Evaluating Interest in Clinical Trial Participation for the Treatment of Pediatric Food Allergy

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EVALUATING INTEREST IN CLINICAL TRIAL PARTICIPATING FOR THE TREATMENT OF PEDIATRIC FOOD ALLERGY

by

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ABSTRACT
EVALUATING INTEREST IN CLINICAL TRIAL PARTICIPATION FOR THE TREATMENT OF PEDIATRIC FOOD ALLERGY

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Food allergy (FA) is a chronic medical condition that affects one out of every 13 children in the United States. Researchers have recently begun utilizing double-blind, placebo-controlled clinical trials to test novel biological treatments designed to retrain the immune system to be less reactive to food allergens. Although these treatments remain in the clinical trial stage, evidence suggests that individuals differentially engage with these options based on a variety of factors. Using a socioecological framework, this study sought to evaluate the effect of child, parent, and family-level factors on parental interest in clinical trial participation for the treatment of pediatric food allergy. Participants were recruited from four pediatric specialty clinics across the United States. Results indicated that child age was a reliable predictor of interest in clinical trial participation for both Black and White parents of food allergic children. However, examination of parent factors yielded mixed results with clear distinctions between racial groups. Interestingly, none of the family factors examined were found to be significant. Interpretations and conclusions are discussed.

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Evaluating Interest in Clinical Trial Participation for the Treatment of Pediatric Food Allergy

Food allergy (FA) is a chronic medical condition that affects one out of every 13 children in the United States (R. S. Gupta et al., 2011). Symptoms of a food-induced allergic reaction can range in severity from mild to life-threatening. Research has found that adolescents and young adults are at increased likelihood of experiencing fatal food-induced anaphylaxis (Turner et al., 2017). Hence, daily food allergy management can be stressful for patients and their families, requiring considerable vigilance and careful planning to avoid accidental exposure. Increased stress related to FA hypervigilance can negatively impact family relationships and prompt parents to limit their child's social activities, which contributes to impairments in food-allergy-related quality of life (FAQoL; Warren et al., 2016).

Equally important are the observed disparities in the distribution of FA burden across racial and socioeconomic strata. Notably, research has found that Black children report higher rates of food-allergic sensitization (Branum & Lukacs, 2009; Liu et al., 2010; Sicherer et al., 2010) and probable FA symptoms (Luccioli et al., 2008) compared to non-Hispanic, White children. Similarly, greater FA prevalence rates have been observed among urban- vs. rural-dwelling individuals (R. S. Gupta et al., 2012). The financial impact of FA also disproportionately affects low-income families, who report spending nearly twice as much on food allergy-related emergency department (ED) visits and hospitalizations than other income groups (Bilaver et al., 2016). These findings suggest that the public health burden of FA is in its prevalence and management.

Existing guidelines for FA management are quite limited and do not sufficiently protect patients from the threat of accidental exposure. In recognition of this, investigators have begun testing novel treatments designed to reduce an affected individual's natural biological response to food allergens. In turn, these treatments can also decrease the emotional and financial toll associated with the condition. However, to ensure the safety and efficacy of these novel treatment modalities, participants in these clinical trials should reflect the full diversity of the affected population. Despite this, we continue to see disproportionate clinical trial participation rates among low-income and minority patients across all disease groups. In addition, literature on factors that influence participation in food allergy-specific clinical trials is sparse. However, medical decision-making literature in other populations was reviewed to identify potential child, parent, and family-level factors that may influence clinical trial participation in pediatric food allergy.

Food Allergy Overview

In 2004, the United States Congress passed the Food Allergy Labeling and Consumer Protection Act, identifying eight common food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybean. Since the enactment of this law, the United States has seen a steady increase in FA prevalence among children (R. S. Gupta et al., 2011). A population-based study conducted between 2007 and 2010 found that roughly 6.5% of children reported having food allergies (McGowan & Keet, 2013). Food-induced allergic reactions are harmful immune responses that often occur within 20 minutes after initial exposure. The most severe type of food-induced allergic reaction is anaphylaxis, characterized by multiple acute severe symptoms (i.e., hives, vomiting,

wheezing) reported within multiple organ systems (i.e., skin, gastrointestinal, respiratory). Epidemiological research suggests that 40-50% of children diagnosed with FA have experienced at least one severe, life-threatening allergic reaction resulting in a trip to the ED (R. S. Gupta et al., 2011, 2018). Between 2008 and 2012, another study found that ED visits and hospitalization due to anaphylaxis spiked 29.1% annually among children (Dyer et al., 2015). Although it is challenging to predict who is at the greatest risk of anaphylaxis, it is essential to note that many people practice strict avoidance of suspected food allergens, despite not reporting convincing FA symptomatology. Consequently, these individuals are likely to experience strained family relationships, impaired quality of life, and additional economic burdens associated with chronic food allergy management (Warren et al., 2016).

Due to the ubiquity of most food allergens and the small amounts needed to induce a reaction, parents of food-allergic children must know the signs and symptoms of allergic reactions. In addition, in some instances, parents may need to respond quickly to emergent allergy situations that require the performance of appropriate life-saving measures. However, one study examining caregiver experiences following their child's first food-induced allergic reaction identified significant gaps in FA knowledge leading to increased fear and anxiety of future reactions (Abdurrahman et al., 2013). Specifically, Abdurrahman et al. (2013) found that caregivers displayed insufficient knowledge of using epinephrine auto-injectors (EpiPen) and a diminished sense of self-efficacy related to managing their child's food allergy. As a result, 94% of caregivers endorsed making social lifestyle changes to avoid future reactions (Abdurrahman et al., 2013). Additional studies have reported impaired FAQoL related to the total number of food allergies and

the patient's overall history with the condition (Allen et al., 2015). Notably, patients with a greater number of food allergies report lower FAQoL than those with fewer food allergies (Allen et al., 2015; Howe et al., 2014; Wassenberg et al., 2012). Also, FAQoL appears to be worse among caregivers of food-allergic children who report a history of severe food allergic reactions, a greater number of symptoms during a previously reported food allergic reaction, and any previous epinephrine use (Allen et al., 2015; Chow et al., 2015; Howe et al., 2014). These findings suggest that daily food allergy management stress is compounded by the degree of vigilance required for allergen avoidance and the resulting impact on family social functioning.

Observed Disparities in FA Across Racial and Socioeconomic Strata

Given FA's significant population health burden, it is necessary to address the observed disparities in its prevalence, management, and outcomes. A review of the extant FA literature revealed striking differences in the distribution of FA burden across racial and socioeconomic strata (Warren et al., 2021). For example, data from a recent population-based study indicate that White adults report lower rates of FA relative to their Black, Hispanic, Asian, and multiracial counterparts (R. S. Gupta et al., 2019). Additionally, this study found that prevalence rates appear to be similar among adults in the highest and lowest income strata (R. S. Gupta et al., 2019). In another study controlling for age, findings suggested that the prevalence of food sensitization among Black Americans was 27% compared to 13.8% for White Americans (Liu et al., 2010).

Research has also identified food-specific disparities in allergic sensitization. For example, one study found that Black adults reported higher rates of seafood allergy than other racial/ethnic groups (Sicherer et al., 2004). Additionally, Black children are

reported to be at nearly two-fold risk of being allergic to any food compared to White children (R. S. Gupta et al., 2011). However, Black children report greater FA sensitization, specifically to peanuts (Sicherer et al., 2010), milk, egg, and shrimp (Branum & Lukacs, 2009; Liu et al., 2010). Interestingly, research suggests that children who receive a physician-diagnosed peanut-, tree-nut, shellfish, and/or finfish allergy are more likely to have a positive history of at least one severe reaction compared to children with other allergies (R. S. Gupta et al., 2018, 2019).

Although Black children report higher rates of probably FA symptoms than White and Hispanic children (Luccioli et al., 2008), minority and low-income children who meet symptom criteria are less likely to report a physician diagnosis (R. S. Gupta et al., 2011). Results of a Detroit-based cohort study suggest that the observed difference in rates of food-allergic sensitization may contribute to disproportionate rates of physician-diagnosed food allergies observed among Black and White children (R. S. Gupta et al., 2018; Joseph et al., 2016). This research is further supported by studies citing issues related to under-diagnosis and/or inadequate access to specialty care for FA among urban minority children (Taylor-Black & Wang, 2012).

Daily food allergy management is also more challenging for minority and low-income families. In particular, Black adults with FA report higher rates of severe allergic reactions and FA-related ED visits than White adults (R. S. Gupta et al., 2018, 2019). Further, Gupta et al. (2018) identified a similar trend among Black and Hispanic children. Notably, studies have found that Black and Hispanic parents are less likely to correctly identify signs of FA reactions and potential triggers (R. S. Gupta, Kim, Springston,

Smith, et al., 2009). Thus, inadequate access to specialty care and insufficient knowledge of FA signs and symptoms can exacerbate existing disparities in FA health outcomes.

The financial impact associated with managing FA can also take a significant toll on patients and families. A study describing the economic impact of childhood FA in the United States found that the annual economic cost was estimated to be $24.8 billion, equating to roughly $4,184 per year per child (R. Gupta et al., 2013). This study also found that the annual direct medical costs associated with hospitalizations, clinician visits, and ED visits were roughly $4.3 billion (R. Gupta et al., 2013). At a more granular level, costs that directly affected families (such as lost labor, out-of-pocket, and opportunity costs) were estimated to be roughly $20.5 billion annually (R. Gupta et al., 2013). These findings are even more alarming when race and SES are considered. Food allergy-related ED visits and hospitalization disproportionately affect families of food-allergic children in the lowest income bracket, who routinely spend more than twice as much as other income groups (Bilaver et al., 2016). Furthermore, a report on urban hospital networks in Chicago and Cincinnati found elevated rates of food-induced anaphylaxis and related ED visits among Black children with FA relative to non-Hispanic, White children (Mahdavinia et al., 2017). Given these findings, it appears that the pipeline from sensitization to physician-diagnosed food allergy, and the associated burdens of that diagnosis, disproportionally affects Black children and their families.

Treatment Options for Food Allergy

Avoidance

Expert guidelines for FA management advise strict avoidance of all products containing potential food allergens (Boyce et al., 2010; Togias et al., 2017). However,

adherence to strict avoidance does not always prevent accidental exposures. Though strict avoidance may be most effective in reducing the potential for accidental exposure, it engenders a risk-averse approach to FA management and does not adequately account for families that may experience food insecurity. Low-income families who experience difficulty meeting basic nutritional needs often have limited control over their food selection. One study found that families of food allergic children who experience food insecurity report a greater perceived risk of accidental ingestion than families who did not report food insecurity (Tackett et al., 2018). Another study revealed that food-allergic children from low-income families account for nearly 2.5 times more ED and hospitalization costs than those from high-income families (Bilaver et al., 2016). This study also found that low-income families spend significantly less on specialty healthcare services for FA than higher-income families (Bilaver et al., 2016). Together, these findings highlight an over-utilization of emergency services among low-income community members, exacerbating existing financial disparities.

Furthermore, strict avoidance does little to address a parent's fear of accidental exposure. Research has shown that parents of food-allergic children experience elevated levels of stress and anxiety, which can be attributed to the constant need to avoid all food-allergen-containing products and the chronic threat of potential anaphylaxis (Primeau et al., 2000; Warren et al., 2016). Parents' perception of threat is a significant predictor of FA-related anxiety and is negatively associated with parental confidence in their ability to manage their child's FA (Roberts et al., 2021). Aside from strict avoidance, managing food allergies is generally limited to medication management, immunotherapy, or clinical trials. Each option proposes a certain level of risk and

potential benefit inherent to treating and managing food allergies. It is recommended that individuals use over-the-counter or prescribed medications, like diphenhydramine or other antihistamines, to reduce symptoms of a minor allergic reaction (Boyce et al., 2010; Togias et al., 2017). Individuals with more severe food allergies are further advised to carry an epinephrine auto injector for use in case of emergencies. The problem with medication management in FA is that this approach requires a reaction to occur and does not provide any preventative assurance against potential adverse reactions.

Immunotherapy

Allergen immunotherapy has been widely practiced for hundred of years. Immunotherapy more recently has been applied to treat food allergy. Research has demonstrated the safety and efficacy of FA immunotherapy (Vickery et al., 2017). The technique of oral immunotherapy (OIT) is a voluntary, FDA-approved treatment option designed to strengthen the body's immune system to tolerate small doses of allergenic foods. Studies have determined that OIT for patients with peanut allergies can safely desensitize an individual to a whole peanut (~300 mg peanut protein), which doctors propose will likely provide adequate protection against most accidental peanut exposures (Vickery et al., 2017). For most patients, peanut OIT has not been shown to be a curative therapy. While immunotherapy is a promising new direction in FA treatment, parents must make an *informed* decision when evaluating this treatment option considering the importance of adherence to at-home dosing. Thus, this option may not be best suited for all patients and families.

The prevalence of FA, the potential danger of accidental exposures, and the resulting stress on patients and families highlight the significant public health burden

related to FA management in children. As a result, healthcare researchers must begin studying novel treatment modalities that can safeguard food-allergic children from the possibility of severe allergic reactions and provide patients and their families with the mental security of immunological protection. It's equally important to consider how parents evaluate these options when they are available.

Clinical Trials Overview

Currently, there is no cure for FA. However, in recent years, health researchers have begun utilizing double-blind, placebo-controlled clinical trials to test novel biological treatments designed to retrain the immune system to be less reactive to food allergens. In general, clinical trials are a type of clinical study that evaluates the effects of novel interventions on relevant biobehavioral health outcomes. Clinical trials for food allergies have the potential to advance medical understanding of food allergy phenotypes and how the condition responds to novel treatment modalities. Given the inherent risks associated with participating in a clinical trial designed to test the effectiveness of experimental products, treatment-related decision-making for these patients and families can be difficult. Further, uncertainty related to treatment outcomes can impede a family's ability to make informed decisions about medical care. To ensure the safety and efficacy of these emerging therapies, participants in clinical trials must reflect the full diversity of the affected population. Although these treatments remain in the clinical trial stage, evidence suggests that individuals differentially engage with these options for a variety of reasons.

Factors Associated with Clinical Trial Participation

Medical decision-making can be complex, especially when multiple treatment options are presented (Redelmeier & Shafir, 1995; Reyna, 2008). Thus, treatment-related decision-making for children with FA requires significant consideration of each treatment's potential costs and benefits, and subjective factors that may influence decision-related outcomes. Currently, there is a paucity of research on how interacting family systems influence parent-led medical decisions in the FA population. However, medical decision-making literature from other populations can help to determine the potential affect various family systems on clinical trial participation for the treatment of pediatric FA.

Child Age

One consideration that parents often make when evaluating treatment options is the age of the child. In a study evaluating enrollment decisions for a randomized controlled trial, researchers found that parents of slightly older children were more likely to consent (Hoberman et al., 2013). In another study evaluating trial participation decisions, the age of the child (≥4 years) was significantly associated with consent (Sureshkumar et al., 2012), suggesting that parents of older children are more likely to consent to this study than parents of younger children. Thus, child age may be a factor that influences parents of older food-allergic children to participate in clinical trials. Importantly, the presence of a relationship between race and child age has not been previously explored in the literature, therefore justifying research into this area.

Parental Knowledge

Previous studies exploring parent treatment preferences found that roughly 50% of respondents felt more comfortable enrolling their child in a trial that involves a drug or

device currently used in their physician's practice (Hoffman et al., 2007). Similar to this study, Dreyzin et al. (2014) found that families were more hesitant to participate in clinical trials with unknown risks. Families in this study also felt less confident in their ability to aptly evaluate different treatment modalities (Dreyzin et al., 2014). Together, these studies highlight the salience of condition-specific knowledge and treatment familiarity among decision-making stakeholders. For parents of food allergic children, FA management requires sufficient knowledge of allergic symptoms and treatment recommendations. As such, parents with greater FA knowledge may have less difficulty evaluating the risks and benefits of novel treatment modalities. However, given existing disparities in FA knowledge, evaluating treatment options may be more difficult for racial and ethnic minority families and therefore result in less interest in clinical trial participation.

Parental Health Beliefs

The likelihood of a parent engaging in a specific health behavior, such as enrollment in a clinical trial, largely depends on their perception of the severity of their child's condition, and their ability to manage it. For example, one study found that parents who perceive their child's condition as more severe expressed greater willingness to enroll in a clinical trial to treat sickle cell disease (Liem et al., 2010). Currently, there is limited empirical evidence on the relationship between parental health beliefs and medical decision-making in the food allergy population. Two studies found that parental confidence in their ability to manage their child's food allergy was associated with lower perceived likelihood of having a severe allergic reaction (Knibb et al., 2015, 2016). Given this finding, we expect parents who express greater self-efficacy may be less

interested in participating in clinical trials for FA. In another study specifically evaluating clinical trial participation, parents who decided to participate in a clinical trial for food allergy perceived that their child was more likely to have a severe allergic reaction that could be fatal (DunnGalvin et al., 2009). Thus, families who perceive their child's food allergy as more severe may express greater interest in clinical trial participation.

Quality of Life

Health is a dynamic phenomenon influenced by physical, psychological, and social factors. The extent to which these factors change over time can impact how a parent perceives their child's quality of life, and subsequently influence their decisions about medical care. Compared to healthcare professionals, parents tend to weigh the child's quality of life more heavily when evaluating treatment options (Janse et al., 2005; Tomlinson et al., 2011). For example, parents of children with life-limiting conditions often strongly consider their child's quality of life over the potential for improved health or prolonged life expectancy when making decisions about the care and treatment of their child (Hinds et al., 1997; Markward et al., 2013; Maurer et al., 2010). In the FA population, research has revealed a diminished quality of life among older children, children with multiple food allergies, and children with a history of severe allergic reactions (Wassenberg et al., 2012). Given the significant burden associated with having a FA, it is essential to capture the extent to which parents of food allergic children consider the quality of life when evaluating treatment options for FA. As such, the decision to participate in different treatment options may depend on how parents perceive their child's health, their quality of life, and the effect treatment may have on the family overall.

Race

Racial diversity in clinical research is essential for the generalizability of research findings (Hussain-Gambles et al., 2004; Yancey et al., 2006) and the equitable distribution of health services (Davis et al., 1985). However, studies have highlighted disparate clinical trial participation rates among Black families (Ni et al., 2016). This reality stems from interpersonal and pragmatic barriers that have impacted Black Americans perceptions of health research and their willingness to participate in clinical trials (Freimuth et al., 2001; Shavers et al., 2002). Specifically, Black Americans have called the integrity of the research institution into question by expressing concerns related to data use (Freimuth et al., 2001), improper treatment of Black research participants (Corbie-Smith et al., 2002), improper consent procedures (Farmer et al., 2007), and the disclosure of private health information (Slomka et al., 2008). Furthermore, studies have found that concerns about the lack of choice over treatment in clinical trials have negatively impacted Black Americans' willingness to participate in health research (Linden et al., 2007). Together, these factors have contributed to the underutilization of health services and the underrepresentation of Black participants in medical research.

Socioeconomic Status

Scarcity and/or lack of resources can significantly impact treatment-related decisions about a child's medical care (Shafir, 2017; Shah et al., 2015). In a study evaluating clinical trial participation, researchers identified disparate clinical trial participation rates among families living in poverty (Ni et al., 2016). This finding highlights the potential barriers to clinical trial participation that may stem from insufficient access to specialty care and information about different treatment options.

It is also important to acknowledge how systemic reactions to race have led to significant pragmatic barriers for Black patients and families. Researchers often conflate being Black with being impoverished. Studies have shown that physicians who possess implicit biases that label Black patients as being medical uncopperative often hesitate to recruit these patients into clinical trials (Kaluzny et al., 1993; Oliver et al., 2014). Taken together, the effect of poverty on illness management and participation in health research can be considered a difference of kind rather than degree when race is considered. In recognition of the various interpersonal and pragmatic barriers Black families of food-allergic children may face, it is necessary to explore how these factors influence parental interest in clinical trial participation.

Insurance Status

Insurance status is often used as an indicator of socioeconomic status, and therefore should be considered in pediatric medical decision-making. Researchers found that individuals with private health insurance were less likely to enroll their children in a clinical trial (Hoberman et al., 2013). Conversely, another study revealed having public health insurance was associated with an increased likelihood of allowing one's child to participate in medical research (Svensson et al., 2012). These findings suggest that health insurance status may influence parental interest in clinical trial participation. However, to date, this relationship has not been explored in the food allergy population. Given the existing literature, parents of food allergic children with public health insurance may to be more interested in clinical trial participation. Additionally, given the demographic make-up of families who are uninsured, publicly insured, and privately insured, it is necessary to explore racial differences across these categories.

Education

Educational attainment is important to consider when evaluating different treatment options and the risks and benefits. Studies have reported having a college degree decreased parents' likelihood of enrolling thier child in a clinical trial (Hoberman et al., 2013). Similarly, another study indicated that low educational attainment was positively associated with a greater likelihood of allowing one's child to participate in medical research (Svensson et al., 2012). Thus, the relationship between parental educational attainment and clinical trial participation may be an important factor to explore in the context of pediatric food allergy. Again, given the racial disparities in educational attainment, it is necessary to evaluate this factor across racial groups as well.

Summary and Aims

Purpose

Treatment-related decision-making for children with FA requires significant consideration of the potential costs and benefits of treatment and subjective factors that may influence decision-related outcomes. Currently, there is a paucity of research on factors may influence parent-led medical decisions in the FA population. Therefore, this study sought to explore the interrelated factors that may influence interest in clinical trial participation for the treatment of pediatric FA. This study has the potential to add to the literature by evaluating the differential effects of child, parent, and family-level factors on interest in clinical trial participation, while also explicitly examining the role of race and socioeconomic status in the analyses.

Specific Aims

The aims and hypotheses of this study are:

Aim 1: Child Factors

Evaluate the effect of child age on parental interest in clinical trial participation among Black and White caregivers. Working hypothesis for Aim 1: Parents of older children will report greater interest in having their child participate in a clinical trial to treat food allergy, regardless of race.

Aim 1a. Evaluate the effect of child age on parental interest in clinical trial participation among the entire sample combining Black and White caregivers.

Aim 1b. Evaluate the effect of child age on parental interest in clinical trial participation among Black caregivers.

Aim 1c. Evaluate the effect of child age on parental interest in clinical trial participation among White caregivers.

Aim 2: Parent Factors

Evaluate the effect of parent FA knowledge, perceived burden, self-efficacy, quality of life, and perceived risk of accidental exposure on parental interest in clinical trial participation among Black and White caregivers. Working Hypothesis for Aim 2: Parents with greater FA knowledge, greater perceived burden, less confidence in their ability to manage their child's food allergy, impaired quality of life, and greater perceived risk of accidental exposure will report greater levels of interest in having their child participate in a clinical trial to treat food allergy. Specific race effects will be evident between Black and White caregivers.

Aim 2a. Evaluate the effect of parent FA knowledge, perceived burden, self-efficacy, quality of life, and perceived risk of accidental exposure on parental interest in

clinical trial participation among the entire sample combining Black and White caregivers.

Aim 2b. Evaluate the effect of parent FA knowledge, perceived burden, self-efficacy, quality of life, and perceived risk of accidental exposure on parental interest in clinical trial participation among Black caregivers.

Aim 2c. Evaluate the effect of parent FA knowledge, perceived burden, self-efficacy, quality of life, and perceived risk of accidental exposure on parental interest in clinical trial participation among White caregivers.

Aim 3: Family Factors

Evaluate the effect of family-level factors on parental interest in clinical trial participation among Black and White caregivers. Working hypothesis for Aim 3: Families with >1 child with FA will report greater interest in having their child participate in a clinical trial to treat food allergy than families with only one child with FA. Families who receive public health insurance will report greater interest in having their child participate in a clinical trial for the treatment of food allergy than families who receive private insurance. Additionally, uninsured and low-SES families will report lower levels of interest in having their child participate in a clinical trial to treat food allergy. Finally, families with higher educational attainment will report less interest in having their child participate in a clinical trial to treat food allergies than families with lower educational attainment. Specific race effects will be evident between Black and White caregiver respondents.

Aim 3a. Evaluate the effect of family-level factors on parental interest in clinical trial participation among the entire sample combining Black and White caregivers.

Aim 3b. Evaluate the effect of family-level factors on parental interest in clinical trial participation among Black caregivers.

Aim 3c. Evaluate the effect of family-level factors on parental interest in clinical trial participation among White caregivers.

Methods

Participating Sites

The study employed a prospective design to identify factors associated with parents' interest in clinical trial participation to treat pediatric FA. The study subsumed under a more extensive parent study funded through the NIH (The FORWARD study: 5R01AI130348-04 to PI – Ruchi Gupta). Recruitment was conducted at four pediatric FA clinics across the United States: Lurie Children's Hospital, Cincinnati Children's Hospital Medical Center (CCHMC), Rush University Medical Center, and Children's National Health System. These sites are world-renowned pediatric FA clinics with inpatient and outpatient Allergy/Immunology services and a strong history of research collaboration. In addition, each hospital operates on an integrated electronic medical record (EMR) system and serve diverse populations with a mix of privately and publicly insured (or uninsured) patients in and around their respective locations. Together, these institutions serve over 15,000 patients annually; thus, the annual patient volume supported enrollment for the study.

Participants

Participants included patients and families seeking services at one of the four pediatric FA clinics mentioned above. Individuals eligible to participate in the FORWARD study met the following criteria: 1) New clinic visit presenting for a possible peanut allergy complaint and/or has a physician diagnosis in a follow-up clinic visit; 2) child is between the age of 6-months and 12 years at intake visit; 3) are English speaking, and 4) no history of developmental disorders. Parents provided written informed consent using procedures approved by the Institutional Review Board at

Northwestern University (NU). An initial intake survey was administered at the time of enrollment, and parents completed quarterly follow-up REDCap surveys via text, email, or phone based on their stated preference.

Marquette University's Institutional Review Board approved the study. Data for this study was extracted by study staff at Northwestern, de-identified, and transferred via a secure, electronic medium. Each participating site signed a reliance and data-sharing agreement, and PIs at each site consented to share data with the investigator.

Measures & Sources of Patient Information

Intake Survey

The intake survey was developed by an expert panel of pediatric allergists and designed by survey methodologists. Basic demographic information was collected—including child age, race/ethnicity, income, education level, and employment status. Food allergy-specific information was also collected, including the number of children with food allergies in the household, history of allergic reactions, severe allergic symptoms, and food allergy management practices. This questionnaire also assessed families' interest in participating in a clinical trial for FA, using a single variable with five response options: 1) Not At All Interested, 2) Slightly Interested, 3) Somewhat Interested, 4) Very Interested, and 5) Extremely Interested. The present study combined these responses to create three interest groups: 1) Not At All Interested, 2) Slightly/Somewhat Interested, and 3) Very/Extremely Interested.

Electronic Health Record

Trained research assistants extracted electronic medical record data to confirm FA diagnosis, patient age at the time of recruitment, and health insurance status for each

child. Health insurance status was stratified by those insured proximal to the study enrollment visit vs. those uninsured. For individuals with health insurance, coverage was further stratified by privately and publicly insured.

Chicago Food Allergy Research Survey for Parents of Children with Food Allergy (*CFARS-PRNT*; R. S. Gupta, Kim, Springston, Pongracic, et al., 2009).

Parental food allergy knowledge was assessed using the Food Allergy Knowledge subscale of the CFARS-PRNT. The Food Allergy Knowledge subscale measure is 15 items (eight true/false, seven multiple choice). Higher scores indicate greater FA knowledge. This measure was assessed at the 6-month timepoint of the FORWARD study. The present study found this scale to demonstrate moderate internal consistency (Cronbach's $\alpha = .56$).

Food Allergy Self-Efficacy Scale for Parents (*FASE-P;* Knibb et al., 2015).

The FASE-P is a validated 21-item measure designed to assess caregiver confidence (self-efficacy) in their ability to manage their child's food allergy. The FASE-P has five subscales: 1) managing social activities, 2) precaution and prevention of an allergic reaction, 3) Identifying allergens, 4) treating an allergic reaction, and 5) seeking information about food allergy. The FASE-P is scored on a 0-100 scale, with higher scores indicating greater confidence in their ability to manage their child's food allergy. The FASE-P has previously demonstrated good internal consistency (Pappalardo et al., 2022; Cronbach's $\alpha = .89$). The present study also found this scale to demonstrate good internal consistency (Cronbach's $\alpha = .90$).

Food Allergy Quality of Life Questionnaire-Parent Form (*FAQLQ-PF-10*; Moynihan et al., 2015).

The FAQLQ-PF-10 is a 10-item short form of the Food Allergy Quality of Life Questionnaire, that assesses the health-related quality of life (HRQoL) of children with food allergies. It is completed by the parent of a food-allergic child, and rated on a 7-point scale ranging from 1 (not at all) to 7 (extremely). Higher FAQLQ-PF-10 scores indicate a more significant negative impact on HRQoL. The present study found this scale to demonstrate excellent internal consistency (Cronbach's $\alpha = .91$).

The Food Allergy Quality of Life – Parental Burden (*FAQL-PB*; Knibb & Stalker, 2013).

The FAQL-PB is a validated 17-item scale designed to assess how troubled parents are by certain aspects of their child's food allergy. Questions cover issues related to going on vacation, participating in social activities, and worries and anxieties over the previous week. Higher scores indicate more significant parental burden associated with their child's food allergy. The FAQL-PB has previously demonstrated excellent internal consistency (Pappalardo et al., 2022; Cronbach's $\alpha = .96$). The present study also found this scale to demonstrate excellent internal consistency (Cronbach's $\alpha = .96$).

Food Allergy Independent Measure (*FAIM*; Van Der Velde et al., 2010)**.**

The FAIM is a validated six-item measure that assesses parents' perceived risk of adverse FA outcomes. Each item is rated on a 7-point Likert scale with higher scores indicating greater perceived risk of adverse FA outcomes. The FAIM has previously demonstrated good internal consistency (Pappalardo et al., 2022; Cronbach's $\alpha = .81$). The present study found this scale to demonstrate good internal consistency (Cronbach's $\alpha = .78$).

Analyses

Data was collected from The FORWARD Study (5R01AI130348-04) and assembled into a dataset that included the following sources: electronic medical record (EMR), Intake Survey, Parental Food Allergy Knowledge Scale, Food Allergy Self-Efficacy Scale, Food Allergy Quality of Life-Parental Burden, and Food Allergy Quality of Life Questionnaire, the Food Allergy Independent Measure; all data was de-identified before transfer. Locally, the dataset was stored on a secure, password-protected external hard drive. Missing data was addressed using full information, maximum likelihood multiple imputations, and limited to no more than 5% of the data.

Aims were examined via six discriminant function analyses (DFA) and three multinomial logistic regressions (MLR). In DFA, the independent variables are the predictors, and the dependent variable is group levels. For the DFA analyses, a single intake variable indicating interest in clinical trial participation for the treatment of pediatric FA served as the DV, with three (3) levels or groups. Families were grouped into the following "interest categories" based on their responses: 1) Not At All Interested, 2) Slightly/Somewhat Interested, and 3) Very/Extremely Interested. For Aim 1, the only child variable used to predict interest group membership was child age (intake survey). Analysis of aim 1 was run three times to evaluate the effect of the child variable in the full dataset and differences between Black and White participants. For Aim 2, parent variables used to predict interest group membership were: parental FA knowledge (Food Allergy Knowledge Scale), FA self-efficacy (Food Allergy Self-Efficacy; FASE), parents' perceived risk of adverse FA outcomes (Food Allergy Independent Measure; FAIM), FA-related quality of life (FAQLQ-PF-10), and perceived parental burden (FA Quality of Life-Parental Burden). Analysis of aim 2 was performed three times to

evaluate the effect of parent variables in the full dataset and differences between Black and White participants.

The same intake variable was used in the MLR analyses to examine the ability of family-level (Aim 3) variables to predict interest group membership. MLR was used (instead of DFA) because this type of analysis is more appropriate for categorical, ordinal, and continuous predictor variables. For Aim 3, family variables used to predict interest group membership were: the number of children with FA in the home (intake survey), insurance status (EMR), income (Intake Survey), and education level (intake survey). Analysis of aim 3 was performed three times to evaluate effect of family-level variables in the full dataset and differences between Black and White participants.

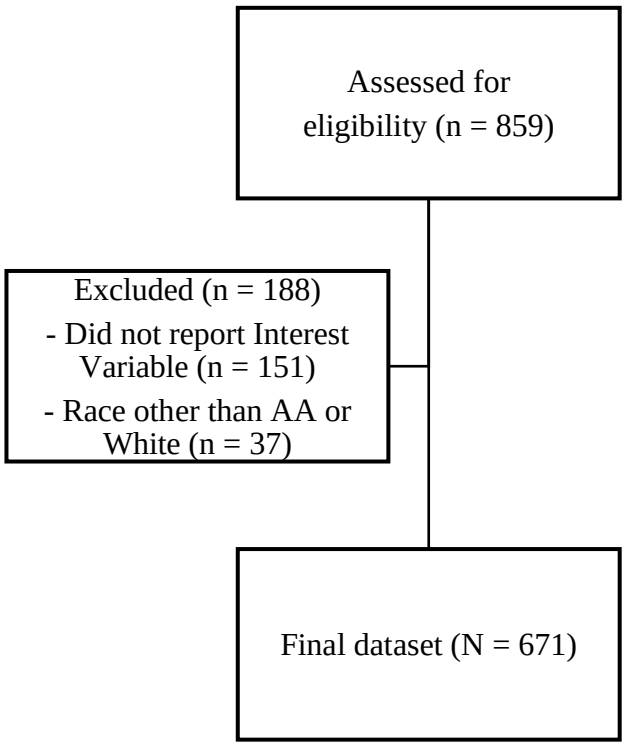
Power for DFA was calculated via power calculations for MANOVA, as DFA is considered the reverse of MANOVA, and the calculations are essentially the same (Tabachnick & Fidell, 2018). An a priori power estimate in GPower 3.1.9, with Cohen's f set to a .1 small effect size, .05 alpha, power of .95, three groups/levels of FA trial interest, and three response variables, indicated that 85 total participants would be necessary for adequate power.

Results

Participant Demographics

Overall, 859 participants in the FORWARD study were assessed for eligibility. Figure 1 displays a consort diagram of eligible participants that were included in the present study. Of note, n = 188 FORWARD participants were excluded for either not reporting on the *Interest* variable (n = 151) or identifying with a race other than Black or White (n = 37). This retained a final sample of *N = 671* for data analyses.

Figure 1
Consort diagram of eligible participants.



The overall sociodemographic characteristics of the sample are displayed in Table 1. 53.1% of parents reported being Very/Extremely Interested in clinical trial participation, followed by 40.2% reporting being Somewhat/Slightly Interested and 6.7% being Not At All Interested. The racial composition of the sample was 65.7% White and 34.3% Black. Overall, there was a relatively even educational and income distribution. Additionally, participants were evenly distributed across all participating sites, and were primarily covered by either public or private insurance.

Table 1
Sociodemographic Characteristics of Participants

Characteristic	N	%
Interest in Clinical Trial Participation		
Not At All Interested	45	6.7
Slightly/Somewhat Interested	270	40.2
Very/Extremely Interested	356	53.1
Race		
White or Caucasian	441	65.7
Black or African American	230	34.3
Level of Education		
Some H.S., No Diploma	9	1.3
H.S. Graduate, Diploma or Equivalent	45	6.7
Some College, No Degree	103	15.4
Associates	46	6.9
Bachelor's	179	26.7
Master's	197	29.4
Professional Degree	25	3.7
Doctorate	67	10
Annual Household Income		
Less than $50,000	163	24.3
$50,000 – $99,000	100	14.9
$100,000 – $149,000	106	15.8
$150,000 – $199,000	63	9.4
$200,000 – $299,000	90	13.4
$300,000 or More	87	13
Unreported	62	9.2
Site		
NU	224	33.4

CCHMC	165	24.6
RUMC	123	18.3
CNH	159	23.7
Insurance Type		
Public	157	23.4
Private	472	70.3
Tricare or Other Military Insurance	3	.4
No Insurance	3	.4
Not Specified	1	.1

Note. H.S = High School; NU = Northwestern University; CCHMC = Cincinnati Children's Hospital Medical Center; RUMC = Rush University Medical Center; CNH = Children's National Hospital.

Aim 1: Child Factors

Child Factors (Overall Sample)

Discriminant analysis was used to determine if child age predicted interest group membership. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in clinical trial participation. The mean age of children in the overall sample was 5.32 years with a standard deviation of 3.65 years. Table 2 presents a summary of the univariate and bivariate statistics for the whole sample. Child age predicted significant differences between groups.

Table 2
Univariate and Bivariate Analyses of Child Factors — Overall Sample.

Child Factor	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
Child Age	4.19 (3.63)	5.08 (3.59)	5.65 (3.67)	.988	2	.018

Note. 652 valid participant responses were included in this analysis, representing 97.2% of the overall sample.

Multivariate analyses revealed that the first discriminant function reliably differentiated among the interest groups (Wilks's $\Lambda = .988$, (2) = 8.07, $p = .018$ for discriminant function 1). The discriminant function explained 100% of the variance. The canonical correlation for DF1 was .111, indicating that 1.2% of the variance in interest group membership was explained by child age. Table 3 shows the structure weight for the discriminant function, revealing that child age contributed to the discrimination among groups, consistent with the bivariate results. The standardized canonical coefficients in Table 3 reveal that child age had a strong, unique contribution to the function.

Table 3
Structure Weights and Standardized Canonical Coefficients for Child Factors.

Child Factors	Structure Weights	Standardized Canonical Coefficients
Child Age	1.00	1.00

Pairwise comparison of the discriminant function scores indicated differences in the following pairs: Not At All Interested (M = -.313) vs. Very/Extremely Interested (M = .089). This indicates that the discriminant function could reliably discriminate parents who were *Not At All Interested* from those who were *Very/Extremely Interested*; however, this function was unable to reliably discriminate parents who were *Not At All Interested* from those who were *Slightly/Somewhat Interested* or *Slightly/Somewhat Interested* from *Very/Extremely Interested*. Figure 2 provides a graphical depiction of the multivariate results, and Table 4 shows the predicted interest group classification results of the discriminant function based on child age. Each show that the discriminant function performed moderately well at differentiating the parents who reported being *Not At All*

Interested in clinical trial participation from parents who reported being *Very/Extremely Interested*. However, there was little success differentiating between the *Not At all Interested* and *Slightly/Somewhat Interested* parents or the *Slightly/Somewhat Interested* and *Very/Extremely Interested* parents. Of note, families who reported being *Not At All Interested* had younger children overall, while parents who reported being *Very/Extremely Interested* had older children.

Figure 2
Graphical Depiction of Group Differentiation based on Child Age.

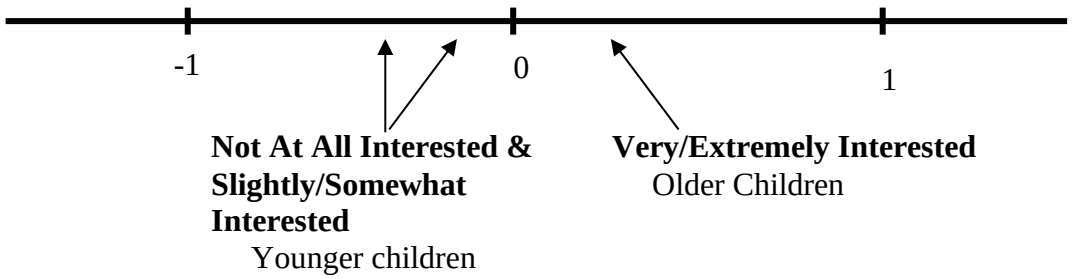


Table 4
Group Classification Results based on Child Age.

Interest Group	Not At All Interested	Slightly/ Somewhat Interested	Very/ Extremely Interested
Not At All Interested	0%	0%	100%
Slightly/Somewhat Interested	0%	0%	100%
Very/Extremely Interested	0%	0%	100%

Note. 53.4% of original group cases were correctly classified.

Black Child Factors

Discriminant function analysis was used to determine if child age was able to predict interest group membership for Black parents. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial

Participation. The mean age of Black children in the sample was 6.49 years with a standard deviation of 3.52 years. Table 5 presents a summary of the univariate and bivariate analyses. Child age predicted significant differences between groups.

Table 5
Univariate and Bivariate Analyses of Child Factors — Black Children.

Child Factors	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
Child Age	5.68 (3.87)	5.67 (3.29)	7.19 (3.48)	.954	2	.008

Note. 218 valid participant responses were included in this analysis, representing 94.8% of the Black participants.

Multivariate analyses revealed that the discriminant function reliably differentiated among the interest groups (Wilks's $\Lambda = .954$, (2) = 10.18, $p = .006$ for discriminant function 1 through 2). The discriminant function explained 100% of the variance. The canonical correlation for DF1 was .215, indicating that 4.62% of the variance in interest group membership for Black parents was explained by child age. Table 6 shows the structure weight for the discriminant function, revealing that child age contributed to the discrimination among groups, consistent with the bivariate results. The standardized canonical coefficient also shown in Table 6 reveal that child age had a strong, unique contribution to the function.

Table 6
Structure Weights and Standardized Canonical Coefficients for Black Child Factors.

Child Factors	Structure Weights	Standardized Canonical Coefficients

Child Age	1.00	1.00

Pairwise comparison on the discriminate function scores indicated that differences were found in the following pairs: Slightly/Somewhat Interested (M = -.238) vs. Very/Extremely Interested (M = .201). This indicates that the discriminant function reliably discriminated Black parents who were *Slightly/Somewhat Interested* from those who were *Very/Extremely Interested*; however, the function was unable to reliably discriminate Black parents who were *Not At All Interested* from those who were *Slightly/Somewhat Interested* or *Very/Extremely*. Figure 3 provides a graphical depiction of the multivariate results, and Table 7 shows the result of DF1 used to re-classify Black parents into their interest groups. Both show that DF1 did moderately well at differentiating the parents who reported being *Slightly/Somewhat Interested* in clinical trial participation from those who reported being *Very/Extremely Interested*. However, there was little success in differentiating between Black parents who were *Not At all Interested* and those who were *Slightly/Somewhat Interested* or *Very/Extremely Interested*. Of note, Black parents who reported being *Not At All* or *Slightly/Somewhat Interested* had younger children overall, while Black parents who reported being *Very/Extremely Interested* had older children.

Figure 3

Graphical Depiction of Group Differentiation based on Child Age – Black Children.

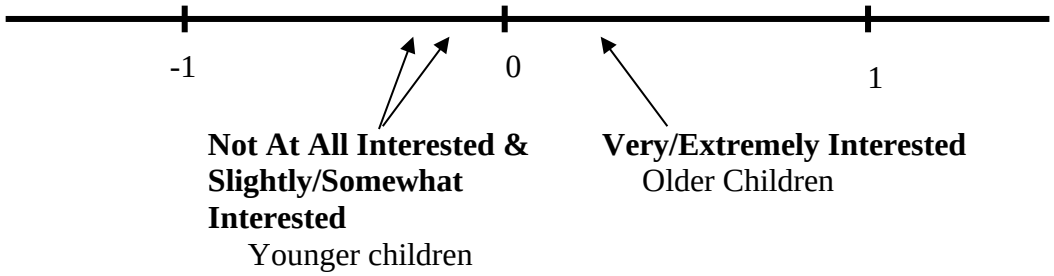


Table 7

Group Classification Results based on Child Age – Black Children.

Interest Group	Not At All Interested	Slightly/Somewhat Interested	Very/Extremely Interested
Not At All Interested	0%	31.8%	68.2%
Slightly/Somewhat Interested	0%	28.2%	71.8%
Very/Extremely Interested	0%	16.9%	83.1%

Note. 55% of original grouped cases were correctly classified.

White Child Factors

Discriminant analysis was used to determine if child age could predict interest group membership for White parents. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. The mean age for White children in this sample was 4.74 years with a standard deviation of 3.58 years. Table 8 presents a summary of the univariate and bivariate analyses. Child age predicted significant differences between groups.

Table 8

Univariate and Bivariate Analyses of Child Factors – White Children.

Child Factors	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
Child Age	2.62 (2.62)	4.83 (3.69)	4.86 (3.52)	.982	2	.021

Note. 434 valid participant responses were included in this analysis, representing 98.4% of the White participants.

Multivariate analyses revealed that the first discriminant function reliably differentiated among the interest groups (Wilks's $\Lambda = .982$, (2) = 7.76, $p = .021$ for discriminant function 1 through 2). The discriminant function explained 100% of the variance. The canonical correlation for DF1 was .134, indicating that 1.7% of the variance in interest group membership for White parents was explained by child age. Table 9 shows the structure weights for the discriminant function, revealing that, consistent with the bivariate results, child age contributed to the discrimination among groups. The standardized canonical coefficients also shown in Table 9 reveal that child age had a strong, unique contribution to the function.

Table 9

Structure Weights and Standardized Canonical Coefficients for White Child Factors.

Child Factors	Structure Weights	Standardized Canonical Coefficients
Child Age	1.00	1.00

Pairwise comparison on discriminant function scores indicated that differences on DF1 were found in the following pairs: Not At All Interested (M = -.596) vs. Slightly/Somewhat Interested (M = .026), and Not At All Interested (M = -.596) vs. Very/Extremely Interested (M = .034). This indicates that DF1 could reliably discriminate White parents who were *Not At All Interested* from those who were *Slightly/Somewhat Interested* and *Very/Extremely Interested*; however, this function was unable to reliably discriminate *Slightly/Somewhat Interested* parents from *Very/Extremely Interested* parents. Figure 4 provides a graphical depiction of the multivariate results, and Table 10 shows the result of DF1 used to re-classify White parents into their interest

groups. Both show that DF1 did moderately well at differentiating White parents who reported being *Not At All Interested* in clinical trial participation from White parents who reported being either *Slightly/Somewhat Interested* or *Very/Extremely Interested* in clinical trial participation. However, there was little success at differentiating between White parents who reported being *Slightly/Somewhat Interested* and *Very/Extremely Interested*. Of note, White parents who reported being *Not At All Interested* in clinical trial participation had younger children overall, while White parents who reported being *Slightly/Somewhat* or *Very/Extremely Interested* had older children.

Figure 4

Graphical Depiction of Group Differentiation based on Child Age – White Children.

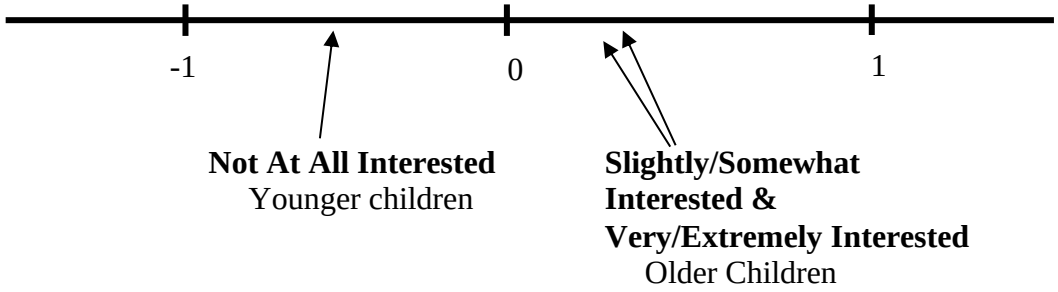


Table 10

Group Classification Results based on Child Age – White Children.

Interest Group	Not At All Interested	Slightly/Somewhat Interested	Very/Extremely Interested
Not At All Interested	0%	0%	100%
Slightly/Somewhat Interested	0%	0%	100%
Very/Extremely Interested	0%	0%	100%

Note. 53% of original grouped cases were correctly classified.

Aim 2: Parent Factors

Parent Factors (Overall Sample)

Discriminant function analysis was used to determine if FA knowledge, parental self-efficacy, FA quality of life, parental burden, and FAIM scores could predict interest group membership. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in clinical trial participation. Table 11 presents a summary of the univariate and bivariate analyses. Parental FA Knowledge and overall FAIM score predicted significant differences between groups; however, Parental burden, Quality of life, and self-efficacy did not.

Table 11

Univariate and Bivariate Analyses of Parent Factors.

Parent Factors	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
FAQLQ-PB	1.96 (1.33)	2.68 (1.50)	2.43 (1.29)	.982	2	.106
Knowledge	8.18 (3.97)	11.32 (2.54)	11.02 (2.98)	.935	2	<.001
FAQLQ-PF-10	2.85 (1.35)	3.46 (1.50)	3.69 (1.56)	.980	2	.083
FAIM	2.87 (1.48)	3.59 (1.16)	3.62 (1.18)	.976	2	.048
FASE-P	80.26 (17.03)	78.18 (13.48)	78.96 (12.28)	.998	2	.800

Note. 250 valid participant responses were included in this analysis, representing 37.3% of the overall sample.

Multivariate analyses revealed that the first discriminant function reliably differentiated among the interest groups (Wilks's $\Lambda = .900$, (10) = 25.70, $p = .004$ for discriminant function 1 through 2); however, the second function did not provide reliable further differentiation (Wilks's $\Lambda = .976$, (4) = 5.92, $p = .205$ for discriminant function 2). The first discriminant function explained 77.5% of the variance. The canonical

correlation for DF1 was .279, indicating that 7.8% of the variance was explained by the relationship between parent predictors and interest group membership by DF1. Discriminant function 1 had the largest relationship with FA knowledge, followed by FAIM, parental burden, FAQLQ-PF, and self-efficacy. Table 12 shows the structure weights for the first discriminant function, revealing that parental knowledge and FAIM scores contributed to the discrimination among groups, consistent with the bivariate results. Inspection of the standardized canonical coefficients also shown in Table 12 reveals that, because of the collinearity amongst other parent factors, only parental FA knowledge and FAIM scores had a strong, unique contribution to the function.

Table 12
Structure Weights and Standardized Canonical Coefficients for Parent Factors.

Parent Factors	Structure Weights	Standardized Canonical Coefficients
Knowledge	.908	.836
FAIM	.538	.344
FAQLQ-PF-10	.404	.138
FAQLQ-PB	.392	.054
FASE-P	-.117	.183

Pairwise comparison on DF1 scores indicated that differences on DF1 were found in the following pairs: Not At All Interested (M = -1.06) vs. Slightly/Somewhat Interested (M = 0.11) and Not At All Interested (M = -1.06) vs. Very/Extremely Interested (M = 0.05). This indicates that DF1 could reliably discriminate Not At All Interested from Slightly/Somewhat Interested and Not At All Interested from Very/Extremely Interested; however, this function was unable to reliably discriminate Slightly/Somewhat Interested from Very/Extremely Interested. Figure 5 provides a graphical depiction of the multivariate results, and Table 13 shows the result of DF1 used

to reclassify patients into their interest groups. These show that DF1 did very well at differentiating the parents who reported being Not At All Interested in clinical trial participation, who reported less FA knowledge and lower FAIM scores than the other two groups. However, there was little success differentiating between the Slightly/Somewhat Interested and Very/Extremely Interested parents.

Figure 5

Graphical Depiction of Group Differentiation based on Parent Factors.

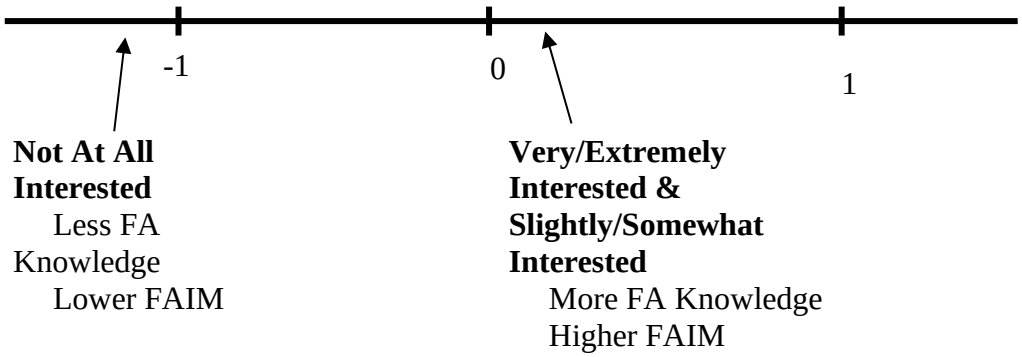


Table 13

Group Classification Results based on Parent Factors.

Interest Group	Not At All Interested	Slightly/Somewhat Interested	Very/Extremely Interested
Not At All Interested	17.6%	0%	82.4%
Slightly/Somewhat Interested	0%	21.4%	78.6%
Very/Extremely Interested	1.5%	9.6%	88.9%

Note. 57.6% of original grouped cases were correctly classified.

Black Parent Factors

Discriminant function analysis was used to determine if FA knowledge, parental self-efficacy, FA quality of life, Parental burden, and FAIM scores could predict interest group membership for Black parents. Interest groups included: Not at All Interested,

Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. Table 14 presents a summary of the univariate and bivariate analyses.

Table 14
Univariate and Bivariate Analyses of Black Parent Factors.

Parent Factors	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
FAQLQ-PB	1.88 (1.17)	2.46 (1.48)	1.99 (1.16)	.965	2	.289
Knowledge	9 (2.31)	9.12 (1.86)	8.57 (2.42)	.986	2	.608
FAQLQ-PF-10	3.09 (1.32)	3.78 (1.57)	3.85 (1.75)	.976	2	.423
FAIM	2.80 (1.39)	3.55 (1.19)	3.41 (1.37)	.967	2	.313
FASE-P	82.87 (14.73)	77.31 (16.37)	84.05 (13.43)	.955	2	.198

Note. 73 valid participant responses were included in this analysis, representing 31.7% of the Black participants.

Multivariate analyses revealed that neither of the discriminant functions reliably differentiated among the interest groups (Wilks's $\Lambda = .877$, (10) = 8.93, $p = .539$ for discriminant function 1 through 2; Wilks's $\Lambda = .966$, (4) = 2.36, $p = .67$ for discriminant function 2). These discriminant functions explained 74.2% and 25.8% of the variance. The canonical correlation for DF1 and DF2 were .30 and .19, indicating that 9% and 3.6% of the variances were explained by the relationship between predictors and group membership for DF1 and DF2, respectively. As neither discriminant function was significant, relationships with individual predictors, structure weights, classification summaries, and pairwise comparisons were not explored.

White Parent Factors

Discriminant function analysis was used to determine if FA knowledge, parental self-efficacy, FA quality of life, Parental burden, and FAIM scores were able to predict interest group membership for White parents. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. Table 15 presents a summary of the univariate and bivariate analyses. Parental FA Knowledge was the only factor that predicted significant differences between groups; overall FAIM scores, parental burden, quality of life, and self-efficacy did not.

Table 15

Univariate and Bivariate Analyses of White Parent Factors.

Parent Factors	Not At All Interested M (SD)	Slightly/ Somewhat Interested M (SD)	Very/ Extremely Interested M (SD)	Wilks' Lambda	df	*p*
FAQLQ-PB	2.07 (1.63)	2.75 (1.51)	2.60 (1.31)	.990	2	.428
Knowledge	7 (5.59)	12.11 (2.28)	11.94 (2.63)	.878	2	<.001
FAQLQ-PF-10	2.49 (1.42)	3.35 (1.47)	3.62 (1.48)	.974	2	.102
FAIM	2.95 (1.72)	3.61 (1.16)	3.69 (1.10)	.984	2	.251
FASE-P	76.52 (20.49)	78.49 (12.39)	77.04 (11.29)	.996	2	.723

Note. 177 valid participant responses were included in this analysis, representing 40.1% of the White participants.

Multivariate analyses revealed that the first discriminant function reliably differentiated among the interest groups (Wilks's $\Lambda = .842$, $(10) = 29.65$, $p < .001$ for discriminant function 1 through 2); however, the second function did not provide reliable further differentiation (Wilks's $\Lambda = .971$, $(4) = 5.04$, $p = .283$ for discriminant function

2). The first discriminant function explained 83.8% of the variance. The canonical correlation for DF1 was .37, indicating that 13.7% of the variance was explained by the relationship between White parent predictors and interest group membership by DF1. Discriminant function 1 had the largest relationship with FA knowledge, followed by FAQLQ-PF, overall FAIM scores, parental burden, and self-efficacy. Table 16 shows the structure weights for the first discriminant function, revealing that parental knowledge contributed to the discrimination among groups, consistent with the bivariate results. Inspection of the standardized canonical coefficients also shown in Table 16 reveals that only parental FA knowledge had a strong, unique contribution to the function because of the collinearity amongst other parent factors.

Table 16
Structure Weights and Standardized Canonical Coefficients for White Parent Factors.

Parent Factors	Structure Weights	Standardized Canonical Coefficients
Knowledge	.950	.928
FAQLQ-PF-10	.326	.168
FAIM	.302	.123
FAQLQ-PB	.222	.044
FASE-P	.057	.293

Pairwise comparison on DF1 scores indicates that differences on DF1 were found in the following pairs: Not At All Interested (M = -1.91) vs. Slightly/Somewhat Interested (M = 0.11) and Not At All Interested (M = -1.91) vs. Very/Extremely Interested (M = 0.06). This indicates that DF1 could reliably discriminate Not At All Interested from Slightly/Somewhat Interested and Not At All Interested from Very/Extremely Interested; however, this function was unable to reliably discriminate Slightly/Somewhat Interested from Very/Extremely Interested. Figure 6 provides a

graphical depiction of the multivariate results, and Table 17 shows the result of DF1 used to reclassify patients into their interest groups. Both of these show that DF1 did very well at differentiating the parents who reported being Not At All Interested in clinical trial participation who reported less FA knowledge from the other two groups. However, there was little success differentiating between the Slightly/Somewhat Interested and Very/Extremely Interested parents.

Figure 6
Graphical Depiction of Group Differentiation based on White Parent Factors.

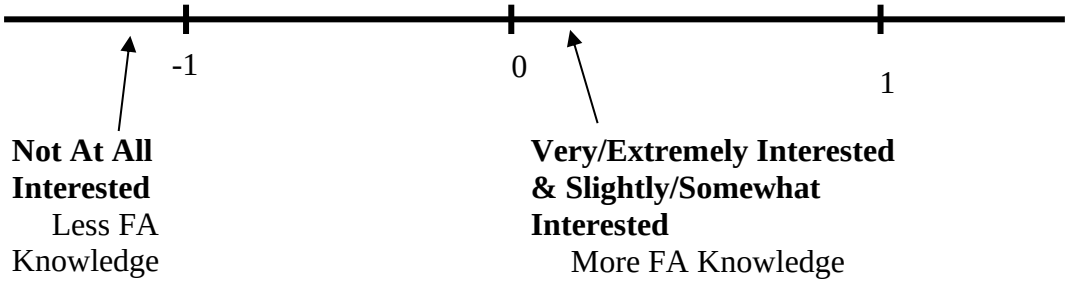


Table 17
Group Classification Results based on White Parent Factors.

Interest Group	Not At All Interested	Slightly/Somewhat Interested	Very/Extremely Interested
Not At All Interested	42.9%	28.6%	28.6%
Slightly/Somewhat Interested	1.4%	27.8%	70.8%
Very/Extremely Interested	0%	13.3%	86.7%

Note. 61% of original grouped cases were correctly classified.

Aim 3: Family Factors

Family Factors (Overall Sample)

Multinomial logistic regression was performed to model the relationship between the family factors and interest group membership. Family factors included: insurance type, income, educational attainment, and the number of children in the home with food allergy. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. The traditional .05 criterion of statistical significance was employed for all tests. Addition of the predictors to a model that contained only the intercept did not significantly improve the fit between model and data, $\chi^2(36, N = 421) = 19.896$, Nagelkerke $R^2 = .055$, $p = .986$. As such, explorations of unique contributions, Goodness of fit, and parameter estimates were not conducted.

Black Family Factors

Multinomial logistic regression was performed to model the relationship between the Black family factors and interest group membership. Family factors included: insurance type, income, educational attainment, and the number of children in the home with food allergy. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. The traditional .05 criterion of statistical significance was employed for all tests. Addition of the predictors to a model that contained only the intercept did not significantly improve the fit between model and data, $\chi^2(34, N = 148) = 30.314$, Nagelkerke $R^2 = .217$, $p = .649$. As such, explorations of unique contributions, Goodness of fit, and parameter estimates were not conducted.

White Family Factors

Multinomial logistic regression was performed to model the relationship between the White family factors and interest group membership. Family factors included:

insurance type, income, educational attainment, and the number of children in the home with food allergy. Interest groups included: Not at All Interested, Slightly/Somewhat Interested, and Very/Extremely Interested in Clinical Trial Participation. The traditional .05 criterion of statistical significance was employed for all tests. Addition of the predictors to a model that contained only the intercept did not significantly improve the fit between model and data, $\chi^2(34, N = 273) = 42.337$, Nagelkerke $R^2 = .173$, $p = .154$. As such, explorations of unique contributions, Goodness of fit, and parameter estimates were not conducted.

Discussion

Clinical trials are essential for evaluating the safety, efficacy, and acceptability of novel treatment modalities. Health researchers aim to recruit representative samples that reflect the full diversity of the affected population, and account for unique phenotypes and endotypes. Considering the decision to enroll a child in a clinical trial may be difficult for parents, therefore it is important to carefully evaluate the various factors that may influence their treatment-related decisions. To date, this is the first study of its kind to evaluate the effect of child, parent, and family-level factors on parental interest in clinical trial participation for the treatment of pediatric food allergy.

Examination of child factors revealed that child age uniquely predicted parental interest in clinical trial participation. Consistent with previous research (Hoberman et al., 2013; Sureshkumar et al., 2012), the present study found that parents of older children were more interested in clinical trial participation than parents of younger children. These findings are particularly timely as recent studies have identified similar trends in COVID-19 vaccine research. Specifically, research in this area suggests parents of older children are more willing to enroll their children in clinical trials of the COVID-19 vaccine (Goldman et al., 2020, 2021). Thus, researchers must carefully consider how to address the potential concerns and motivations of parents of younger children, in order to enroll the full age spectrum of the affected population.

Additionally, the significance of child age and its ability to differentiate between interest groups varied by race. On average Black children in this study were slightly older than White children. This finding can be partially understood in the context of other studies citing under-diagnosis and/or inadequate access to specialty care for FA among

urban minority children, contributing to increased age at the time of initial diagnosis (Mahdavinia et al., 2017; Taylor-Black & Wang, 2012). Interestingly, there was a small difference in the percentage of the variance in interest group membership explained by child age between Black and White parents, suggesting child age may play a greater role Black parent's decision-making process.

In the overall sample, child age reliably differentiated parents who reported being not at all interested in clinical trial participation from parents who were very/extremely interested. However, child age alone was unable to reliably differentiate parents who were *Not At All Interested* from those who were *Slightly/Somewhat Interested* or *Slightly/Somewhat Interested* from *Very/Extremely Interested*.

Similar to the overall sample, child age reliably differentiated White parents who reported being *Not At All Interested* in clinical trial participation from White parents who reported being either *Slightly/Somewhat Interested* or *Very/Extremely Interested* in clinical trial participation. However, among White parents, child age alone was unable to reliably differentiate White parents who reported being *Slightly/Somewhat Interested* from those who were *Very/Extremely Interested*. The slight nuance in the difference between White parents and the overall sample might be explained by the removal of Black respondents from this analysis, and the results of the overall sample may be a more accurate representation. Additionally, child age reliably differentiated Black parents who were *Slightly/Somewhat Interested* from those who were *Very/Extremely Interested*, but was unable to reliably differentiate Black parents who were *Not At All Interested* from those who were *Slightly/Somewhat Interested* or *Very/Extremely*. This finding could be in part due to the relatively small number of Black respondents who reported being *Not At*

All Interested in clinical trial participation. Despite these marginal differences, child age remained a notable factor that influenced interest in clinical trial participation among *all* families included in the study.

Regarding parent factors, FA knowledge and parents' perceived risk of adverse FA outcomes significantly predicted interest in clinical trial participation. Parents who reported less FA knowledge and less perceived risk of adverse FA outcomes were less interested in clinical trial participation. At present, this is the first study to elucidate the effect of condition-specific knowledge and perceived outcome risk on interest in clinical trial participation for parents of food-allergic children.

Interestingly, race effects were evident in this study. Among White parents, FA knowledge was the only reliable predictor of interest in clinical trial participation, but perceived risk of adverse FA outcomes was no longer significant. This finding suggests that White parents are influenced more by FA knowledge alone when considering whether or not to participate in a clinical trial. As such, White parents who report less FA knowledge may require specific interventions to increase their knowledge before they consider enrolling their child in a clinical trial.

On the other hand, among Black parents, none of the parent variables examined were reliable predictors of interest in clinical trial participation. In other words, interest in clinical trial participation does not seem to be about knowledge or perceived risk of adverse FA outcomes for Black parents. Literature has shown that poor and working-class Black individuals have a different relationship with the medical field (George et al., 2014). In a systematic review of barriers to minority research participation, researchers highlighted five distinct barriers to health research participation among Black Americans,

all of which fell under the umbrella of a legacy of distrust (George et al., 2014). These themes included: knowledge of the Tuskegee Study (Shavers et al., 2002), lack of research integrity (Corbie-Smith et al., 2002; Freimuth et al., 2001; Slomka et al., 2008), a legacy of racism and discrimination in the healthcare system (Kaluzny et al., 1993), and concerns with the research process (Farmer et al., 2007).

In addition to distrust, the perception of risk involved with clinical trials (Ding et al., 2007) and the associated fear of research participation (Katz et al., 2006) have also been recognized in the literature as impeding factors to clinical trial enrollment for Black Americans. Although past research has found that Black Americans perceive greater risk involved in clinical trial participation (Braunstein et al., 2008; Kim et al., 2015), this was not directly explored in the present study. This study suggests that interest in clinical trial participation for Black parents may be influenced by factors not considered in the present study. Inevitably, there is more to be explored to determine what helps Black parents make decisions related to treatment options for their food-allergic children.

Lastly, and contrary to our study hypothesis, no family factors were reliable predictors of interest in clinical trial participation. The variables included for the family analyses did not appear to affect parents' decision-making regarding interest in clinical trials. This pattern of null relationships was also observed across racial groups. Although this aim was not supported in the present analysis, it provides valuable insight into what families may consider more strongly when evaluating treatment options. In the present study, insurance status, educational attainment, and income were used as proxy indicators of socioeconomic status due to their known associations with clinical trial participation in other populations (Hoberman et al., 2013; Svensson et al., 2012). Additionally, past

research has identified disparate clinical trial participation rates among families living in poverty (Ni et al., 2016). However, the mechanisms that could lead to these findings are complex and multidimensional. Experiencing socioeconomic disadvantage can result in several pragmatic barriers to research participation (e.g., lack of childcare and inability to miss work). As such, studies have reported that intervention research requiring active caregiver participation has lower recruitment and retention rates than solely child-focused studies (Cui et al., 2015). Thus future studies should explore the effect of pragmatic barriers on clinical trial interest and participation in the food allergy population.

Limitations & Future Directions

The current study had several limitations that should be considered. First, the study examined interest in clinical trial participation as the outcome variable and not actual enrollment. Data on actual clinical trial enrollment (i.e., whether families followed through on that interest) was unavailable and those a gap exists that cannot be explained by the current study. This difference between interest and actual enrollment may depend largly on demographic and economic variables. For example, in the event a parent does not have the resources to travel to a trial or take off work to participate, they may report interest in enrollment but not follow through with actual enrollment because of these barriers. As such, it is not possible to extrapolate the findings of the present study to predict actual clinical trial enrollment.

Additionally, the present study had a small number of participants who reported not being interested in clinical trial participation. Future qualitative studies should target these individuals specifically to get richer data about what drives their decision-making. Learning about the individuals who decline to participate, or express a lack of interest in

clinical trials altogether, would be valuable information for clinicians and researchers. Aspects of clinical trials themselves may create practical barriers to clinical trial participation that are not yet explored. Thus, gathering qualitative information could help providers understand if patient and family decision-making is based on the characteristics of the study itself.

Further, considering the decision to participate in clinical trials is dichotomized (i.e., consent or decline to consent), it is also important to understand individuals' reasons for declining to participate in these studies. For instance, what factors influence their actual decision for families who express interest in trial participation but decline to participate. Qualitative research could provide greater insight into the potential barriers between interest and actual participation. Therefore future studies should employ qualitative methods to explore the subjective elements influencing parents' decisions to participate in clinical trials.

Second, the present study found that child age is an important factor for both White and Black families in predicting interest in clinical trial participation for pediatric food allergy. As children age, their caregivers may have different values and beliefs about care decisions. However, child age alone accounted for a very small amount of the variance explained making it a considerable limitation. Given the small variance in interest group membership explained by child age, future studies should explore additional child factors that may influence parental interest in clinical trial participation. Additional factors may include condition severity, child gender, and perceived capacity for shared decision-making.

Third, parental FA knowledge was also a salient factor for White parents. However, the FA knowledge measure used in the present study narrowly focused on the condition itself and its management, thereby limiting the ability to assess parental knowledge more broadly. Previous studies suggest that parental understanding of basic clinical research concepts and the research process itself can influence their medical decision-making (Cousino et al., 2018; Kim et al., 2015; Kodish et al., 2004). Thus, future studies should explore how knowledgeable parents are about clinical trials themselves to determine where psychoeducation can support the optimal recruitment of diverse research samples.

Finally, none of the demographic variables emerged as important factors in predicting interest, suggesting that prior assumptions about lack of participation due to these factors may not be entirely correct, at least in the United States. Future studies should incorporate these findings and address these issues to improve clinical trial enrollment and equitable participation of diverse samples in food allergy clinical trial research. One consideration is to explore parents subjective social status, which has been identified as a better indicator of health behavior change compared to income, education, or insurance status alone (Adler, 2009).

Although there were limitations, the results of this study suggest some important avenues for future research on clinical trial participation in pediatric food allergy. This translational study significantly advances decision science, addresses existing disparities, and can have far-reaching clinical implications. Specifically, this project attended to two fundamental issues in the FA literature: 1) What considerations do parents of food allergic children make when evaluating treatment options, and 2) how can healthcare

professionals improve the generalizability of clinical findings through recruitment of diverse research samples? Furthermore, this study was unique in that it leveraged pediatric medical decision-making literature from other conditions to examine the extent to which different levels within a family system interact to influence treatment-related decision-making and health management for FA. As such, this focus improves our understanding of the factors that influence parent's FA-related medical decision processes, and the mechanisms that contribute to existing disparities in health research participation. In turn, this study has the potential to inform research practices and future clinical guidelines aimed at recruiting representative samples and achieving health equity.

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