

Goals and motivations of families pursuing oral immunotherapy for food allergy



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Clinical Implications

- Families who pursue oral immunotherapy for food allergy are driven by a fear of fatal food reaction and a desire to decrease risks of reaction, rather than to incorporate the allergenic food in the diet.

TO THE EDITOR:

Food allergy is a growing problem in the United States. Oral immunotherapy (OIT) has been the subject of much research as a therapy for food allergy. Although not officially recommended or approved for food allergy, many patients are pursuing OIT nonetheless.¹ Very little is understood about patients' motivations for pursuing OIT, especially in nonresearch settings.² Understanding patients' motivations for pursuing OIT in these settings may help us tailor future therapies for food-allergic patients.

From January to March 2017 we distributed a survey via social media platforms and food allergy list serves (see [Table E1](#) and [Figure E1](#) in this article's Online Repository at www.jacionline.org) to engage patient families pursuing private practice OIT. Respondents were included if they were the parent of a child who had undergone OIT to any food, agreed to complete the survey, and were able to read English. Some questions were adapted from the Food Allergy Quality of Life Questionnaire.³ This survey was approved by the Johns Hopkins institutional review board.

There were 123 responses to our survey. Children treated with OIT ranged in age from 1 to 20 years (median, 10 years), with time since initiation of OIT ranging from 0.02 to 7 years (median, 1 year). Thirty-four percent were in the dose build-up phase of OIT, 33% in the maintenance phase, and 22% had completed OIT and were consuming the food, while 11% discontinued OIT. Fourteen percent reported receiving OIT as part of a research study, whereas 86% reported receiving OIT in a private practice setting. Most reported being treated for peanut and/or tree nut allergy (83%), with 17% of respondents reporting treatment for milk, egg, and/or wheat allergy.

Before initiating OIT, 5% reported no reactions to the culprit food(s), whereas 43% reported respiratory symptoms, 15% hypotension, 67% urticaria, 52% gastrointestinal symptoms, 50% oral symptoms, 24% nasal symptoms, and 21% difficulty with swallowing.

When asked about their primary goal for OIT, 62% of respondents selected "reducing the risk of a fatal food reaction," 10.6% "reducing the hassle of strict avoidance," and only 9% "Being able to incorporate the food into the diet normally." Sixty-five percent agreed with a definition of successful OIT as "avoiding the food but having a lower rate of reaction than prior

to treatment," whereas only 19% agreed that success was "eating the allergenic food but having a higher rate of reaction."

Asked to quantify their child's risk of death from a food reaction before undergoing OIT, 35% of respondents felt that the risk was greater than or equal to 1 in 1,000 and 23% thought that the risk was about 1 in 10,000 ([Figure 1](#)). When asked about how difficult or troublesome various aspects of food allergy were before initiating OIT, 32% of families reported that anxiety about death was "extremely difficult" and 45% reported that it was somewhat difficult. Fifty-nine percent reported the hassle of avoidance very or extremely difficult and 37% found symptoms related to food very or extremely difficult, whereas only 18% thought that nutritional aspects of avoidance were very or extremely difficult and 17% thought that social isolation was very or extremely difficult (see [Figure E2](#) in this article's Online Repository at www.jacionline.org, which includes subanalysis by food treated, because patients with allergies to milk, egg, and wheat may differ in motivation from those with peanut and/or tree nut allergy). Globally, patients with milk, egg, and/or wheat allergy reported worse quality-of-life scores than did those with peanut and/or tree nut allergy.

Overall, we found that the primary motivation for undergoing OIT was to lower the risk of fatal reactions, likely resulting from inflated estimates of fatal food reactions. Only a minority consider inclusion of the allergenic food the primary goal of OIT. Rather, the hassle of avoidance, symptoms of food allergy, and anxiety about death were seen as problematic. Most families would not consider OIT a success if the food could be included in the diet but reactions increased.

Given that for most families the goal of OIT is to decrease reactions, one should consider whether this goal is likely to be met with current treatments. In most published studies, OIT is accompanied by a rate of allergic reactions during build-up that far exceeds what may be expected with strict avoidance.⁴ In fact, in a meta-analysis of peanut OIT, 80% of subjects experienced OIT-related adverse events during treatment.⁵ Long-term data are sparse, but reaction risk may be elevated for years.⁴ Thus, with current OIT protocols, results of treatment may not align with the families' goals. Alternative methods of food allergy treatment, such as low-dose oral, epicutaneous immunotherapy or sublingual immunotherapy (eg, Clinicaltrials.gov NCT0223182; Clinicaltrials.gov NCT00932828) may provide results that better reflect patients' goals, although the ability of these treatments to reduce reactions in the long-term remains unproven.

A significant proportion of families surveyed demonstrated an inflated estimate of risk of death from food allergy, and reported that anxiety about death significantly affects quality of life. Previous analyses of the incidence of fatal food allergy reactions estimated an incidence of about 3.25 per million person-years among patients with food allergy aged 0 to 19 years,⁶ or 1 in 325,000 over 10 years. In our survey, most respondents assessed the risk of death as 1 in 10,000 or greater. The fact that many families have unrealistically high estimates of food allergy risk suggests an opportunity for improved education regarding risk. Better education about real risks together with comprehensive interventions that improve family self-efficacy in preventing and treating allergic reactions may improve families' anxiety.

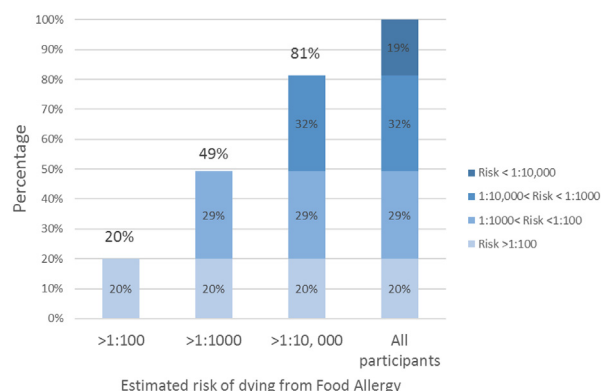


FIGURE 1. Risk assessment. Families were asked, “Prior to starting OIT, what did you think your child’s risk of dying from a reaction to (the allergen) in the next 10 years?”

Threshold challenges, threshold determination, and increases in low threshold eliciting doses may also be useful in this regard.

Our survey was done cross-sectionally, and may be influenced by recall bias. The survey was administered via web link, and we used existing social media and interest group networks, which may not be generalizable to the community of food-allergic patients as a whole. Broadening the networks for survey distribution may help us to better assess those patients undergoing OIT in various settings. Furthermore, in this exploratory survey, we did not use validated food allergy questionnaires, which should be considered for further research.

In summary, patients pursuing OIT as a therapy for food allergy are motivated by fear of fatal reactions, which they may

overestimate, rather than introducing the allergenic food into the diet.

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ONLINE REPOSITORY

TABLE E1. Survey distribution sites

Food Allergy Research and Education Facebook page and email list
NOVA (Northern Virginia) Food Allergy Support Group
Kids with Food Allergies (A division of the Asthma and Allergy Foundation of America) email group
Food Allergy Support, Facebook group

Several national and local organizations as well as social media groups were approached for potential distribution of this survey.

Online Survey

Please complete the survey below.

Thank you!

This is a survey about your experiences with oral immunotherapy for food allergy. Sharing your experiences will help us understand patient experiences and improve treatments for patients with food allergy.

The survey is being conducted by Dr. Corinne Keet at the Johns Hopkins School of Medicine. Dr. Keet is an Associate Professor of Pediatrics, and specializes in Pediatric Allergy and Immunology. If you have any questions about the survey, you can contact the Principal Investigator at ckeet1@jhmi.edu or 410-955-5883.

Unless you agree to provide contact information at the end of this survey, this survey will not be linked to any identifying information about you.

It should take about 10 minutes to complete. You may stop at any time. You do not have to answer any question that you do not feel comfortable answering.

Your completion of this survey or questionnaire will serve as your consent to be in this research study.

This survey is designed for parents of children who are either currently being treated or have been previously treated with oral immunotherapy (OIT) for food allergy. The questions are designed to apply to just one individual, so if you have more than one child treated with OIT, answer for the child who started OIT first.

After you complete questions regarding your first child, you will have an opportunity to answer questions about your second child's experience with OIT.

What food allergies(s) are/were being treated with OIT?

- ☐ Peanut
- ☐ Milk
- ☐ Egg
- ☐ A tree nut
- ☐ Wheat
- ☐ Soy
- ☐ Shellfish
- ☐ Other

Which tree nut?

Please describe the other food

Which food(s) did your child start first (if only one food was treated, write that food)

Questions about status of OIT

How long has it been since your child started OIT for [foodtext] in years?

What best describes your child's current status with OIT?

- ☐ In dose build-up
- ☐ In maintenance
- ☐ Finished with maintenance, eating [foodtext]
- ☐ Discontinued OIT
- ☐ Other

Describe other

Since finishing maintenance, how often does your child consume [foodtext]?

- ☐ Daily
- ☐ Several times each week
- ☐ Weekly
- ☐ Occasionally

At what stage of OIT did your child discontinue OIT?

- ☐ During dose build-up
- ☐ During maintenance
- ☐ After maintenance
- ☐ Other

Describe other

Why did your child discontinue OIT? (Check all that apply)

- ☐ Symptoms with dosing
- ☐ Hassle of dosing
- ☐ Cost
- ☐ Other

Describe other

What kind of symptoms led you to stop OIT (check all that apply)?

- ☐ Gastrointestinal problems (vomiting, nausea, abdominal pain)
- ☐ Breathing problems (coughing, wheezing, asthma flares)
- ☐ Mouth or throat itch or pain
- ☐ Eczema flare
- ☐ Hives
- ☐ Multisystem reactions
- ☐ Anxiety
- ☐ Other

What other symptoms did your child have?

Prior to starting OIT, how difficult/troublesome were the following aspects of food allergy?					
	Not at all	Slightly	Moderately	Very	Extremely
Social isolation	☐	☐	☐	☐	☐
Hassle of food avoidance	☐	☐	☐	☐	☐
Nutritional aspects of food avoidance	☐	☐	☐	☐	☐
Anxiety about death from food reactions	☐	☐	☐	☐	☐
Symptoms related to food reactions	☐	☐	☐	☐	☐

FIGURE E1. (CONTINUED).

Goals of therapy

What was your primary goal when starting OIT for [foodtext]?

- ☐ Reducing the risk of a fatal food reaction
- ☐ Reducing the hassle of strict avoidance
- ☐ Being able to incorporate the food into the diet normally
- ☐ Other

Describe other

When your child started OIT, would you have considered treatment successful if:

	yes	no
Your child was able to eat [foodtext] but had a higher rate of reactions compared to before treatment?	☐	☐
Your child had a lower rate of reactions than before treatment, but could not eat [foodtext] in regular amounts in the diet?	☐	☐

FIGURE E1. (CONTINUED).

Risk perceptions

Before starting OIT, what did you think your child's risk of dying from a reaction to [foodtext] in the next 10 years was?

- ☐ less than 1 in 10,000
- ☐ about 1 in 10,000
- ☐ about 1 in 1,000
- ☐ about 1 in 100
- ☐ more than 1 in 100

Prior to starting OIT, what kinds of symptoms had your child had due to reactions to [foodtext]? (check all that apply)

- ☐ Breathing problems (wheezing, coughing, shortness of breath)
- ☐ Hives or swelling
- ☐ Stomach problems (pain, vomiting, nausea, diarrhea)
- ☐ Localized mouth symptoms (lip swelling, mouth itch, throat pain)
- ☐ Difficulty swallowing
- ☐ Nose problems (sneezing, runny nose)
- ☐ Low blood pressure or dizziness
- ☐ none

**How often has your child had symptoms to the OIT dose or [foodtext] since starting OIT?
(check the best answer)**

	never	less than once a month	less than once a week	at least once a week
Breathing problems (wheezing, coughing, shortness of breath)	☐	☐	☐	☐
Hives, skin itching or swelling	☐	☐	☐	☐
Digestive problems (pain, vomiting, nausea, diarrhea)	☐	☐	☐	☐
Localized mouth symptoms (lip swelling, mouth itch, throat pain)	☐	☐	☐	☐
Difficulty swallowing	☐	☐	☐	☐
Nose problems (sneezing, runny nose)	☐	☐	☐	☐
Low blood pressure, dizziness, passing out	☐	☐	☐	☐

What restrictions, if any, does your child practice regarding dosing? (check all that apply)

- ☐ Restrict exercise
- ☐ Limit showering or other exposure to heat
- ☐ Change/hold dosing with illness
- ☐ Change/hold dosing with menses
- ☐ Change diet with dosing (eat more carbs, for example)
- ☐ Other

Please describe other

Has your child had to use epinephrine for an OIT dosing related reaction or a reaction to [foodtext] during or after OIT?

- ☐ Yes
- ☐ No

Has your child had to go to the emergency room for an OIT dosing reaction or a reaction to [foodtext] after or during OIT?

- ☐ Yes
- ☐ No

Has your child been diagnosed with eosinophilic esophagitis (EoE or EE) since starting OIT?

- ☐ Yes
- ☐ No
- ☐ Not officially, but it was suspected

At any point did you consider stopping OIT because of dosing related reactions?

- ☐ Yes
- ☐ No

Compared to what you expected before starting OIT, have reactions happened more, less, or the same as you expected?

- ☐ There have been more symptoms than expected
- ☐ The amount of symptoms is the same as expected
- ☐ There have been fewer symptoms than expected

Currently, how difficult/troublesome are the following aspects of food allergy, including OIT for you/your child?

	Not at all	Slightly	Moderately	Very	Extremely
Social isolation	☐	☐	☐	☐	☐
Hassle of food avoidance	☐	☐	☐	☐	☐
Nutritional aspects of food avoidance	☐	☐	☐	☐	☐
Anxiety about death due to food	☐	☐	☐	☐	☐
Symptoms related to food reactions	☐	☐	☐	☐	☐
Hassle of OIT	☐	☐	☐	☐	☐

OIT status

What dose did your child go home with the first day of OIT?	
What dose is your child currently on?	
What is/was your child's goal dose for maintenance?	
Outside of OIT, how much [foodtext] is your child eating at a time?	☐ none ☐ trace amounts ☐ more than trace amounts but less than a serving ☐ at least a serving but not freely ☐ more than a serving, freely
Is your OIT treatment directed by an allergist?	☐ Yes ☐ No
Was your child's OIT part of a research study?	☐ Yes ☐ No
Was your child's OIT part of a research study?	☐ Yes ☐ No
Did your child have a food challenge to verify allergy to [foodtext] before starting OIT?	☐ Yes ☐ No
Is a food challenge at the end of OIT part of your treatment?	☐ Yes ☐ No
How far do you travel to do OIT?	☐ less than 30 min ☐ 30 min to 1 hour ☐ between 1 and 2 hours ☐ more than 2 hours
While on dosing, does your doctor dispense the OIT, or do you measure it out at home?	☐ The doctor dispenses the doses ☐ We measure them at home ☐ A mixture of doctor dispensing and measuring at home ☐ Other
Describe other	
What percent of the costs of OIT are paid by your insurance?	☐ Insurance pays at least 80% ☐ Insurance pays 50-80% ☐ Insurance pays some but less than 50% ☐ Costs are all out of pocket
How much do you estimate you have or will have to pay out of pocket for OIT in total?	

Demographics

How old is your child?

What gender is your child?

- ☐ Female
☐ Male

How would you describe your child's ethnicity (check as many as apply)?

- ☐ Hispanic
☐ White
☐ Black, African-American
☐ Asian
☐ Other

What best fits your estimated family annual income?

- ☐ Less than \$20,000
☐ \$20,000 to \$49,999
☐ \$50,000 to \$99,999
☐ \$100,000 to \$149,999
☐ \$150,000 or more

What is your relationship to your child?

- ☐ Mother
☐ Father
☐ Other

How did you hear about OIT? (Check all that apply)

- ☐ My child's physician
☐ Print media (Magazines, newspapers, etc.)
☐ Social media (Facebook, websites, etc.)
☐ Word of mouth
☐ Other

Describe other

Thank you for completing the survey questions regarding your first child. In a moment, you will be given an opportunity to answer questions regarding a second child.

Would you be willing to give your contact information for future studies following up on oral immunotherapy? If you do so, this form will no longer be anonymous and there is a risk of loss of confidentiality. We will take steps to protect your confidentiality, including storing any identifying information in a secure database that is only accessible to the researchers conducting this study and never using any information except to contact you for future studies.

- ☐ Yes
☐ No

Please provide your best contact information, either email or telephone number or both. By providing your contact information, you are agreeing to be contacted by these researchers in the future.

Please provide your first name for future correspondence

Do you have another child who is either currently being treated or has been previously treated with oral immunotherapy (OIT) for food allergy?

- ☐ Yes
☐ No

Thank you for your participation in this survey! Are you done with the survey?

- ☐ Yes
☐ No

By clicking YES you will exit the survey. If you have any changes you would like to make to your answers, click NO.

Would you like to answer questions regarding this second child?

- ☐ Yes
☐ No

What food allergies(s) are/were being treated with OIT?

- ☐ Peanut
☐ Milk
☐ Egg
☐ A tree nut
☐ Wheat
☐ Soy
☐ Shellfish
☐ Other

Which tree nut?

Which food(s) did your second child start first (if only one food was treated, write that food)

How long has it been since this child started OIT for [foodtext2] in years?

What best describes this child's current status with OIT?

- ☐ In dose build-up
☐ In maintenance
☐ Finished with maintenance, eating [foodtext2]
☐ Discontinued OIT
☐ Other

Describe other

Since finishing maintenance, how often does your child consume [foodtext2]?

- ☐ Daily
- ☐ Several times each week
- ☐ Weekly
- ☐ Occasionally

At what stage of OIT did your child discontinue OIT?

- ☐ During dose build-up
- ☐ During maintenance
- ☐ After maintenance
- ☐ Other

Describe other

Why did your second child discontinue OIT? (Check all that apply)

- ☐ symptoms with dosing
- ☐ hassle of dosing
- ☐ cost
- ☐ other

Describe other

What kind of symptoms led you to stop OIT (check all that apply)?

- ☐ Gastrointestinal problems (vomiting, nausea, abdominal pain)
- ☐ Breathing problems (coughing, wheezing, asthma flares)
- ☐ Mouth or throat itch or pain
- ☐ Eczema flare
- ☐ Hives
- ☐ Multisystem reactions
- ☐ Anxiety
- ☐ Other

Prior to starting OIT, how difficult/troublesome were the following aspects of food allergy?

	Not at all	Slightly	Moderately	Very	Extremely
Social isolation	☐	☐	☐	☐	☐
Hassle of food avoidance	☐	☐	☐	☐	☐
Nutritional aspects of food avoidance	☐	☐	☐	☐	☐
Anxiety about death from food reactions	☐	☐	☐	☐	☐
Symptoms related to food reactions	☐	☐	☐	☐	☐

Before starting OIT, what did you think your child's risk of dying from a reaction to [foodtext2] in the next 10 years was?

- ☐ less than 1 in 10,000
☐ about 1 in 10,000
☐ about 1 in 1,000
☐ about 1 in 100
☐ more than 1 in 100

What was your primary goal when starting OIT for [foodtext2] for this child?

- ☐ Reducing the risk of a fatal food reaction
☐ Reducing the hassle of strict avoidance
☐ Being able to incorporate the food into the diet normally
☐ Other

Describe other

Prior to starting OIT, what kinds of symptoms had your child had due to reactions to [foodtext2]? (check all that apply)

- ☐ Breathing problems (wheezing, coughing, shortness of breath)
☐ Hives or swelling
☐ Stomach problems (pain, vomiting, nausea, diarrhea)
☐ Localized mouth symptoms (lip swelling, mouth itch, throat pain)
☐ Difficulty swallowing
☐ Nose problems (sneezing, runny nose)
☐ Low blood pressure or dizziness
☐ none

What restrictions, if any, does this child practice regarding dosing? (check all that apply)

- ☐ Restrict exercise
☐ Limit showering or other exposure to heat
☐ Change/hold dosing with illness
☐ Change/hold dosing with menses
☐ Change diet with dosing (eat more carbs, for example)
☐ Other

How often has this child had symptoms to the OIT dose or [foodtext2] since starting OIT?
(check the best answer)

	never	less than once a month	less than once a week	at least once a week
Breathing problems (wheezing, coughing, shortness of breath)	☐	☒	☐	☐
Hives, skin itching, or swelling	☐	☐	☐	☐
Digestive problems (pain, vomiting, nausea, diarrhea)	☐	☐	☐	☐
Localized mouth symptoms (lip swelling, mouth itch, throat pain)	☐	☐	☐	☐
Difficulty swallowing	☐	☐	☐	☐
Nose problems (sneezing, runny nose)	☐	☐	☐	☐
Low blood pressure, dizziness, passing out	☐	☐	☐	☐

Please describe other _____

Has your child had to use epinephrine for an OIT dosing related reaction or a reaction to [foodtext2] during or after OIT?

- ☐ Yes
☐ No

Has this child had to go to the emergency room for an OIT dosing reaction or a reaction to [foodtext2] after or during OIT?

- ☐ Yes
☐ No

Has this child been diagnosed with eosinophilic esophagitis (EoE or EE) since starting OIT?

- ☐ Yes
☐ No
☐ Not officially, but it was suspected

At any point did you consider stopping OIT because of dosing related reactions?

- ☐ Yes
☐ No

Currently, how difficult/troublesome are the following aspects of food allergy, including OIT for you/your child?

	Not at all	Slightly	Moderately	Very	Extremely
Social isolation	☐	☐	☐	☐	☐
Hassle of food avoidance	☐	☐	☐	☐	☐
Nutritional aspects of food avoidance	☐	☐	☐	☐	☐
Anxiety about death from food reactions	☐	☐	☐	☐	☐
Symptoms related to food reactions	☐	☐	☐	☐	☐
Hassle of OIT	☐	☐	☐	☐	☐

Compared to what you expected before starting OIT, have reactions happened more, less, or the same as you expected?

- ☐ There have been more symptoms than expected
☐ The amount of symptoms is the same as expected
☐ There have been fewer symptoms than expected

What dose did your child go home with the first day of OIT?

What dose is your child currently on?

What is/was your child's goal dose for maintenance?

Outside of OIT, how much [foodtext] is your child eating at a time?

- ☐ none
☐ trace amounts
☐ more than trace amounts but less than a serving
☐ at least a serving but not freely
☐ more than a serving, freely

Is your OIT treatment directed by an allergist?

- ☐ Yes
☐ No

Did your child have a food challenge to verify allergy to [foodtext2] before starting OIT?

- ☐ Yes
☐ No

Is a food challenge at the end of OIT part of your treatment?

- ☐ Yes
☐ No

While on dosing, does your doctor dispense the OIT, or do you measure it out at home?

- ☐ The doctor dispenses the doses
☐ We measure them at home
☐ A mixture of doctor dispensing and measuring at home
☐ Other

How old is this child?

What gender is your child?

- ☐ Female
☐ Male

How would you describe your child's ethnicity (check as many as apply)?

- ☐ Hispanic
☐ White
☐ Black, African-American
☐ Asian
☐ Other

Thank you for completing the survey.

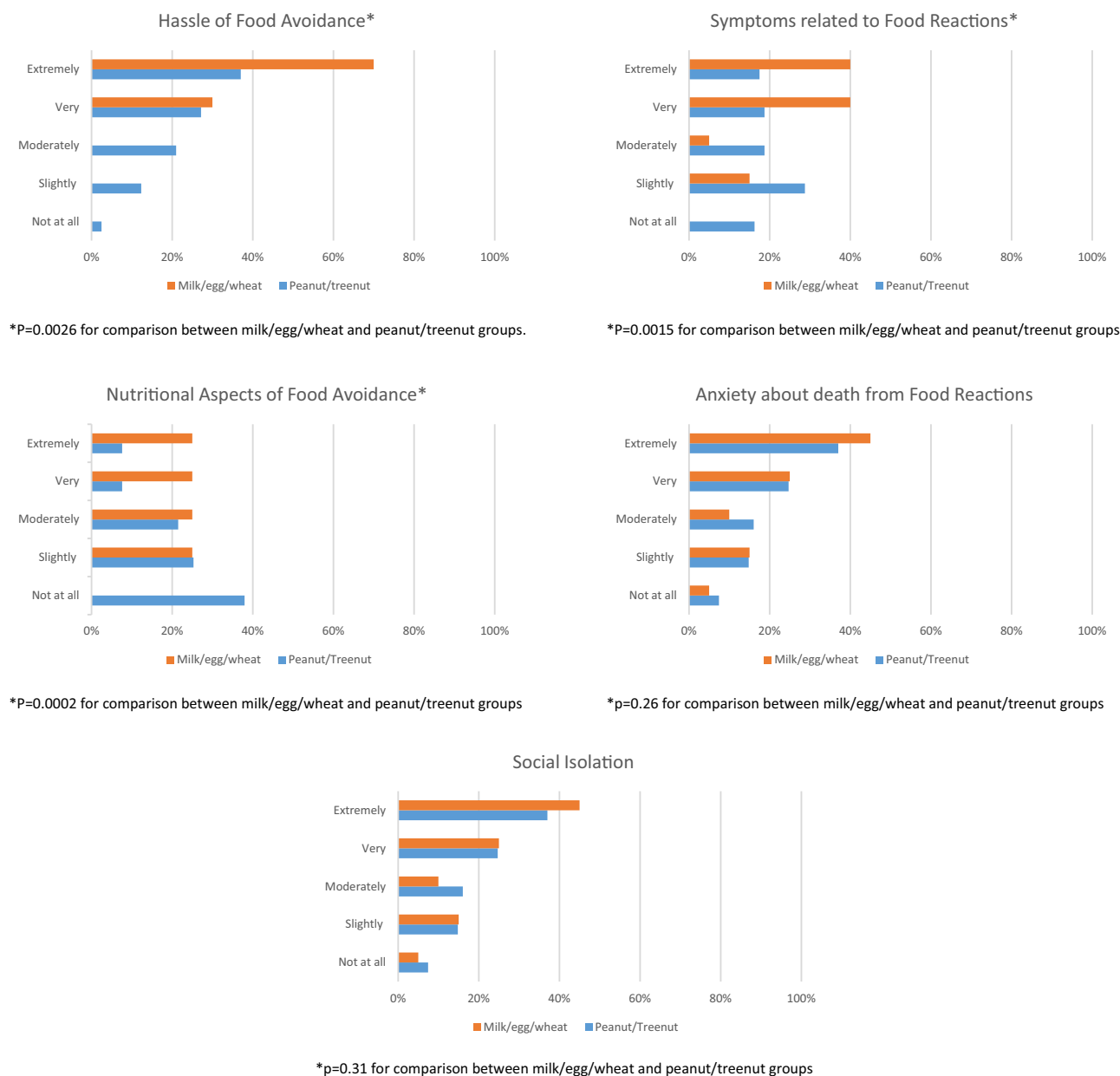


FIGURE E2. Quality of life before starting OIT, stratified by food (peanut and/or tree nut vs egg, wheat, and/or milk). Responses to quality-of-life questions, referring to quality of life before starting OIT, were stratified by the milk, egg, and/or wheat allergic compared with peanut and/or tree nut allergic.