents with IgE-mediated food allergies and guidelines implementations to address those at high risk. The overall objective of the program is to guide healthcare providers in the use and advantages of a protocol for addressing food allergy anxiety in children and adolescents with IgE-mediated food allergies to improve patient outcomes.
ALTERNATIVES
There are no known alternatives available to you other than not taking part in this project. However, if you like to receive the educational material given to the participants in this project, it will be provided to you at no cost.

CONFIDENTIALITY
The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

COMPENSATION & COSTS
There is no cost or payment to you for receiving the health education and/or participating in this project.

RIGHT TO DECLINE OR WITHDRAW
Your participation in this project is voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION
If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Rochelle Bradley at 786-564-4092, rbrad003@fiu.edu or Dr. Charles Buscemi at 305-348-4870, cbuscemi@fiu.edu.

IRB CONTACT INFORMATION
If you would like to talk with someone about your rights of being a subject in this project or about ethical issues with this project, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT
I have read the information in this consent form and agree to participate in this project. I have had a chance to ask any questions I have about this project, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____________________________
Signature of Participant

_____________________________
Printed Name of Participant

_____________________________
Signature of Person Obtaining Consent

_____________________________
Date

_____________________________
Date
Appendix C
Pre-Implementation Questionnaire

INTRODUCTION

The primary aim of this QI project is to improve the healthcare provider knowledge of addressing food allergy anxiety in children and adolescents with IgE-mediated food allergies in order to improve patient outcomes in this population. Please answer the questions below to the best of your ability. These questions are meant to measure knowledge and perceptions on identification, referral, and management on food allergy anxiety.

Participant Demographics

1. **Age:** 25-45 years 46 and up
2. **Licensure:** RN APRN PA MD/DO
3. **Certification in Specialty:** Yes No
4. **How many years of experience do you have working in pediatric immunology?**
   - 0-2 years
   - 3-5 years
   - 6-9 years
   - 10+ years
5. **How many trainings (in any format) have you attended in the past year that focused on food allergy anxiety?**
   - None
   - 1
   - 2
   - 3
   - More than 3
   - I don’t know/I don’t remember
QUESTIONNAIRE

1. Do you currently use a screening tool to assess patients at an increased risk for food allergy anxiety?
   
   Yes  No

2. How confident do you feel in identifying patients at risk for food allergy-related anxiety?
   
   Not confident at all
   Somewhat confident
   Very confident

3. On average how many patients do you identify at risk for food allergy-related anxiety and refer to mental health services per month?
   
   I have not referred any patients to mental health services
   1-10 patients
   11+ patients

4. Which is an example of food allergy anxiety?
   
   a. When a patient presents with flushed face, hives, swelling of the face, tongue, mouth and throat after contact with a food allergen.
   b. When a patient exhibits a fear of coming in contact with a food allergen or experiencing an allergic reaction and that fear interferes with their ability to function on a daily basis.
   c. When a patient reads food labels before consumption.
5. **Food allergy anxiety is often attributed to:**
   a. Anaphylaxis and Epinephrine use
   b. Life limitations
   c. Both A and B

6. **Which food allergy anxiety tool is used to assess child food allergy anxiety in self-report and parent-proxy forms?**
   a. Food Allergy Anxiety Scale
   b. Scales of Food Allergy Anxiety
   c. Worry About Food Allergy Questionnaire

7. **Generalized anxiety questionnaires are designed to capture disease-specific anxiety:**
   True. False

8. **Checking food labels before purchasing is an example of excessive food allergy anxiety:**
   True. False

9. **Select all that apply: Possible treatment options for food allergy anxiety include**
   a. Inpatient Hospitalization
   b. Distraction Techniques
   c. Relaxation Techniques
   d. Cognitive Behavioral Therapy
Appendix D

Post-Implementation Questionnaire

INTRODUCTION

The primary aim of this QI project is to improve the healthcare provider knowledge of addressing food allergy anxiety in children and adolescents with IgE-mediated food allergies in order to improve patient outcomes in this population. Please answer the questions below to the best of your ability. These questions are meant to measure knowledge and perceptions on identification, referral, and management on food allergy anxiety.

QUESTIONNAIRE

1. Was the screening tool helpful in your everyday practice in identifying patients at risk screening for food allergy anxiety?
   Yes       No

2. How confident are you in identifying patients at risk for food allergy-related anxiety?
   Not confident at all
   Somewhat confident
   Very confident

Page 1 of 3
3. On average how many patients were identified at an increased risk for food allergy-related anxiety while using the screening tool?

0 patients

1-10 patients

11+ patients

4. Which is an example of food allergy anxiety?

a. When a patient presents with flushed face, hives, swelling of the face, tongue, mouth and throat after contact with a food allergen.

b. When a patient exhibits a fear of coming in contact with a food allergen or experiencing an allergic reaction and that fear interferes with their ability to function on a daily basis.

c. When a patient reads food labels before consumption.

5. Food allergy anxiety is often attributed to:

a. Anaphylaxis and Epinephrine use

b. Life limitations

c. Both A and B

6. Which food allergy anxiety tool is used to assess child food allergy anxiety in self-report and parent-proxy forms?

a. Food Allergy Anxiety Scale

b. Scales of Food Allergy Anxiety

c. Worry About Food Allergy Questionnaire

7. Generalized anxiety questionnaires are designed to capture disease-specific anxiety:
8. Checking food labels before purchasing is an example of excessive food allergy anxiety:
   True False

9. Select all that apply: Possible treatment options for food allergy anxiety include
   a. Inpatient Hospitalization
   b. Distraction Techniques
   c. Relaxation Techniques
   d. Cognitive Behavioral Therapy
Appendix E

Survey of Food Allergy Anxiety Tools

SOFAA-C Full Version

SOFAA-C | SURVEY OF FOOD ALLERGY ANXIETY
CHILD REPORT

Directions: FOR THE LAST WEEK ONLY, circle the number next to each statement that best describes you.

Even if there are safe foods for me...

<table>
<thead>
<tr>
<th>Statement</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am scared to eat the food from a NEW restaurant.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I am scared to eat the food from a restaurant I have already been to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I try NOT to be touched by someone, because I am scared this will give me an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I am scared to eat at parties or the homes of my friends.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I am scared to eat at the regular lunch table at school or camp.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. I am scared to eat the food served by my school or camp.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. I am scared to eat anything at school or camp, even if I brought the food from home.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. I am too scared to eat food when I am with an adult who is not my parent, like when I am staying with a family member or at a friend's house.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. I am afraid of smelling the foods I am allergic to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. I am scared to touch safe foods because of the chance of an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. I am scared that a food I am allergic to will make me very sick if it touches me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12. I am scared to sit next to someone who is eating a food that I am allergic to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13. I am scared to eat safe foods that have been next to foods I am allergic to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14. I spit out food too much because I am afraid of having an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15. I wash my hands too much because I am afraid of having an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16. I will not try new foods, even if my parent says the food is safe to eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17. I visit the nurse too much because of my fears about my food allergy.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>18. I check or ask my parent to check my mouth or body too much to make sure I am not having an allergic reaction to food.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>19. I check food labels more than I need to because I am scared.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>20. I ask my parents too many times if a food is safe for me to eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>21. I try not to touch things like door handles, phones, or clean surfaces because I am afraid of having a food allergy reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
SOFAA-P Full Version

SOFAA-P | SURVEY OF FOOD ALLERGY ANXIETY
PARENT REPORT

Directions:
FOR THE LAST WEEK ONLY, circle the number next to each statement that best describes your child.

<table>
<thead>
<tr>
<th>Even if there are safe foods available, my child...</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Avoids eating the food in NEW restaurants.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Avoids eating the food in FAMILIAR restaurants.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Avoids being touched by others because of fears of having an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Avoids eating at parties or social gatherings at other people’s homes.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Avoids eating at the regular lunch table at school or camp.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Avoids eating foods at school or camp that they did not bring from home.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Avoids eating at school or camp even if they brought the food from home.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Avoids eating when they are with an adult who is not their parent, for example with a relative or at a friend’s house.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Avoids smelling the foods they are allergic to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. Avoids touching safe foods because of fears of having an allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. Avoids allowing an allergy food to touch their body, because they believe it will cause a serious allergic reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12. Avoids sitting near someone they believe is eating food containing allergens.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13. Avoids eating safe foods that were stored near foods that they are allergic to.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14. Frequently spits out food because they believe it contains allergens.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15. Washes their hands too much in order to avoid food allergens.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16. Refuses to try new foods, even if I say the foods are safe to eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17. Visits the nurse too much due to fears of having an allergic reaction to food.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>18. Frequently checks or asks me to check their mouth or body to make sure that they are not having an allergic reaction to food.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>19. Over-checks labels of foods.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>20. Asks me too many times whether a food is safe for them to eat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>21. Avoids touching everyday objects like doorknobs, phones, or clean surfaces due to fears of having a food allergy reaction.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix F

Educational Presentation

Introduction to Food Allergy Anxiety

The Current Problem

Available Knowledge

Intervention: The Outpatient Protocol

Management of Food Allergy Anxiety

Summary

Food Allergy Anxiety

- Reported when the food in question causes an anaphylactic reaction or elicits an allergic reaction that is severe enough to require medical intervention.

Prevalence:

- About 8% of children in the US

- Anxiety resulting in avoidance and fear of exposure to allergens

- Developmental impact

- Behavioral issues

- Nutritional deficiencies

- Psychological impact

What is the Problem?

- The prevalence of food allergies in the pediatric population is rising, leading to increased anxiety and fear among children and their families.

- The management of food allergies requires a holistic approach that addresses both the medical and psychological needs of patients.

- The introduction of an outpatient protocol aims to provide a structured and supportive environment for patients to learn and manage their food allergies effectively.
Management of Food Allergy Anxiety

Mild
- Relaxation Techniques
- Deep Breathing
- Guided Imagery
- Biofeedback
- Meditation
- Progressive Muscle Relaxation

Moderate-Severe
- Cognitive-Behavioral Therapy
- Antidepressant Medications
- Clonidine
- Thought Stopping

Summary
- There are tools available to help patients address the psychosocial needs of children and adolescents with food allergy anxiety.
- Addressing these needs can help patients achieve a better quality of life.
- Routine monitoring is beneficial.

References
Appendix G

Florida International University Internal Review Board Exemption Letter

MEMORANDUM

To: Dr. Rosa Roche
CC: Rochelle Bradley
From: Carrie Bassols, BA, IRB Coordinator
Date: April 13, 2023
Proposal Title: “Implementation of an Outpatient Protocol for Children and Adolescents with Food Allergy-Related Anxiety: A Quality Improvement Project”

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the Exempt Review process.

IRB Protocol Exemption #: IRB-23-0167  IRB Exemption Date: 04/13/23
TOPAZ Reference #: 112823

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.
Appendix H

University of Miami Internal Review Board Exemption Letter

May 31, 2023

Gary Kleiner
141 Batchelor Childrens
Miami, FL 33136-1013
+1 (305) 2434863
gary.kleiner@miami.edu

On 5/31/2023, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Initial Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study:</td>
<td>Implementation of an outpatient protocol for children and adolescents with food allergy related anxiety. A quality improvement project</td>
</tr>
<tr>
<td>Investigator:</td>
<td>Gary Kleiner</td>
</tr>
<tr>
<td>IRB ID:</td>
<td>20230411</td>
</tr>
<tr>
<td>Funding:</td>
<td>None</td>
</tr>
<tr>
<td>IND, IDE, or HDE:</td>
<td>None</td>
</tr>
</tbody>
</table>

Documents Reviewed:
- Educational Presentation.pdf.pdf, Category: Other;
- SOFPA-C.pdf, Category: Other;
- SOFFA-P.pdf, Category: Other;
- UM Post Questionnaire.PDF.pdf, Category: Questionnaire/Survey/Interview/Diary;
- UM Pre Questionnaire.PDF.pdf, Category: Questionnaire/Survey/Interview/Diary;
- Recruitment Email Letter editable.pdf, Category: Recruitment Materials;
- UM IRB Consent rev.pdf, Category: Consent Form;

The IRB determined this study meets the criteria for an exemption as described in Federal Regulation 45 CFR 46.104. This determination is effective on 5/31/2023.