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Oral Immunotherapy (OIT)-related awareness, attitudes, and experiences among a Nationally-Representative Sample of Food Allergy Patients/Caregivers

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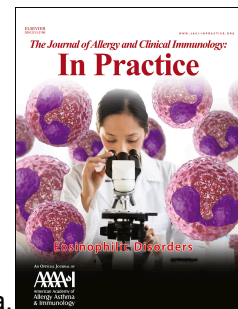
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32 Technologies, ICER, DOTS Technology, and FARE.

33 Dr. Warren has served as an epidemiological consultant for Alladapt Immunotherapeutics.

34 Dr. Casale served as an investigator on Aimmune clinical trials and currently serves as Distinguished
35 Chairman of the FARE Clinical Network

36 Dr. Vickery reports research grants from NIH-NIAID and Food Allergy Research and Education (FARE)
37 as well as other research support from Aimmune Therapeutics; DBV Technologies; Genentech; and
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39 capacity for Aimmune Therapeutics; AllerGenis, LLC; FARE; Reacta Biosciences; and Regeneron.

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41 Anita Roach is Vice President of Community Access & Education at FARE.

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51 Abstract

52 **Background:** Advances in oral immunotherapy (OIT) have led to recently expanded treatment options
53 for food allergy (FA) patients. However, to inform future outreach efforts and ensure equitable access to
54 emerging treatments, a greater understanding of current OIT-related awareness, attitudes and experiences
55 is needed.

56 **Objective:** To characterize current OIT awareness, attitudes and experiences among a nationally-
57 representative sample of US adults with FA and parents/caregivers of pediatric patients.

58 **Methods:** A probability-based sample of US adults and parents/caregivers of children with FA was
59 surveyed about OIT-related knowledge, attitudes, and experiences.

60 **Results:** Surveys were completed by respondents (N=781) from all 50 states. Overall, 72% did not know
61 what OIT was prior to the survey. Respondents from households earning over \$100,000/year or with a
62 college degree each had significantly greater odds of reporting any OIT awareness compared to lower-
63 income (OR=2.0; 95%CI:1.2-3.4) and non-college-educated (OR=1.9; 95%CI:1.2-3.0) respondents.
64 Among respondents familiar/unfamiliar with OIT, 54%/34% reported their expected treatment outcome
65 was to obtain protection against accidental exposure. Among respondents familiar/unfamiliar with OIT,
66 38%/35% reported their expected treatment outcome to be curing the allergy. Furthermore, 55% of OIT
67 unfamiliar respondents said they would not be comfortable initiating a conversation with their healthcare
68 provider about their suitability for OIT.

69 **Conclusion:** This study shows that among a nationally-representative sample of FA patients and pediatric
70 caregivers, awareness of OIT is low, and over 95% of patients lack personal experience with OIT.
71 Furthermore, the data suggest current OIT awareness is disproportionately elevated among wealthier,
72 more highly-educated respondents.

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76 Highlights Box**77 What is already known about this topic?**

78 Clinical trials have found oral immunotherapy (OIT) to be a promising method of food allergy (FA)
79 treatment. However, data surrounding OIT awareness, attitudes, and experiences among FA patients and
80 their parents/caregivers remains lacking.

81 What does this article add to our knowledge?

82 This study provides valuable data on current OIT awareness, attitudes and experiences among a nationally-
83 representative sample of US adults with FA and caregivers of pediatric patients.

84 How does this study impact current management guidelines?

85 This study shows that OIT awareness lies disproportionately with wealthier, more-educated FA patients
86 and families. Future outreach efforts are needed to ensure equitable access to OIT.

87

88 **Keywords:** Food allergy; food allergy treatment; oral immunotherapy

89

90 Abbreviations:

91 FA: Food Allergy

92 SCIT: Traditional Subcutaneous Immunotherapy

93 OIT: Oral Immunotherapy

94 FAQL: Food Allergy-Related Quality of Life

95 EAI: Epinephrine Auto-Injector

96 ED: Emergency Department

97 FDA: Food and Drug Administration

98 LABA: Long-Acting Beta Antagonist

99 ICS: Inhaled Corticosteroid

100 OFC: Oral Food Challenge

101 US: United States

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125 **Introduction**

Food allergy (FA) is a significant health concern affecting approximately 8% of children¹ and 10% of adults² in the U.S. Currently, recommended food allergy management involves strict avoidance of the offending food and ensuring ready access to epinephrine.^{3, 4} This poses a great challenge for patients and families as it can impair quality of life,⁵ impose financial burdens,⁶ and potentially result in life-threatening anaphylaxis following accidental ingestion.⁷ The substantial population-level burden of FA has spurred advances in food allergen immunotherapy, which aims to systematically desensitize patients to target allergens through repeated exposure to subthreshold doses of their allergen.⁸ Traditional subcutaneous immunotherapy (SCIT) is well-established as a treatment for allergic rhinitis,⁹ asthma,¹⁰ and venom allergy,¹¹ but has been found unsuitable for FA treatment due to a high rate of systemic reactions.¹²

A growing body of clinical research has found oral immunotherapy (OIT) to be a promising method of FA treatment and several clinical trials have shown positive results.¹³⁻¹⁵ While this treatment has been shown to induce desensitization for egg,¹⁶ milk,¹³ peanut,¹⁷ and tree nuts, the ability to induce sustained unresponsiveness to the food allergen after discontinuation of OIT appears limited. Though desensitization is an advance for patients, the ultimate therapeutic goal remains a more long-term clinical effect, such as sustained unresponsiveness or true tolerance, where clinical protection endures following discontinuation of therapy. In 2020, the FDA approved *Palforzia*®, a drug product comprised of peanut flour,¹⁸ for use in OIT, making it the first approved treatment for patients, ages 4-17, with peanut allergy. The efficacy of this product was established in a 52-week randomized double-blind trial where peanut-allergic patients were able to tolerate higher doses of peanut protein with lower symptom severity during exit food challenges compared to placebo.¹⁹ Crucially, a growing literature has also found that in some but not all studies, OIT can lead to significant improvements in food allergy-related quality of life (FAQL). For example, one recent longitudinal²⁰ study reported significant improvements in FAQL after reaching OIT maintenance, with additional improvement six months later. However, effects are complex and FAQL changes reported by patients do not always match parent/caregiver report.

As scientific understanding improves regarding the safety and effectiveness of OIT, more data are needed to understand current awareness, attitudes, and experiences regarding OIT among food allergy patients and their caregivers.^{21, 22} Additionally, much of what is known about patient/caregiver knowledge and attitudes regarding OIT has been solicited disproportionately from patient/caregivers in well-resourced families with high levels of parental education. Therefore a major limitation of existing literature is the difficulty in generalizing the experiences of their highly selected study samples to the broader food allergy population, which is much more diverse.^{22, 23} For example, the population enrolled in clinical trials for Palforzia¹⁹ was not representative of the US food allergy population, particularly with respect to underrepresentation of racial/ethnic minorities.

There are numerous geographic, clinical and socioeconomic barriers to participation in OIT via ongoing clinical trials and through private practice allergists. To better understand and address these barriers, it is essential to reach out to a diverse sample of food allergy patients and solicit their perspectives. To this end, this study aims to characterize current OIT awareness, attitudes and experiences among a geographically, clinically, and socioeconomically diverse, nationally-representative sample of US households--including both adult patients and caregivers of children with food allergy.

Methods

Study Participants, Recruitment, and Survey Weighting

Eligible study participants included adults (>18 years old) able to complete the survey in English or Spanish via the web or telephone who resided in a US household and reported at least one household-member with a current, physician-diagnosed food allergy. Participants were recruited from the nationally-representative “*AmeriSpeak*” household panel for US population-level inference. Informed consent was obtained from all participants during enrollment into the *AmeriSpeak* panel. The NORC at the University of Chicago Institutional Review Board approved all study activities.

176 Participants were surveyed from October 21-25, 2019 about OIT-related knowledge, attitudes, and
177 experiences as well as food allergy characteristics. Surveys were developed by a multidisciplinary team
178 of caregivers, patient advocates, allergists, pediatricians, and statisticians using expert consensus and
179 literature review. Among 18,574 invited *AmeriSpeak* panelists 3844 completed a screener, of whom 876
180 were eligible for the interview and 781 completed the survey. Respondents were offered the cash
181 equivalent of \$3.00 upon survey completion.

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183 Each respondent was assigned a base, study-specific sampling weight equal to their or their responding
184 parent's nonresponse-adjusted *AmeriSpeak* sampling weight. Iterative proportional fitting methods were
185 applied to rake adult sampling weights to external population totals associated with age, sex, educational
186 attainment, race/ethnicity, housing tenure, telephone status, and Census Division to improve external
187 validity. Frequencies and complex survey weighted proportions were calculated to estimate the relative
188 frequency of key study variables using the *survey* package of R 4.0.

189 In order to determine the extent to which key hypothesized determinants--household income, educational
190 attainment, and race/ethnicity--were associated with OIT awareness, a multiple logistic regression model
191 was fit using the following set of covariates, which were identified a priori as potential confounders of
192 associations between these demographic indicators of socioeconomic privation and OIT awareness.

193 Dichotomous indicators of respondent Race/Ethnicity were included, which modeled Black, Hispanic,
194 Asian, and Multiple/Other, each of which used White Race/Ethnicity as the reference group. A
195 dichotomous indicator of annual household income was included using a cutoff of \$100,000/year, while a
196 dichotomous indicator of respondent educational attainment compared those with at least a 4-year college
197 degree vs. those with less than a college education. Residence in a US Census-designated metropolitan
198 area was also modeled (vs. residence in a non-Metropolitan region). Participant male gender was modeled
199 dichotomously with female as the reference group, as was age, which was modeled as continuous via the
200 following 7 categories (18-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+); respondents aged 18-24 were the

reference group. Additional dichotomous indicators of the presence of each of the “Top 9” food allergens were included with separate indicators for crustacean vs mollusk shellfish. A dichotomous indicator reflecting lifetime history of Epinephrine Auto-Injector (EAI) use to treat severe food-induced anaphylaxis (vs no EAI use) was also included, as was a continuous indicator of the number of years since the target individuals’ food allergy was diagnosed. Finally, indicators of whether the respondent was completing the survey on behalf of a food-allergic child <13 years of age; 13-18 years of age; or >18 years of age were included, each of which used adult respondents reporting about their own food allergy as a reference group. OIT awareness/familiarity was modeled as a dichotomous outcome (Totally Unfamiliar=0; Slightly Familiar, Familiar, Very Familiar, or Experienced=1). Complex survey-weighted logistic regression analyses were conducted using the svyglm function from the “survey” package. Exponentiated regression coefficients and corresponding 95% CIs are visualized in Figure 1 via dot and whisker plots, created using the dwplot package in R 4.0. Two-sided hypothesis tests were used, with 2-sided $P < .05$ considered to be statistically significant.

Results

Demographics

A total of 781 survey responses were obtained from 879 households meeting screener eligibility criteria, resulting in a survey completion rate of 88.9%. Survey-weighted demographics are reported in Table 1 and were consistent with national data from the Current Population Survey. For example, 51.5% of the sample was non-Hispanic White, 15.7% were non-Hispanic Black, 4.6% were non-Hispanic Asian and 22.0% were Hispanic, with roughly half of the sample reporting annual household income of <\$50,000/year. Slightly over half (56.2%) of respondents were female, and participant age and educational attainment was broadly distributed. Over half of respondents were food-allergic adults and completed the survey with respect to their own food allergy, while 17% provided parent-proxy report on

behalf of a <13-year-old. Nine percent of respondents reported on behalf of a 13 to 18-year-old child, while 15% reported on behalf of a child >18 years of age.

As reported in Table 2, among surveyed individuals, 61% were diagnosed by a primary care provider, while 32% were allergist-diagnosed. The most common food allergies reported were milk (26.5%), peanut (20.9%), crustacean (19.8%), tree nut (15.3%), egg (11.7%), wheat (11.3%), mollusk (9.2%), fin fish (8.4%), soy (6.4%), and sesame (2.3%). Among participants 41.0% had a food allergy for >10 years, while 8.5% had a food allergy for less than 1 year. Approximately a quarter (25.4%) of respondents reported at least 1 ED or urgent care physician visit for acute food allergy treatment within the past 12 months, while 37.8% reported having visited an allergist for food allergy care within the past 12 months. Approximately 1 in 4 (25.6%) had ever been treated with an EAI due to a food-allergic reaction, with over half (56.9%) of those reporting previous EAI use having been treated with an EAI at least once within the previous 12 months.

OIT Awareness

Approximately three-quarters of respondents from this general-population sample of food-allergic households reported that they were either totally unfamiliar with OIT (43%), or that they had heard of OIT but didn't know what it was (29%) (Table 3). Moreover, 22% reported familiarity with OIT, but that nobody in their household planned to start. Four percent of respondents had a household member who either planned to start OIT or had already received OIT.

The majority (54%) of respondents who were familiar with OIT (Table E1), reported their expected treatment outcome was to obtain protection against accidental exposure--substantially more than the 34% of OIT unfamiliar respondents who shared this same expectation after reading a brief description of OIT (Table E2). In contrast, the most desired treatment outcome, reported by 35% of OIT unfamiliar respondents was "*a treatment that would 'cure the allergy' allowing large amounts of protein to be eaten*". Patients who were initially familiar with OIT were more likely to endorse "*a treatment that*

249 would: allow socializing in the presence of the allergen (38%), decrease the number of ER/Urgent Care
250 visits (44%), and/or decrease the number of times an epinephrine auto-injector is needed (37%)”.

251 Among respondents reporting familiarity with OIT (Table E1), 34% spoke with a healthcare provider
252 about OIT as a treatment option. Among individuals who spoke with a healthcare provider about OIT,
253 roughly 49% spoke with an allergist and 38% spoke with a primary care provider. Of individuals familiar
254 with OIT, 48% reported receiving information about what OIT is and how it works, which in most cases
255 was gleaned from healthcare providers (74%) and general medical education websites (44%). Fewer than
256 1 in 3 respondents reported receiving any other particular type of information about OIT, including 28%
257 who received information about OIT risks / side effects, 23% who received information about OIT
258 benefits/expected treatment outcomes, 19% who received information about OIT dosing protocols, and
259 14% who received scientific evidence or studies on OIT. Nine percent reported receiving information
260 about clinical trials available for enrollment.

261 When participants reporting familiarity with OIT were asked what information would make them feel
262 more confident in their ability to make an informed treatment decision about OIT (Table E1), the most
263 desired types of information were scientific studies on OIT (32%), information about its potential risks
264 (32%), benefits (26%), how it works (28%), and how much it would cost (23%). Twenty six percent of
265 respondents reported that none of the aforementioned information would potentially change their level of
266 interest in OIT. Furthermore, among respondents in the present survey who reported initial familiarity
267 with OIT, 15%/21% reported treatment-induced reactions occurring in the physician’s office/outside of
268 the physician’s office was a major concern that would likely prevent them from trying OIT. In contrast,
269 among respondents who were initially unfamiliar with OIT, 28%/35% reported that such reactions
270 occurring inside/outside of the physician’s office would likely prevent them from trying OIT.

271 When participants reporting no familiarity with OIT were read a brief description of OIT (Table E2) and
272 asked their attitude about OIT, 42% were neutral, 28% were somewhat interested and 10% were very
273 interested. In contrast, 16% reported that they were not interested, while 5% reported absolute opposition

to OIT. When asked why they were opposed to or uninterested in considering OIT, 43% reported that allergen avoidance is preferable, 35% reported they were unsure of its potential benefits and 30% reported they were unsure they could accept the risks of OIT. Nineteen percent reported multiple office visits and 13% reported the potential inconvenience of scheduling/traveling to such visits contributed to their disinterest/opposition to OIT. When asked if they would feel comfortable initiating a conversation with their healthcare provider about their suitability for OIT, more than half (55%) said no.

Among the 14 survey respondents who reported starting and prematurely discontinuing OIT, 6 reported their reason for discontinuing therapy was that it did not achieve their desired outcomes. This is comparable to the number of patients who attributed their discontinuation of therapy to fear of allergic reactions or anaphylaxis (N=6) or experiences with treatment-induced allergic reactions or anaphylaxis (N=7). However, 70% of patients who discontinued treatment said they would consider resuming OIT at a later date.

Multiple logistic regression analyses identified systematic differences in OIT awareness across household income and respondent education strata (Figure 1). For example, as reported in Table 4, respondents from households earning over \$100,000/year or with a college degree each had approximately double the odds of reporting awareness of OIT compared to participants from lower earning households. In contrast, while respondents of Hispanic, Black or Asian ethnicity were less likely to report awareness of OIT, this difference was not statistically significant after covariate adjustment. Greater respondent age and male gender were each associated with significantly reduced odds of OIT awareness, as was being an adult with food allergy (vs. being a caregiver of a food allergic child age ≤ 18 (vs. being an adult respondent with food allergy).

Discussion

This survey is the first to comprehensively assess food allergy patient and caregiver awareness, attitudes, and experiences pertaining to OIT among a large, nationally-representative sample. In general, findings

299 indicate that, as of Q4 2019, over 4 in 10 US food-allergic households surveyed reported total
300 unfamiliarity with OIT, while an additional 3 in 10 were familiar with the term OIT but did not know
301 what it was. Only 3% reported that a member of their household planned to start OIT while an additional
302 4% had someone in the household who had received OIT. The data suggest that knowledge and awareness
303 of OIT is skewed toward wealthier, highly-educated patients—who generally enjoy greater access to
304 specialist allergy care and tend to be over-represented in clinical trials.

305 With the ongoing expansion of private-practice OIT offerings, recent FDA approval of a commercially-
306 available peanut OIT product (*Palforzia*) and additional therapies on the horizon, it is important to ensure
307 equitable access of all treatments for food allergy. In Spring 2020, just after the FDA approval of
308 *Palforzia*, study co-author Richard Wasserman surveyed a national network of private OIT practitioners –
309 the “OIT Advisors Google group”—asking if members were offering OIT and how many patients had
310 been treated to date (Personal Communication). As of March 1, 2020, 80 participating allergy practices
311 reported treating 15,659 patients via OIT—many of whom paid out-of-pocket. However, the
312 demographics of this population, including educational level and socioeconomic status, are unknown.

313 These survey findings underline the potential impact of expanding access to, education about, and
314 coverage of OIT by insurance to the large, growing number of patients living with food allergy.

315 Moreover, many OIT practitioners report local demand for OIT exceeds their clinical capacity to offer it.

316 Given that randomized clinical trials are acknowledged to provide the highest level of scientific evidence
317 regarding treatment efficacy, it is crucial that clinical trial participants reflect the full diversity of the
318 affected population. Such efforts not only help ensure equality of opportunity and promote equity but also
319 are necessary to provide sufficient data regarding the feasibility, safety, and efficacy of these emerging
320 therapies among heterogenous populations, including those that may benefit most or least. For example, a
321 recent study highlighted how current asthma management guidelines recommending poorly controlled
322 patients “step-up” to a long-acting beta agonist (LABA), rather than increasing their inhaled corticosteroid
323 (ICS) dose, did not include substantial numbers of Black patients in the clinical trials informing the

guidelines.²⁴ Unfortunately, data indicated that “stepping-up” to LABA use is less effective among Black patients than increasing their ICS dose. Given this evidence for racial heterogeneity in treatment effects, it is remarkable that the landmark Phase 3 trial of *Palforzia* included only 9 Black participants among the intent-to-treat population of 551 participants, and did not report whether or not patients reported Hispanic/Latinx ethnicity nor any other indicators of socioeconomic status (e.g. household income or educational attainment). In contrast, the latest epidemiological data indicates that approximately half of US food-allergic children are either Black, Hispanic, or multi-racial,¹ populations which have historically encountered greater barriers to specialty care owing to lower socioeconomic status. Other major trials of both proprietary and non-proprietary OIT either do not report participant demographics (e.g. STOP II)²⁵ or enroll participants who do not fully reflect the demographics of the broader food allergy patient population. Previous reviews have highlighted how, given current trends, the population-level burden of food allergies is likely to increase until emerging therapies are both proven effective, and made widely available.^{26, 27} Given well-established socioeconomic disparities in allergic disease burden, it is important that the emergence of effective therapies does not further exacerbate these disparities.

One influential recent meta-analysis and systematic review of 12 peanut-OIT randomized controlled trials highlighted that these regimens “*considerably increase allergic and anaphylactic reactions over avoidance or placebo, despite effectively inducing desensitisation*”.²⁸ This review was criticized by some patient advocates and OIT practitioners²⁹ for failing to adequately distinguish between adverse events occurring in the clinic under close physician supervision vs. adverse events occurring at home. However, data from this survey suggests food allergy patients and their caregivers are only slightly, and not statistically-significantly more likely to report major concern about the possibility of adverse reactions to OIT occurring at home compared to in the physician’s office. Moreover, patients who reported some familiarity with OIT appear less likely to report the possibility of such adverse reactions is a major barrier to their willingness to try OIT. This suggests appropriate patient education and greater awareness among eligible patients could increase receptivity to OIT. Such efforts may also lower the perceived barriers to

engaging trusted healthcare providers in conversations about their suitability for OIT, an important first step on the food allergy treatment journey. Alternatively, those familiar with the process of OIT may better understand the potential risks of exposure in the home setting and/or have a different level of risk tolerance, leading them to seek information about OIT. Since caregivers must assume responsibility for preparing and administering daily doses at home, and treating any allergic symptoms that result, it is important for providers to include informed discussions of the risks of OIT, including those occurring at home and at later phases of treatment, as part of a thorough shared decision-making process.

Along these lines, it is noteworthy that among patients who were familiar with OIT and reported speaking to a healthcare provider, over 1 in 3 reported speaking with a primary care physician about OIT. When considering additional steps necessary to expand OIT access among affected patients, including through clinical trials, it may be beneficial to consider initiatives that inform not only patients, caregivers, and allergists, but also reach primary care physicians, who increasingly find themselves as first-line providers of food allergy care, especially for low-income families and play an essential role in referring patients to specialists for OIT. Additionally, nearly one-third of participants familiar with OIT reported a desire to receive information on OIT from scientific studies to feel more confident in their ability to make informed treatment decisions. This highlights the need for accessible evidence-based education to enable patients and caregivers to make informed decisions, particularly on risks versus benefits and expected treatment outcome, with their physician.

Limitations and Conclusions

The present study is limited because the data are self/parent-proxy reported and therefore reported disease characteristics were not confirmed either through testing or chart-review. Although survey respondents were required to report a physician-diagnosed food allergy to be eligible for the survey, it is possible that some had physician-diagnosed non-IgE-mediated conditions that are not treatable via OIT. It is also notable that study data was collected in October 2019, prior to both the FDA's approval of *Palforzia* as

well as the COVID-19 pandemic, which has had substantial, largely adverse, impacts on the accessibility of clinical allergy care—including OIT.³⁰ Furthermore, OIT—which encompasses both private allergy practice and standardized clinical trial approaches—is practiced heterogeneously, with variable dosing schedules,³¹ guidance regarding behavioral restrictions, and concomitant medications (e.g. probiotics),³² biologics.³³ Therefore, it is important that it is natural for patient attitudes and awareness to evolve in tandem with emerging scientific evidence and greater clinical accessibility of these approaches. As such, future re-evaluation of these trends should be considered, both to validate these findings and to glean new insights into this growing field. For example, while to date most clinical trials and private allergy practice/off-label OIT has studied pediatric samples, an evidence base is growing showing that such approaches can also benefit adult patients—who comprise the majority of the affected patient population in the United States.¹ However, it is worth noting that by studying a representative sample of US food allergy patients (and/or their caregivers), our overall population-based estimates of OIT familiarity are strongly influenced by the preponderance of adult food allergy patients, who our data indicate are less familiar with OIT than caregivers of pediatric food allergy patients. This is likely at least in part attributable to the fact that OIT is more commonly studied and practiced with pediatric patients relative to adults.

In sum, these data indicate that among a nationally-representative sample of US food allergy patients and caregivers, awareness of OIT is generally low. The overwhelming majority of respondents lack personal experience with OIT and do not plan to start in the near future. These data suggest that knowledge and awareness of OIT was greater among wealthier, more highly-educated respondents, suggesting additional efforts are needed to increase awareness of, and access to, OIT and other food allergy treatments through clinical trials and in routine care, as they become available in the future. As the therapeutic landscape expands, providers should work to ensure that all eligible patients, regardless of their background, have an equitable opportunity to benefit from the latest immunotherapeutic advances.

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Figure Legends

Figure 1: Factors associated with reporting any familiarity with Oral Immunotherapy (OIT)

Table 1. Respondent Demographics

	N (%)
Race/Ethnicity	
White, NH	402 (51.5%)
Hispanic	172 (22.0%)
Black NH	123 (15.7%)
Asian, NH	36 (4.6%)
Multiple/Other, NH	48 (6.2%)
Household Income	
<\$50,000/year	412 (53.0%)
\$50,000-\$99,999/year	212 (27.1%)

\$100,000-\$149,999/year	95 (12.1%)
>\$150,000/year	63 (8.0%)
Educational Attainment	
No High School Diploma	86.3 (11.1%)
High School Diploma Only	226 (28.9%)
Some College	216 (27.6%)
BA or Above	253 (32.4%)
Gender	
Female	439 (56.2%)
Male	342 (43.8%)
Respondent Age	
18-24	110 (14.1%)
25-34	176 (22.6%)
35-44	147 (18.8%)
45-54	140 (17.9%)
55-64	115 (14.7%)
65-74	65 (14.7%)
75+	28 (3.6%)
Perspective of Survey Responses	
Adult self-report	464 (59.0%)
Parent proxy report for <13-year-old	130 (17.0%)
Parent proxy report for 13-18-year-old	71 (9.0%)
Parent proxy report for >18-year-old	115 (15.0%)

Table 2. Food Allergy Characteristics

Have you / has your child's food allergy been diagnosed by a healthcare provider?	N (%)
Primary care	473 (61.0%)
Pediatrician	154 (20.0%)
Allergist	251 (32.0%)
Other Physician	33 (4.0%)
PA or NP	29 (4.0%)
Dietician/Nutritionist	19 (2.0%)
Alternative Medicine	30 (4.0%)

Other Provider (non-physician)	18 (2.0%)
Current Food Allergy	
Peanut	163 (20.9%)
Tree Nut	120 (15.3%)
Milk	207 (26.5%)
Egg	91 (11.7%)
Crustacean	154 (19.8%)
Mollusk	72 (9.2%)
Fin Fish	65 (8.4%)
Soy	50 (6.4%)
Wheat	89 (11.3%)
Sesame	18 (2.3%)
Mustard	19 (2.4%)
Other	221 (28.3%)
How long ago were you / was your child first diagnosed with food allergy by a healthcare provider?	
<1 year	66 (8.5%)
1-5 years	262 (33.6%)
6-10 years	132 (16.9%)
>10 years	320 (41.0%)
In the past 12 months, how many times have you/your child been to an ED, urgent care or physician to treat an acute FA reaction?	
0 times	582 (74.6%)
1-2 times	137 (17.6%)
3-5 times	47 (6.1%)
6-10 times	8 (1.0%)
>10 times	5 (0.7%)
In the past 12 months, how many times have you/your child been to an allergist's office about your/their food allergy?	
0 times	480 (62.2%)
1-2 times	199 (25.8%)
3-5 times	60 (7.8%)
6-10 times	22 (2.9%)
>10 times	9 (1.2%)
How many times have you/your child been treated with an EAI in the past year?	
0 times	84 (43.1%)
1-2 times	91 (46.4%)
3-5 times	14 (7.3%)

6-10 times	1 (0.7%)
>10 times	5 (2.6%)

Table 3. Reported OIT Awareness Across Sociodemographic Strata

Educational Attainment	No HS Diploma	High School Only	Some College	BA or Above	Overall
Totally Unfamiliar-- <i>I've never heard of it before this survey</i>	34 (39.0%)	117 (52.0%)	101 (47.0%)	80 (32.0%)	332 (43.0%)
Slightly Familiar-- <i>I've heard of it but don't know what it is</i>	34 (40.0%)	58 (26.0%)	55 (25.0%)	80 (32.0%)	227 (29.0%)

Familiar-I know what it is but no one in my household plans to start	9 (11.0%)	38 (17.0%)	49 (23.0%)	74 (29.0%)	169 (22.0%)
Very Familiar-- Someone in my household plans to start OIT	5 (6.0%)	5 (2.0%)	3 (2.0%)	8 (3.0%)	22 (3.0%)
Experienced-- Someone in my house tried OIT/ is currently receiving OIT/completed OIT	4 (4.0%)	8 (4.0%)	7 (3.0%)	10 (4.0%)	30 (4.0%)
Household Income	<\$50,000/year	\$50,000-\$99,999/year	\$100,000-\$149,999/year	\$150,000+/year	Overall
Totally Unfamiliar-- I've never heard of it before this survey	184 (45.0%)	104 (49.0%)	26 (28.0%)	18 (28.0%)	332 (43.0%)
Slightly Familiar-I've heard of it but don't know what it is	124 (30.0%)	55 (26.0%)	27 (29.0%)	21 (34.0%)	227 (29.0%)
Familiar-I know what it is but no one in my household plans to start	79 (19.0%)	41 (19.0%)	33 (35.0%)	17 (27.0%)	169 (22.0%)
Very Familiar-- Someone in my household plans to start OIT	8 (2.0%)	6 (3.0%)	3 (4.0%)	4 (6.0%)	22 (3.0%)
Experienced-- Someone in my house tried OIT/ is currently receiving OIT/completed OIT	17 (4.0%)	4 (2.0%)	5 (5.0%)	3 (5.0%)	30 (4.0%)
Race/Ethnicity	Hispanic	White	Black	Asian	Multi/Other
Totally Unfamiliar-- I've never heard of it before this survey	78 (46.0%)	163 (41.0%)	56 (46.0%)	16 (44.0%)	19 (40.0%)
Slightly Familiar-I've heard of it but don't know what it is	51 (30.0%)	122 (30.0%)	32 (26.0%)	8 (22.0%)	14 (29.0%)
Familiar-I know what it is but no one in my	32 (19.0%)	96 (24.0%)	21 (17.0%)	11 (29.0%)	9 (18.0%)

<i>household plans to start</i>					
Very Familiar-- <i>Someone in my household plans to start OIT</i>	3 (2.0%)	11 (3.0%)	3 (3.0%)	0 (0.0%)	4 (9.0%)
Experienced-- <i>Someone in my house tried OIT/ is currently receiving OIT/completed OIT</i>	7 (4.0%)	9 (2.0%)	10 (8.0%)	2 (5.0%)	2 (4.0%)

Table 4. Multiple Logistic Regression Examining Determinants of OIT Awareness

	OR	95% CI	
Race/Ethnicity			
Hispanic (vs. White Race/Ethnicity)	0.81	0.48	1.36
Non-Hispanic Black (vs. White Race/Ethnicity)	0.72	0.40	1.28
Non-Hispanic Asian (vs. White Race/Ethnicity)	0.60	0.20	1.80
Multiple/Other (vs. White Race/Ethnicity)	1.15	0.45	2.95
Household Income			

Household Income >\$100K (vs. Income <\$100K)	2.00	1.17	3.41
College Degree (vs. < College Degree)	1.91	1.23	2.96
Metropolitan Area Residence (vs. Non-Metro)	1.27	0.75	2.16
Gender			
Male (vs. Female)	0.64	0.43	0.94
Perspective of Survey Respondent			
Parent -report for child <13 years (vs. adult self-report)	1.92	1.11	3.32
Parent -report for child 13-18 years (vs. adult self-report)	2.05	1.02	4.11
Parent -report for child >18 years (vs. adult self-report)	1.38	0.76	2.49
Current Food Allergy			
Peanut Allergy (vs no Peanut Allergy)	1.55	0.94	2.54
Milk Allergy (vs no Milk Allergy)	1.01	0.65	1.57
Tree nut Allergy (vs no Tree nut Allergy)	1.45	0.84	2.49
Egg Allergy (vs no Egg Allergy)	1.40	0.73	2.68
Crustacean Allergy (vs no Crustacean Allergy)	1.07	0.63	1.82
Mollusk Allergy (vs no Mollusk Allergy)	0.58	0.28	1.18
Finfish Allergy (vs no Finfish Allergy)	0.53	0.26	1.08
Soy Allergy (vs no Soy Allergy)	1.24	0.52	2.98
Wheat Allergy (vs no Wheat Allergy)	1.55	0.84	2.83
Sesame Allergy (vs no Sesame Allergy)	1.39	0.28	6.89
Respondent Age**	0.86	0.76	0.98
History of Epinephrine Use (vs no Hx)	1.74	1.05	2.87
Years since initial FA diagnosis***	1.15	0.92	1.42

* OIT Awareness was defined as any response to "How familiar are you with Oral Immunotherapy?" except "Not familiar at all-I've never heard of it before this survey".

**Respondent age was assessed using the following 7 response categories and treated as continuous (18-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+).

***Years since initial FA diagnosis was assessed using the following 4 response categories and was treated as continuous (Less than 1 year, 1-5 years, 6-10 years, more than 10 years).

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Table E1. OIT Knowledge, Attitudes and Experiences among Respondents Familiar with OIT

Have you spoken with a healthcare provider about oral immunotherapy (OIT) as an option for treating food allergy?	N (%)
Yes	74 (33.5)
No	146 (66.5)
Which healthcare provider type(s) have you spoken to about OIT?	
Spoke with Primary Care	
Yes	28 (37.8%)
No	46 (62.2%)
Spoke with Pediatrician	
Yes	17 (22.4%)
No	57 (77.6%)
Spoke with Allergist	
Yes	36 (49.3%)
No	37 (50.7%)
Spoke with Different Doctor	
Yes	3 (3.6%)
No	71 (96.4%)
Spoke with Physician Assistant or Nurse Practitioner	
Yes	3 (3.8%)
No	71 (96.2%)
Spoke with Dietician/Nutritionist Care	
Yes	4 (5.6%)
No	70 (94.4%)
Spoke with Complementary/Alternative Medicine Professional	
Yes	2 (2.8%)
No	72 (97.2%)
What information have you received about OIT?	
Additional information on what OIT is and how it works	105 (47.6%)
OIT instructions or protocols (for example, dosing schedule	41 (18.6%)
Information about OIT risks / side effects	61 (27.5%)
Information about OIT benefits / expected treatment outcomes	50 (22.8%)
Information about OIT clinical trials available for enrollment	20 (9.2%)
Information about oral food challenge	47 (21.4%)
Scientific evidence or studies on OIT	31 (13.9%)

Contact information for local, regional doctors who prescribe OIT	12 (5.5%)
Information about OIT cost and whether or not my health insurance will cover it	18 (8.2%)
Whether there are recommendations from professional medical organizations and/or patient groups	14 (6.1%)
None of the above would change my level of interest	67 (30.5%)
Please indicate the source from which you have received the following types of information about OIT:	
Information on what OIT is and how it works	
Social media	17 (16.1%)
General medical education websites	46 (44.1%)
Government websites	15 (14.4%)
Healthcare provider	78 (74.0%)
Friends and family	20 (19.0%)
Pharmacist	13 (12.2%)
Biotech/pharma companies	3 (3.2%)
Insurance providers/Medicaid	7 (6.2%)
Other	1 (1.2%)
OIT instructions or protocols	
Social media	8 (20.2%)
General medical education websites	16 (38.1%)
Government websites	5 (13.3%)
Healthcare provider	35 (85.9%)
Friends and family	7 (18.0%)
Pharmacist	9 (22.2%)
Biotech/pharma companies	1 (2.7%)
Insurance providers/Medicaid	5 (11.0%)
Other	0 (0.0%)
Information about OIT risks / side effects	
Social media	61 (27.5%)
General medical education websites	23 (37.5%)
Government websites	10 (16.7%)
Healthcare provider	48 (79.7%)
Friends and family	11 (18.5%)
Pharmacist	6 (10.3%)
Biotech/pharma companies	1 (0.9%)
Insurance providers/Medicaid	2 (3.9%)
Other	1 (1.8%)
Information about OIT benefits / expected treatment outcomes	

Social media	9 (17.9%)
General medical education websites	19 (36.9%)
Government websites	11 (22.7%)
Healthcare provider	40 (80.2%)
Friends and family	8 (15.5%)
Pharmacist	9 (17.2%)
Biotech/pharma companies	3 (5.4%)
Insurance providers/Medicaid	4 (8.6%)
Other	1 (2.4%)
Received information about OIT clinical trials available for enrollment	
Social media	1 (3.1%)
General medical education websites	1 (6.4%)
Government websites	4 (17.4%)
Healthcare provider	12 (59.3%)
Friends and family	3 (13.9%)
Pharmacist	3 (13.4%)
Biotech/pharma companies	1 (1.4%)
Insurance providers/Medicaid	2 (12.1%)
Other	2 (8.3%)
Received information about oral food challenge	
Social media	8 (16.0%)
General medical education websites	19 (40.2%)
Government websites	17 (35.8%)
Healthcare provider	31 (66.7%)
Friends and family	12 (26.1%)
Pharmacist	10 (20.4%)
Biotech/pharma companies	3 (6.2%)
Insurance providers/Medicaid	6 (12.8%)
Other	1 (1.1%)
Received scientific evidence or studies on OIT	
Social media	10 (32.6%)
General medical education websites	19 (62.7%)
Government websites	8 (25.7%)
Healthcare provider	17 (54.7%)
Friends and family	13 (42.4%)
Pharmacist	7 (24.3%)
Biotech/pharma companies	1 (3.3%)
Insurance providers/Medicaid	2 (7.2%)
Other	1 (4.3%)

Received contact information for local, regional doctors who prescribe OIT	
Social media	8 (64.6%)
General medical education websites	4 (31.5%)
Government websites	4 (30.2%)
Healthcare provider	9 (77.6%)
Friends and family	3 (21.7%)
Pharmacist	5 (37.2%)
Biotech/pharma companies	
Insurance providers/Medicaid	3 (21.1%)
Other	0
Received information about OIT cost and whether or not my health insurance will cover it	
Social media	3 (15.7%)
General medical education websites	3 (15.7%)
Government websites	0
Healthcare provider	13 (71.2%)
Friends and family	2 (12.3%)
Pharmacist	7 (37.8%)
Biotech/pharma companies	
Insurance providers/Medicaid	11 (63.7%)
Other	0
Whether there are recommendations from professional medical organizations and/or patient groups	
Social media	6 (44.3%)
General medical education websites	3 (22.1%)
Government websites	2 (11.4%)
Healthcare provider	4 (29.8%)
Friends and family	6 (41.0%)
Pharmacist	5 (36.9%)
Biotech/pharma companies	
Insurance providers/Medicaid	2 (16.4%)
Other	1 (8.2%)
What information regarding OIT would you like to have received in order to feel more confident in your ability to make an informed decision?	
Additional information on what OIT is and how it works	62 (28.0%)
OIT instructions or protocols (for example, dosing schedule)	59 (27.0%)
Information about OIT risks / side effects	70 (32.0%)
Information about OIT benefits / expected treatment outcomes	58 (26.0%)

Information about OIT clinical trials available for enrollment	41 (19.0%)
Information about oral food challenge	37 (17.0%)
Scientific evidence or studies on OIT	70 (32.0%)
Contact information for local, regional doctors who prescribe OIT	34 (16.0%)
Information about OIT cost and whether or not my health insurance will cover it	50 (23.0%)
Whether there are recommendations from professional medical organizations and/or patient groups	31 (14.0%)
None of the above would change my level of interest	56 (26.0%)
While evaluating whether to try OIT, what treatment outcome(s) did you expect? (Select all that apply)	
A treatment that would “cure” the allergy, allowing large amounts of the allergen to be eaten	20 (38.0%)
A treatment that would allow socializing in the presence of the allergen	20 (38.0%)
A treatment that would provide protection against accidental exposure to the allergen	28 (54.0%)
A treatment that would decrease the number of emergency room/urgent care visits due to allergic reactions	23 (44.0%)
A treatment that would decrease the number of times an epinephrine auto-injector is needed	19 (37.0%)
Knowing that these side effects* are possible, how does this affect your willingness to try OIT, if allergic reactions may occur under a healthcare provider’s supervision (in the physician’s office)?	
No Concern	8 (15.0%)
Minor	11 (21.0%)
Moderate	25 (49.0%)
Major	8 (15.0%)
Knowing that these side effects* are possible, how does this affect your willingness to try OIT, if allergic reactions may occur at home (outside of the physician’s office)?	
No Concern	4 (9.0%)
Minor	13 (25.0%)
Moderate	23 (45.0%)
Major	11 (21.0%)

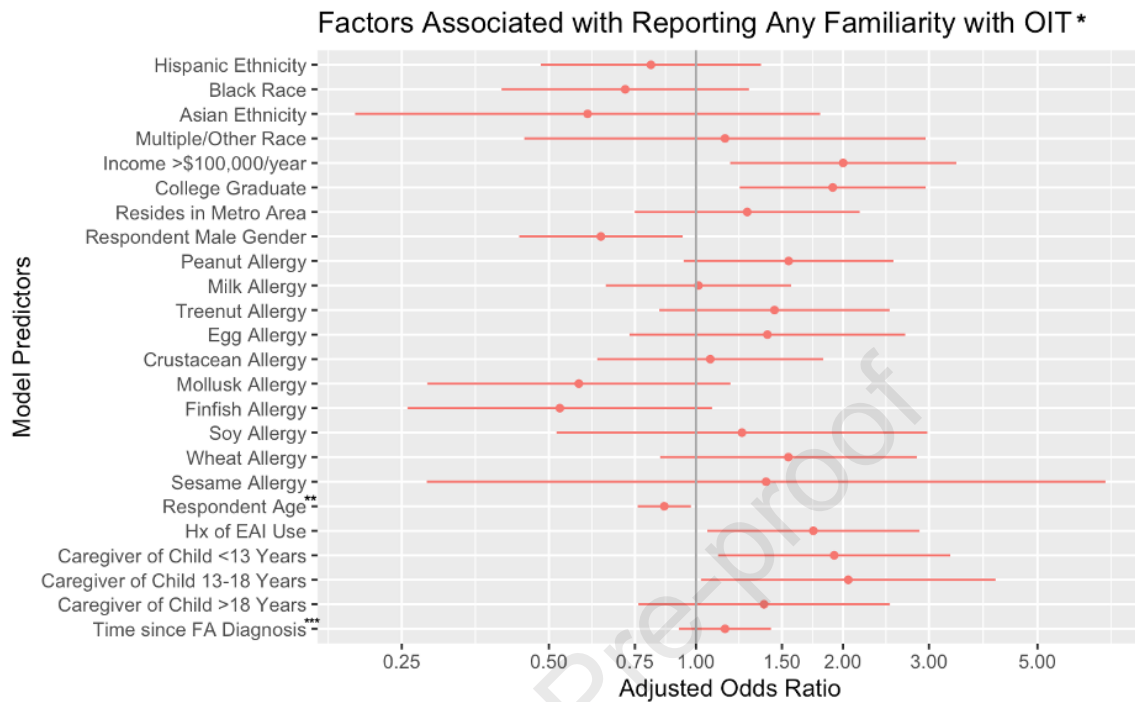
**Predictable, anticipated allergic reactions requiring the use of epinephrine injection may occur with OIT use. Anaphylaxis is a severe, potentially life-threatening allergic reaction with symptoms affecting several areas of the body, including breathing and blood circulation, and is possible while on OIT. Dosing might be performed at the physician’s office while other times it might performed at home. The patient should be closely monitored for allergic reactions while undergoing treatment.*

Table E2. OIT Knowledge, Attitudes and Experiences among Respondents Unfamiliar with OIT

	N (%)
Based on this description of OIT[^], what is your attitude toward OIT?	
Very interested in considering OIT as a treatment option	52 (9.5%)
Somewhat interested in learning about OIT as a treatment option	151 (27.5%)
Neutral / not sure	228 (41.5%)
Not interested in considering OIT as a treatment option	90 (16.4%)
Absolutely opposed to considering OIT as a treatment option	29 (5.3%)
What would you expect to be the outcome of OIT? (Select all that apply)	
A treatment that would “cure” the allergy, allowing large amounts of the allergen to be eaten	258 (35.4%)
A treatment that would allow socializing in the presence of the allergen	196 (26.9%)
A treatment that would provide protection against accidental exposure to the allergen	251 (34.3%)
A treatment that would decrease the number of emergency room/urgent care visits due to allergic reactions	158 (21.7%)
A treatment that would decrease the number of times an epinephrine auto-injector is needed	147 (20.1%)
None of these outcomes are worth the risks associated with OIT	173 (23.7%)
I am opposed to or not interested in considering OIT because...	
Not sure that I / my child would benefit from OIT	42 (34.7%)
Not sure that I / my child can accept the risks of OIT	36 (29.5%)
Oral Food Challenge is required to start OIT	6 (4.7%)
It would be inconvenient to schedule/travel to appointments	16 (13.4)
Multiple healthcare provider office visits are required	23 (18.7%)
Avoiding the allergen is preferable over OIT	52 (43.0%)
Cost of OIT may be high...	15 (12.2%)
There is no FDA-approved therapy available	10 (8.6%)
There is no recommendation from professional...	7 (5.6%)
I have heard of bad experiences related to receiving OIT	0 (0.0%)
Other, please specify	14 (11.6)
Would you feel comfortable initiating a conversation with your healthcare provider about your suitability for OIT?	
Yes	224 (40.3%)

Conditional Yes	26 (4.6%)
No	305 (55.1%)
Knowing that these side effects** are possible, how does this affect your willingness to try OIT, if allergic reactions may occur under a healthcare provider's supervision (in the physician's office)?	
No Concern	119 (16.4%)
Minor	172 (23.8%)
Moderate	229 (31.6%)
Major	205 (28.3%)
Knowing that these side effects** are possible, how does this affect your willingness to try OIT, if allergic reactions may occur at home (outside of the physician's office)?	
No Concern	114 (15.7%)
Minor	164 (22.7%)
Moderate	195 (27.0%)
Major	250 (34.6%)
[^]Oral immunotherapy (OIT) refers to the medically supervised therapy of feeding an allergic individual an increasing amount of allergen with the goal of increasing the threshold of allergen that triggers a reaction. Currently, OIT is not approved by the U.S. Food and Drug Administration (FDA). OIT often starts with an oral food challenge under medical supervision. Then, very low doses of the allergen are given to the patient, increasing dosage over a period of time. After the maximum desired dose has been reached, the patient is put on a maintenance dose schedule where they are frequently exposed to the allergen to ensure that they maintain this level of tolerance. The goal of therapy is to raise the threshold dose of allergen that may trigger an allergic reaction to provide the person with food allergy protection against accidental ingestion of the allergen. *Predictable, anticipated allergic reactions requiring the use of epinephrine injection may occur with OIT use. Anaphylaxis is a severe, potentially life-threatening allergic reaction with symptoms affecting several areas of the body, including breathing and blood circulation, and is possible while on OIT. Dosing might be performed at the physician's office while other times it might be performed at home. The patient should be closely monitored for allergic reactions while undergoing treatment.	

Figure 1: Factors associated with reporting any familiarity with Oral Immunotherapy (OIT)



* OIT Awareness was defined as any response to "How familiar are you with Oral Immunotherapy?" except "Not familiar at all-I've never heard of it before this survey".

**Respondent age was assessed using the following 7 response categories and treated as continuous (18-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+).

***Years since initial FA diagnosis was assessed using the following 4 response categories and was treated as continuous (Less than 1 year, 1-5 years, 6-10 years, more than 10 years).